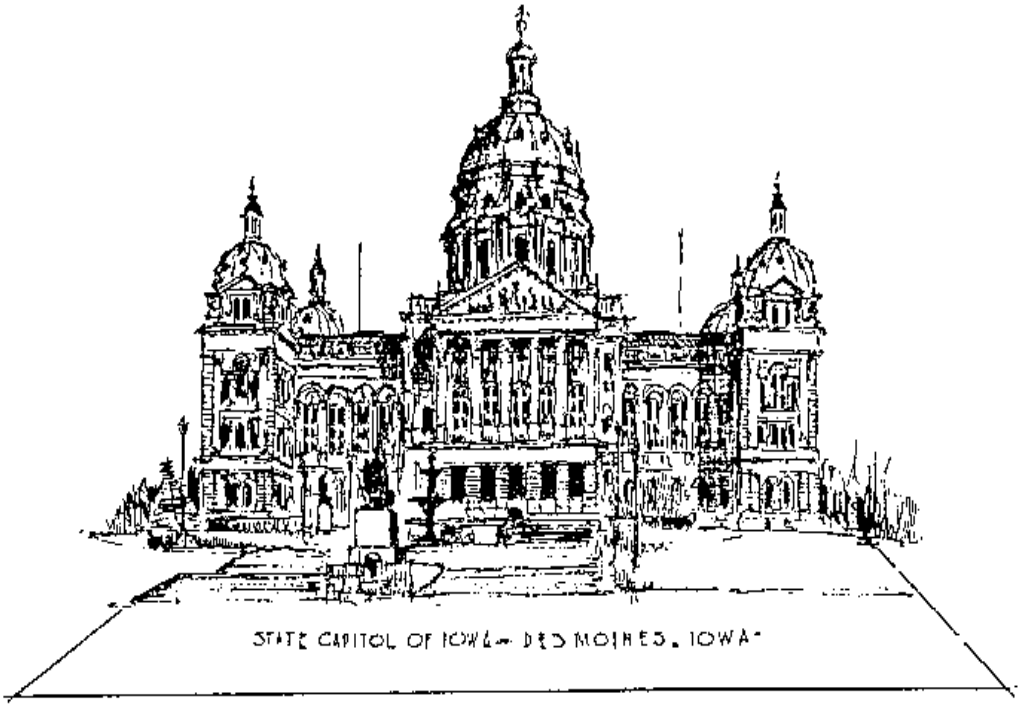
IOWA DEPARTMENT OF PUBLIC HEALTH

CALIBRATION OF RADIATION SURVEY AND MONITORING INSTRUMENTS REGULATORY GUIDE



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Bureau of Radiological Health
Radioactive Materials Section
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IDPH Calibration Regulatory Guide for
CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS

REGULATORY GUIDE Calibration FOR
CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This guide identifies the information needed by the IDPH to evaluate an application for a “Calibrating Radiation Survey and Monitoring Instruments” license and to describe the by-product material regulations.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing a 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. You may go to 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 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 form 229-0514, "Application for Radioactive Materials License." 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 drawings, should be on 8 1/2 x 11-inch paper to facilitate handling and review, if possible. 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, experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 for yourself 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. You will be bound by the statements and representations you make as if they were regulations.

3. CONTENT OF APPLICATION

This portion of the guide explains, item by item, the information requested on IDPH Form 229-0514. 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, or call 515-281-3478.

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 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. If by-product material is to be used at more than one location, you must give the specific address of each location. In items 6 through 12 of the application, describe the intended use and the facilities and equipment at 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 Radiation Safety Officer (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

Responsible individuals are the authorized users and the RSO. 641-39.4(25) requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. These persons are those who directly supervise the use of radioactive material or who will use radioactive material without supervision. Referencing Items 6 and 7 of the application, indicate the specific uses of each user.

Submit a resume for each authorized user that includes the type (on-the-job or formal course work), location, and duration of the training. Training should cover:

1. Principles and practices of radiation protection;
2. Radioactivity measurements, standardization, and monitoring techniques and instruments;
3. Mathematics and calculations basic to the use and measurement of radioactivity;
4. Biological effects of radiation;

On-the-job training should encompass hands-on experience in calibrating the types of monitoring and measuring instruments typical of those expected to be calibrated for your customers. It should be for 1 to 2 weeks; the sources or devices used should be similar in activity to those listed in Item 6. Describe the on-the-job training for each individual and include where, when, and by whom the training was given.

Outline any additional training that will be provided periodically to keep users up to date on instrument calibration techniques and on any new-model survey and monitoring instruments that will be accepted for calibration and maintenance services. You should state that such training will be augmented by using the manufacturer's most recent service manuals and instruction sheets, which provide new information on the instrument manufacturer's recommended servicing and calibration procedures and methods.

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 in the handling of radioactive materials. 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 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 or its equivalent.

ITEM 6. -- RADIOACTIVE MATERIAL

Describe the by-product material by isotope, chemical and/or physical form, and activity, in millicuries or microcuries. Possession limits requested should cover the total anticipated inventory, including stored materials (but not decay-in-storage), and should be based on the applicant's needs and facilities for safe handling.

If the use of sealed or plated sources is being considered, specify the isotope, manufacturer, and model number of each sealed source or plated source. You should consult with your proposed supplier for 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.

Also list any survey meter or calibration source not exempted under 39.4(3)"c"(9).

Example:		
Cesium-137	Sealed rod source XYZ Inc. Model 10	Not to exceed 250 microcuries/source
Co-60	Sealed source XYZ, Inc. Model 351	Not to exceed 20 millicuries/source

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 any source other than those listed in Item 6.

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

Specify the purpose for which each type of source listed in Item 6 will be used. If a source is contained in a device, you need to specify the manufacturer and model number of each device (calibrator). For example:

1. To be used for low-range (.01 to 2 mr/hr) calibration of portable survey meters.
2. To be used for medium (1 to 500 m/R/hr) and low-range calibration of survey meters.
3. To be used in a Nuclides, Inc. Model 100 shielded calibrator for the high-range (>1 R/hr) calibration of radiation measuring meters and devices.
4. To be used for calibration of medium- and low-range portable survey meters.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

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

Items 9. - through - 12.

Your response to these items should be:

- You will follow the model procedure in Appendix __ in IDPH Calibration Regulatory Guide;
- You have enclosed your procedure for review; or
- The notation "NA" for "not applicable."

Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your response to Items 9 through 12 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to name specific individuals, equipment by serial number, room numbers, or other site-specific information, there is no need to submit that procedure for review. Other than hot labs, procedures should allow for replacement of identical equipment and personnel.

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

Describe your training program for individuals who work in the vicinity of radioactive material described in Item 6.a. See Appendix C of this guide.

ITEM 10. -- FACILITIES AND EQUIPMENT

10.1. -- Annotated Drawing

Submit an annotated drawing of the room or rooms and adjacent areas where by-product material will be used. Append it as ATT 10.1. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The direction of north.
3. Room numbers and principal use of each room or area (for example, in vitro, hot lab, office, file, fresh materials storage, radioactive waste storage, hallway).
4. Any shielding available, auxiliary shielding and description of use.
5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors) including manufacturer and model or serial numbers where appropriate.
6. Restricted areas within calibration lab areas.
7. Location of any beam calibrators and calibration range facilities, including a description of the range facility.
8. Means of minimizing scatter.
9. Location of any self-contained calibration facilities.
10. Source storage facilities.
11. Source handling equipment.
12. Means of preventing entry into high radiation areas.
13. Means of preventing unauthorized use or removal of licensed material.

Sketches and descriptions should show the relationship of material use areas to any adjoining unrestricted areas (e.g., offices, rest rooms, cafeterias, and other areas not under your control).

10.2. -- Radiation Detection Instruments and Instrument Calibration

Each licensee must make surveys as necessary to evaluate the extent of radiation hazards that may be present during the possession and use of licensed material. List the radiation detection (survey or monitoring) instruments that you will have available for your own use in manipulating the requested sealed sources and in performing your calibration services. Your list must specify for each instrument:

(1) type of instrument,
(2) number of instruments available,
(3) type of radiation detected,
(4) sensitivity range, and
(5) specific use, and the calibration interval. Survey instruments should be calibrated at least annually and following servicing.

The following is an example:

Portable thin-window GM survey meter,
2 units are available,
Radiation detected is beta and gamma.
Sensitivity range is 0-500 mr/hr.
Used for survey and monitoring,
Calibrated annually

ITEM 11. -- RADIATION SAFETY PROGRAM

11.1. -- Operating and Emergency Procedures

Each individual who will perform calibration on customers' radiation survey and monitoring instruments should have a set of operating and emergency procedures. You should state in your application that personnel will be provided with operating and emergency procedures. Submit a copy of the procedures listed below.

1. Systematic instructions for performing calibrations of survey and monitoring instruments (including pocket dosimeters, if applicable). For acceptable criteria, see Appendix G as a guide. You should also consider "Radiation Protection Instrumentation Test and Calibration," ANSI N323-1978. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018.
2. A program for routine area survey. See Appendix K for guidance.
3. The procedures for use of shielding and remote handling equipment when handling hard (high energy) beta- or gamma-emitting materials.
4. Special precautions to be used when handling large sealed calibration sources.
5. Your program for routine personnel monitoring. See Appendix D for guidance.
6. Emergency procedures to be followed in case of fires, equipment malfunction, etc., including notification procedures to the IDPH.
7. Leak test procedures. See 11.2 for guidance.
8. A copy or description of the certificate of instrument calibration that you will provide to customers with each calibrated instrument as part of your documentation of the elements of the radiation protection program and instrument calibration procedure. See Appendix H for guidance.

11.2. -- Leak Testing

As a licensee, you must perform leak testing of sealed sources according to 641-40.32(2). The IDPH requires tests to determine whether or not there is any leakage from the radioactive source in the device. The leak test should be performed at 6-month intervals unless otherwise authorized by your license.

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. Take the sample using a commercial leak-test kit and send the sample to the kit supplier who reports the results to you.
3. Perform the test and analysis yourself.

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

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 F.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 these 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 F or submit your own procedures.

11.3. -- Inventories

State that you will conduct inventories, at intervals not to exceed 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 3 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 device, location of each device, and date of inventory.

11.4 -- Annual Audit of Radiation Safety Program

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

11.5 -- Appendices

In addition to Appendix A, review each of the following appendixes carefully. Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate "not applicable."

Appendix B	Duties of the RSO
Appendix C	Model training program
Appendix D	Personnel exposure monitoring program
Appendix E	Reserved
Appendix F	Leak-testing sealed sources
Appendix G	Calibrating Survey Instruments

Appendix H Certificate of Instrument Calibration
Appendix I Guidance for ordering and receiving radioactive material
Appendix J Safely opening packages containing radioactive material
Appendix K Area survey procedures
Appendix L Waste Disposal
Appendix M Calibration Equipment Required
Appendix N Maintenance of Quality of Calibration

ITEM 12. -- WASTE MANAGEMENT

Submit your procedures for waste disposal. See Appendix L. Be sure to include a procedure for all material listed in Item 6.

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

State that you will conduct inventories at intervals not to exceed 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 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.

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, must be signed by the person delegated in Item 14/15., and must include the appropriate amendment fee.

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

5. RENEWAL OF 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 by-product 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 Calibration Regulatory Guide." 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 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 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 month) 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. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required. The RSO 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 RSO and management 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 Calibration Regulatory Guide."

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 but are not limited to the following:

1. Ensure that licensed material possessed by the licensee 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 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 TRAINING PROGRAM
In addition to 641-40.111

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix C to IDPH Calibration Regulatory Guide." You may use lectures, videos-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.111. Say on your application, "We have developed a training program for your review that is appended as Appendix C." Be sure to include the groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instructions have been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work near radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel to be instructed:

1. All workers that might receive an occupational dose.
2. Ancillary personnel (e.g. clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material.

Frequency of instruction:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals will include the following subjects in addition to 40.111:

1. Applicable regulations and license conditions.
2. Licensee's in-house work rules.
3. 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.
4. Question and answer period.
5. Record of date of program, subject and attendees.

APPENDIX D

MODEL PERSONNEL EXPOSURE MONITORING PROGRAM

In addition to 641-40.36 and 40.37

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application. "We will establish and implement the model personnel exposure monitoring program published in Appendix D to IDPH Calibration Regulatory Guide."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.36 and 40.37. Say on your application, "We have developed an exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.

If personnel monitoring will not be used, you should submit calculations or documentation from radiation surveys that demonstrate that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 40.36 or 40.37.

MODEL PROGRAM FOR EXTERNAL EXPOSURE

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, or OSD whole body monitor that will be processed by a contract service on a (specify time period).
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor that will be processed by a contract service on a (specify time period).
4. All individuals who are exposed to radiation on an occasional basis such as secretarial personnel and service personnel who deliver packages will not normally be issued exposure monitors.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Monitoring devices should be stored in a cool, dry place away from possibility of accidental exposure.
7. Working conditions shall not cause excessive radiation exposure of personnel. Personnel shielding, remote instrument reading and positioning facilities, automatic source handling mechanisms and other mechanical or remote operations will be used.

APPENDIX E
(Reserved)

APPENDIX F

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources. If you, or a contractor, 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 (F.1) to IDPH Calibration Regulatory Guide."

You may provide leak test analysis as a service. If you wish to analyze leak tests for other licensees, you should indicate in your application that you will be doing so. You may use the model procedure to analyze test samples. 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 (F.2) to IDPH Calibration Regulatory Guide."

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 (F.1 and/or F.2)," and submit your leak-test procedure.

F.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.

F.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES (for Option 3 of Item 11.1)

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 detector with 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 source. 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 microcurie for beta or gamma emitters or 0.001 microcurie for alpha emitters, 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 5 years.

APPENDIX G

MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

You may use the following guidance to calibrate survey instruments. If you follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix G to IDPH Calibration Regulatory Guide."

If your procedure does not follow the guidance in the model, 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 a survey instrument calibration procedure for your review that is appended as Appendix G," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

PRE-CALIBRATION

The following conditions shall be established before exposing the instrument to a source for adjustment and calibration:

1. The instrument should be free of significant radioactive contamination.
2. The meter shall be adjusted to zero or the point specified by the manufacturer using the adjustment or adjustments provided.
3. The batteries or power supply shall comply with the instrument manufacturer's specification.
4. The instrument shall be turned on and allowed to warm up for the period specified by the manufacturer.
5. Electronic adjustments such as high voltage shall be set, as applicable, to the manufacturer's specifications.
6. Geotropism shall be known for orientation of the instrument in the three mutually perpendicular planes, and this effect shall be taken into account during calibration and performance testing.
7. The performance of any internal sampling time base in digital readout instruments should be verified as being within the manufacturer's specifications.

MODEL PROCEDURE FOR PRIMARY CALIBRATION

1. The source must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.
3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
4. The source should be of sufficient strength to give an exposure rate of about 30 mr/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cesium-137 or 21 millicuries of Cobalt-60.
5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record must be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent. A correction chart or graph must be conspicuously attached to the instrument if the difference is greater than

10 percent. Any instrument with an exposure rate that differs from the calculated exposure rate by more than 20 percent must be repaired and cannot be considered calibrated.

8. Three kinds of scales are frequently used on survey meters:
   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be separated by at least 50 percent of scale rating.
   b. Meters that have a multi-decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.
   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.
9. Readings above 1,000 mr/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained and should be retained for three years. The description of the calibration will include:
    a. The owner or user of the instrument:
    b. A description of the instrument that includes
       - manufacturer,
       - model number,
       - serial number, and
       - type of detector.
    c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
    f. The angle between the radiation flux field and the detector. For external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel or perpendicular to the central axis of the detector. For instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument.
    g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
    h. The apparent exposure rate from the check source; and
    i. The name of the person who performed the calibration and the date on which the calibration was performed.
12. The following information will be attached to the instrument as a calibration sticker or tag:
    a. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
    b. The apparent exposure rate from the check source.
    c. The name of the person who performed the calibration and the date on which the calibration was performed.
    d. For each scale or decade, one of the following <u>as appropriate</u>:
       (1) The average correction factor,
       (2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or
       (3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;

13. To check reproducibility, the instrument should be exposed to a radiation field three or more times under identical conditions. The readings obtained should normally not deviate from the mean value by more than ± 10 percent.
14. The response of an instrument may vary as a function of such parameters as energy, temperature, pressure, humidity, and source/detector geometry. Primary calibration should be accomplished with known values of these parameters and under the conditions specified by the manufacturer. Any of these parameters may be fixed to the condition in which the instrument is to be used routinely, and notation made of these values.
15. Readout Scale and Linearity Calibration and Adjustment:
    a. Linear Readout Instruments
        (1) Linear instruments usually have a scale selection switch. If controls are provided for each scale, adjustment of each shall be made according to the manufacturer's specifications or at the midpoint of each scale. If only one control is provided, adjustment shall be made
            - at the point specified by the manufacturer,
            - near the midpoint of the middle scale, or
            - near the midpoint of a scale that is particularly important to the user's requirements.
        (2) After adjustment, calibration shall be checked near the ends of each scale (approximately 20 percent and 80 percent of full scale). After an adjustment has been completed, instrument readings shall be within ± 10 percent of known radiation values at these two points. However, readings between 10 and 20 percent shall be acceptable if a calibration chart or graph shall be prepared and attached to the instrument.
    b. Logarithmic readout instruments
        (1) These instruments commonly have a single readout scale spanning several decades with two or more adjustments. The instrument should be adjusted for each scale according to the manufacturer's specifications, or, alternatively, at points of particular importance to the user.
        (2) As a minimum, calibration shall be performed at one point near the midpoint of each decade after adjustment. Instrument readings shall be within ± 10 percent of known radiation values at these points. Readings between 10 and 20 percent is acceptable if a calibration chart or graph is prepared and attached to the instrument.
    c. Digital readout instruments
        These may have manual scale switching (auto ranging) or no scale switching. For instrument with either manual or automatic scale switching, the calibration shall be performed according to 15.a. above. For instruments without scale switching, the calibration shall be performed as in 15.b. above.

MODEL PROCEDURES FOR SPECIAL CONDITIONS

1. If the instrument is to be used under conditions that vary significantly from those for which the instrument is designed, the instrument should be adjusted, calibrated, and used only for the special conditions. Examples of such conditions are radiation energy, temperature and pressure, or source/detector geometry). When an instrument is calibrated for special conditions, an identification label shall be attached, in addition to any required calibration labels, to indicate its restriction to the special use. If instrument is also to be used within its design limits, the adjustments made during primary calibration shall remain the same, and instrument readings for the special conditions shall be corrected using correction factors obtained from appropriate tables or graphs. Only one parameter should be varied at a time during calibration for the special conditions, but the interrelationships of the variables should be known.

2. Radiation Energy.
   a. Calibration shall be performed with a standard source or source-providing radiation fields similar to those in which the instrument will be used. Where instruments will be used in radiation fields of widely differing energies, the response of the instrument at several energies over the energy range shall be determined.
   b. The response of the instrument to various energies of radiation shall be
      (1) plotted as a function of energy, or otherwise called out;
      (2) normalized to the response to a specific energy obtained during primary calibration; and
      (3) provided with the instrument.

   This type of graph is commonly called an energy dependence or spectral sensitivity curve.
3. Temperature, Pressure, and Humidity.
   a. Instruments to be used outside the manufacturer's recommended temperature range or at temperatures that differ by more than 30 degrees from the calibration temperature shall be calibrated over the temperature range at which they will be used. Care should be taken to ensure that instruments are not exposed to temperatures that will damage detector or electronic components.
   b. If the manufacturer has not stated operating limits for humidity or atmospheric pressures, the instruments shall be calibrated at the approximate humidity or pressure expected to be encountered in use. Care should be taken to ensure that an instrument is not damaged by exceeding its pressure or humidity limits.
4. Detector Directional Dependence.
   If an instrument is to be used in a detector orientation relative to the source that is different from that used during primary calibration, correction factors, should be developed.

DISCRIMINATION AGAINST UNWANTED RADIATION. If adjustments or changes are made which might alter the instrument response to unwanted ionizing and non-ionizing radiation, the discrimination against unwanted radiation should be determined for all unwanted radiation that may be encountered.

PERIODIC PERFORMANCE TEST

To assure proper operation of the instrument between calibrations, the instrument shall be tested with the check source during operation and before each intermittent use.

Reference readings shall be obtained on each instrument when exposed to a check source in a constant and reproducible manner at the time of, or promptly after, primary calibration. If at any time the instrument response to the check source differs from the reference reading by more than $\pm$ 20 percent, the instrument shall be returned to the calibration facility for calibration or for maintenance, repair, and re-calibration, as required. Reference readings should be obtained for one point on each scale or decade normally used. The check source should accompany the instrument if it is specific to that instrument.

PRIMARY CALIBRATION FREQUENCY

All instruments shall receive a pre-calibration inspection and the primary calibration prior to first use. Primary calibration will be required at least annually even when the performance test requirements outlined in PERIODIC PERFORMANCE TEST above are met. Where instruments are subjected to extreme operational conditions, hard usage, or corrosive environment, calibration that is more frequent should be scheduled.

Re-calibration shall be scheduled after any maintenance or adjustment of any kind has been performed on the instrument. For this requirement, battery change is not normally considered maintenance.

CALIBRATION FREQUENCY FOR SPECIAL CONDITIONS

Calibration for special conditions need be performed only once unless
(1) the instrument is modified or physically altered,
(2) the special conditions are changed, or
(3) the primary calibration is altered, providing that the conditions in PRIMARY CALIBRATION FREQUENCY are met.

PERFORMANCE TEST FREQUENCY

A performance check shall be made prior to each use, during intermittent use conditions and several times a day during continuous use.

NOTE: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

APPENDIX H

MODEL PROGRAM FOR CERTIFICATE OF INSTRUMENT CALIBRATION

The following guidance may be used to develop a procedure for the certificate of instrument calibration to be given to the customer with each calibrated instrument. If you use this procedure, you may say on your application, "We will establish and implement the model procedure for instrument calibration certificates as published in Appendix H to IDPH Calibration Regulatory Guide."

If you prefer, you may develop your own procedures for review. If you do so, you should consider for inclusion all the feature in the model procedure. Say on your application, "We have developed a procedure that is appended as Appendix H," and submit your procedures.

MODEL PROCEDURE

Certificates to be issued to the customer with a calibrated instrument shall include the following information:

1. The customer's name, address, and person to be contacted;
2. Identification of the instrument by manufacturer, type, and model and serial number;
3. Calibration data, such as instrument readings at a point on a given scale;
4. Any specific comments on the calibration or calibration data;
5. Identification of the calibration source or sources used in calibrating nuclide and exposure rates at specified distances (include calibration accuracy);
6. Identification of the individual performing the calibration;
7. The date of the calibration;
8. Energy correction factors, where required;
9. Unusual or special use conditions or limitations;
10. Date that primary calibration is again required;
11. Special condition identification label, if applicable. See special condition model procedures in Appendix G.

APPENDIX I

MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

In addition to 641-40.65

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix I to IDPH Calibration Regulatory Guide."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 641-40.65. Say on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix I," and submit your procedure.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials. That individual must ensure that the user is authorized the requested materials and quantities and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

    a. For routinely used materials

        (1) Written records identifying the authorized user or department, isotope, chemical form, activity, and supplier will be made.
        (2) A check to confirm that material received was ordered through proper channels.

    b. For occasionally used materials

        (1) The authorized user who will use the material will make a written request to confirm that the material received is what was ordered.
        (2) The person who receives the material will check the written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.

4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum.

SAMPLE MEMORANDUM

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrives during other than normal working hours. Packages should be placed on a cart and taken immediately to the Radioactive Materials Department, Room _____. Unlock the door, place the package on top of the counter, and re-lock the door.

If the package appears damaged or leaking, you should immediately contact one of the individuals identified below. Ask the carrier to remain until it can be determined that the driver and the delivery vehicle are not contaminated.

If you have any questions concerning this memorandum, please call our Radiation Safety Officer.

_____ _____

Name Home Telephone

APPENDIX J

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

In addition to 641-40.65 and 39.5

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix J to IDPH Calibration Regulatory Guide."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion 641-40.65 and 39.5. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix J," and submit your procedure.

MODEL PROCEDURE

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination according to 40.65.

2. The following procedure for opening each package will be followed:

   a. Put on gloves to prevent hand contamination.
   b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
   c. Measure the exposure rate from the package at 1 meter . If it is in excess of 10 millirems per hour at 3 feet (1 meter), stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface.)
   d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour on the external surface of the package.
   e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

      Beta-gamma-emitting radionuclides; all radionuclides
      with half-lives less than ten days.....22 dpm/cm ^{2}
      All other alpha-emitting radionuclides.....2.2 dpm/cm ^{2}

      Open the package with the following precautionary steps:
      (1) Remove packing slip.
      (2) Open outer package following the supplier's instructions, if provided.
      (3) Open inner package and verify that the contents agree with the packing slip.
      (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
      (5) If anything is other than expected, stop and notify the RSO.

   g. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe

sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(T1) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.

h. Check the user request to ensure that the material received is the material that was ordered.

i. Before discarding the packing material and the empty packages, monitor for contamination with a radiation survey meter.
   (1) If contaminated, treat this material as radioactive waste.
   (2) If not contaminated, remove or obliterate the radiation labels before discarding it.

j. Make a record of the receipt.

3. For packages received under the general license in 641-39.4(22)"i", the following procedure for opening each package will be followed:

   a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
   b. Check to ensure that the material received is the material that was ordered.

APPENDIX K

MODEL PROCEDURE FOR AREA SURVEYS
in addition to 641-40.27

You may use the following procedure to perform area surveys. If you follow this procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix K to IDPH Calibration Regulatory Guide."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 641-40.27. Say on your application, "We have developed survey procedures for your review that are appended as Appendix K" and submit your survey procedures.

MODEL PROCEDURE

Surveys will be repeated when quantity or type of radioactive material changes or changes occur in containment systems or methods of use.

AMBIENT DOSE RATE SURVEYS

1. Survey Areas: restricted areas

    a. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
    b. In sealed source storage areas, survey quarterly with a radiation survey meter.
    c. Protective clothing should be surveyed by the wearer after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the restricted areas. Any contamination above expected levels should be reported to the RSO.

2. Survey areas: unrestricted

    Quarterly surveys should be accomplished in areas
    - adjacent to restricted areas
    - through which radioactive materials are transferred
    - where radioactive material is temporarily stored before shipment

    More frequent surveys will be necessary if radiation levels are suspect.

REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas: unrestricted:

    In any area where the potential for spreading contamination is likely to occur, (cafeterias, snack bars, furniture and equipment), survey at least quarterly. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm to disintegrations per minute or dpm).

3. Immediately notify the RSO if you find levels that exceed the established action levels. See Table K-1 below for guidance in establishing your action levels.

RECORDS

1. Records must include the information in 40.82 as well as actions taken in the case of excessive dose rates or contamination and follow-up survey information.

2. The RSO will review and initial the record at least monthly and promptly in those cases in which action levels were exceeded.

TABLE K-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX L

MODEL PROCEDURE FOR WASTE DISPOSAL

In addition to 641-40.88

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that was published in Appendix L to IDPH Calibration Regulatory Guide."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of 641-40.70. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as Appendix L" and attach your procedure.

OVERVIEW

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. Nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See 641-38.4(1) and 40.88))

GENERAL GUIDANCE

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that unnecessary radioactive waste is not created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 641-40.72. There are monthly limits based on the total sanitary sewerage release of your facility. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to Chapter 641-40. These limits normally apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (641-40.74). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by decay-in-storage. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all decay-in-storage waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the decay-in-storage area.

3. Decay the material for at least 10 half-lives. If the material is not segregated by isotope, decay the material for at least 10 half-lives of the longest-lived radionuclide.

4. Before disposal as in-house waste, monitor each container as follows:
   a. Check your radiation detection survey meter for proper operation;
   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;
   c. Remove any shielding from around the container;
   d. Monitor all surfaces of each individual container;
   e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be that sure no radiation labels are visible.
   f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mr/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for decay-in-storage and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to 641-39.4(22)"i" is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

APPENDIX M

CALIBRATION EQUIPMENT REQUIRED

The following general guidance and procedure may be used for the requirements for calibration equipment. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for the requirements for calibration equipment that was published in Appendix M to IDPH Calibration Regulatory Guide."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of the Iowa Rules. Say on your application, "We have developed a procedure for the requirements for calibration equipment for your review that is appended as Appendix M" and attach your procedure.

MODEL PROCEDURE

Calibration Standards. Instruments should be calibrated either against National Standards or with Derived Standards. If National or Derived Standards are not available, Laboratory Standards may be used. Procedures for Laboratory Standards are demonstrated in ANSI N323-1978.

Calibration Assemblies. Instrument calibration assemblies shall be mechanically precise to ensure that positioning errors of either instruments or radiation sources do not affect the radiation field values by more than $\pm$ 2 percent. A sufficient range of radiation fields shall be available to satisfy calibration requirements.

Standard Instruments. An instrument used as a Derived Standard shall have an uncertainty no greater than $\pm$ 10 percent. Calibration shall be reestablished after maintenance or repair or at intervals specified by the manufacturer but in no case at intervals greater than three years.

A periodic instrument check procedure shall be established by the licensee to assure proper operation.

Check Sources. Check sources should provide radiation of the same type or types as provided by those sources used in instrument calibration. Check sources may provide radiation different than that used for calibration if:

1. The source instrument geometry is well understood and easily reproduced, or
2. The instrument response to this radiation is well understood and is not critically dependent on instrument adjustment. For example, the use of a photon source to check instruments sensitive to beta radiation may be acceptable; the use of a photon source to check a detector utilizing a BF_3 response to neutrons is not acceptable.

Reproducible source detector geometry shall be established and used for all performance test measurements.

APPENDIX N

MODEL PROCEDURE FOR MAINTENANCE OF QUALITY OF CALIBRATION

The following general guidance and procedure may be used for the maintenance of quality of calibration. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for the maintenance of quality of calibration that was published in Appendix N to IDPH Calibration Regulatory Guide."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of the Iowa Rules. Say on your application, "We have developed a procedure for the maintenance of quality of calibration for your review that is appended as Appendix N" and attach your procedure.

MODEL PROCEDURE

Radiation Field

Either narrow or broad beam geometry may be used to compare the response of similar instruments with that of a standardized instrument.

For calibration of X-ray machines or particle accelerators, a calibrated instrument shall be used. If a continuous monitor is available, it can be calibrated simultaneously and used in subsequent work with periodic checks on its constancy.

Alpha radiation sources shall be standardized in terms of activity per unit area of the source, or both. The reference geometry 2π or 4π, shall be stated.

Beta radiation sources shall be standardized in terms of air or soft tissue absorbed dose rate at the surface or at a specified distance from the source, or in terms of activity.

Photon-emitting radionuclide sources shall be standardized in terms of exposure rate (in roentgens per hour) at a specified distance from the source.

Neutron sources shall be standardized in terms of (1) the number of neutrons emitted per unit time and (2) the effective or average neutron energy. The concomitant photon exposure-rate should be known and stated.

For photon and neutron monitoring instrument calibrations, the source-to-detector distance shall be the distance measured between the effective center of the radioactive source and the effective center of the radiation detector. Either this distance shall be greater than seven times the maximum dimension of the source or detector, whichever is larger, or suitable corrections shall be used.

Calibration Facility

Free-space geometry should be achieved for photon and neutron instrument calibration. The distance to scattering objects from the source and from the detector should be at least twice the distance between the detector and the source. Where scattering contributions to instrument readings are significant, they shall be included in stating the value of the radiation field for all detector positions used for calibration purposes.

The radiation background at the calibration facility shall be low, known, and stable and shall be accounted for during calibration.

Temperature, relative humidity, and atmospheric pressure shall be noted at the time of instrument calibrations. Calibrations should be performed within the temperature range 25 $\pm$ 10°C, except when the instrument is to be used outside this temperature range.

Other.

If an instrument may exhibit an incremental response, the entire instrument should be placed in the radiation field during calibration and the results compared to calibration with just the detector in the field. The fractional contribution, if any, to the instrument reading due to an incremental response should be determined and noted on the instrument.

A reasonable delay should occur before reading to allow warm-up and to accommodate switching transients and the time constant of the instrument.

Revision	Section	Description
04/20/00		Revised the items necessary on a calibration sticker (Appendix G).
12/26/00	ALL	Reformat text. Changed address for Bureau of Radiological Health
01/18/02	Section 7	Added information concerning inspections.
03/13/02	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.