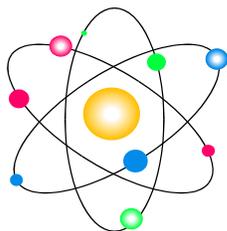
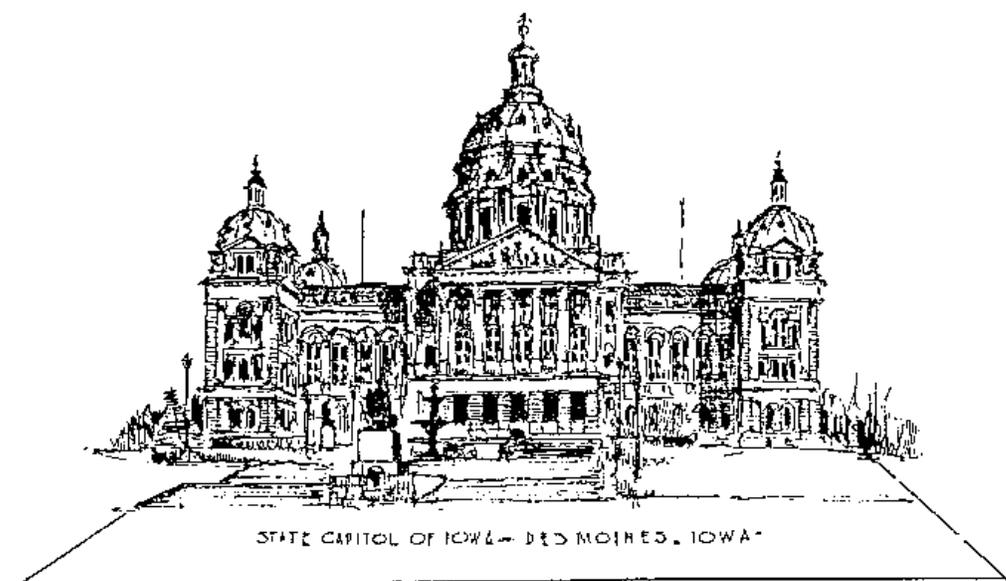

IOWA DEPARTMENT OF PUBLIC HEALTH

RESEARCH AND DEVELOPMENT, LABORATORY, AND INDUSTRIAL USE OF SMALL QUANTITIES OF BY-PRODUCT MATERIAL REGULATORY GUIDE



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

REGULATORY GUIDE FOR RESEARCH AND DEVELOPMENT, LABORATORY, AND INDUSTRIAL USE OF SMALL QUANTITIES OF BY-PRODUCT MATERIAL

1.	INTRODUCTION.....	4
1.1	PURPOSE OF GUIDE	4
1.2	APPLICABLE REGULATIONS.....	4
1.3	AS LOW AS REASONABLY ACHIEVABLE (ALARA PHILOSOPHY)	4
2.	FILING AN APPLICATION.....	4
3.	CONTENT OF APPLICATION.....	5
	ITEM 1.A. -- APPLICANT'S NAME AND MAILING ADDRESS.....	5
	ITEM 1.B. -- LOCATIONS OF USE	5
	ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION	6
	ITEM 3. -- LICENSE INFORMATION	6
	ITEM 4. -- INDIVIDUAL USERS -- THEIR TRAINING AND EXPERIENCE	6
	ITEM 5. -- RADIATION SAFETY OFFICER (RSO).....	7
	ITEM 6. -- RADIOACTIVE MATERIAL	7
	ITEM 7. -- PURPOSE.....	7
	ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM	7
	ITEM 9. -- TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.....	8
	ITEM 10. -- FACILITIES AND EQUIPMENT	8
	ITEM 11. -- RADIATION SAFETY PROGRAM.....	9
	11.1. -- LEAK TESTING.....	9
	11.2. -- INVENTORIES.....	9
	11.3. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM.....	9
	11.4. -- APPENDICES.....	10
	ITEM 12. -- WASTE MANAGEMENT	10
	ITEM 13. -- LICENSE FEES.....	10
	ITEM 14, 15 -- CERTIFICATION	10
4.	AMENDMENTS TO LICENSE.....	10
5.	RENEWAL OF LICENSE	11
6.	IMPLEMENTATION	11
7.	INSPECTIONS	11
	APPENDICES	12
	MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA	12
	DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO).....	16
	MODEL TRAINING PROGRAM	17
	MODEL PERSONNEL EXPOSURE MONITORING PROGRAM.....	19
	<i>Model Program for External Exposure</i>	19
	<i>Bioassays</i>	19
	<i>SPECIAL MONITORING</i>	20
	RADIOACTIVE MATERIALS USED IN ANIMALS.....	22
	MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES	25
	MODEL RULES FOR SAFE HANDLING OF RADIOACTIVE MATERIALS.....	27
	MODEL SPILL PROCEDURES.....	28
	MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	30
	MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL	32

MODEL PROCEDURE FOR AREA SURVEYS	34
<i>TRAINING</i>	34
<i>FACILITIES AND EQUIPMENT</i>	34
<i>AMBIENT RADIATION LEVEL SURVEYS</i>	35
<i>CONTAMINATION SURVEYS</i>	35
<i>CONTAMINATION SURVEY FREQUENCY</i>	35
<i>CONTAMINATION IN UNRESTRICTED AREAS</i>	36
<i>SURVEY RECORD REQUIREMENTS</i>	38
MODEL PROCEDURE FOR WASTE DISPOSAL.....	39
INFORMATION REQUIRED FOR FIELD USE OF BYPRODUCT MATERIAL	42
RADIONUCLIDE STORAGE AND USAGE LOG	43

RESEARCH AND DEVELOPMENT, LABORATORY, AND INDUSTRIAL USE OF SMALL QUANTITIES OF BY-PRODUCT MATERIAL REGULATORY GUIDE

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This guide is designed to describe the type and extent of information needed by the IDPH to evaluate an application for a "laboratory and industrial use of small quantities of by-product material (Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material)" license. It also provides the user with a synopsis of the by-product material regulations.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in the Iowa Rules and should then complete the application form, IDPH Form 299-0514. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection.

1.2 APPLICABLE REGULATIONS

Regulations pertaining to this type of license are found in Chapters 38, 39, and 40 of the "Radiation Machines and Radioactive Materials Rules. 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, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

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

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by IDPH.

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

3. 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, State) 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 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;
5. Specific isotopes handled, maximum quantities of materials handled;
6. Where and when experience was gained.

Persons using millicurie quantities of a number of radionuclides for general laboratory tracer work under unspecified conditions should have more extensive training and experience. Depending on the exact nature of the proposed program of use, they may need to have completed formal course work at the college or university level.

The use of larger quantities of material (approaching a curie) under conditions where a potential exists for significant loss, ingestion, inhalation, or absorption of the material, is normally done under carefully controlled conditions using specialized equipment. A person who is to use radioactive materials independently under these conditions should have formal training in all areas, extensive experience working with radioactive material, and a thorough working knowledge of the equipment required to handle the material safely.

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 use and handling of radioactive materials. Even if you employ a consultant to assist the RSO, you are still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations that are considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals and in a safe manner. The RSO's duties and responsibilities should include those areas listed in Appendix B 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 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, model number and activity of each sealed source or plated source. Also list any survey meter or calibration source not exempted under 39.4(3)"c"(9).

ITEM 7. -- PURPOSE

The use of each isotope form should be clearly described in enough detail to allow a determination of the potential for exposure to radiation both of those working with the materials and to the public.

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 the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material;
- 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 with or 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, and hallway).
4. Any shielding available.
5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors) including manufacturer and model or serial numbers where appropriate.
6. For airborne effluents, describe ventilation systems to show airflow rates, differential pressures, filtration, and any other effluent treatment equipment or monitoring equipment.

10.2. -- Specify for each radiation detection instrument the following:

1. Manufacturer's name and model number.
2. Number of each type of instrument available.
3. Type of radiation detected (alpha, beta, gamma, or neutron).
4. Sensitivity range (milliroentgens per hour or counts per minute).
5. Window thickness in mg/cm².
6. Type of use (monitoring, surveying, assaying, or measuring).
7. Frequency of calibration. Quantitative measuring instruments used to maintain the adequacy of containment and contamination control such as those used for measuring leak tests, air, effluent, bioassay, work area, and equipment contamination samples are usually calibrated prior to each use.

10.3. -- If respiratory protective equipment will be used to limit inhalation of airborne radioactive material, describe the equipment and program as stated in 641-40.50.

If using gas, volatile liquid, or finely divided forms, consider monitoring effluents by air sampling, stack monitoring, water sampling, etc. Provide the following for both restricted and unrestricted areas:

1. Frequency of sampling.
2. Location of samples with respect to workers' breathing zones.
3. Methods to relate results to actual personnel exposure.

10.4. -- If you are using an outside contractor to calibrate your survey instruments, provide the name, address, and license number of the company or individual. If you are calibrating your own instruments, please request the specific regulatory guide for calibrating instruments from the IDPH.

Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing".

ITEM 11. -- RADIATION SAFETY PROGRAM

11.1. -- 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 sent 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.

11.2. -- INVENTORIES

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

- the radionuclide and amount of material in each container, source, or device
- the manufacturer's name
- any unique identifying information (e.g., product number, lot number, model number, serial number, etc.)
- the location of each container, sealed source, or device
- date of inventory
- the name of person conducting the inventory

For inventories of loose or liquid isotopes, the licensee should record all of the pertinent information noted above including the volume and activity of the material when it was received. A log should be established to document the amounts removed, the date removed and the person removing the material. This "running log" should be reviewed for accuracy at intervals not to exceed (6) months.

11.3. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

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

11.4. -- 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	Training program
Appendix D	Personnel exposure monitoring program
Appendix E	Radioactive Materials Used In Animals
Appendix F	Leak-testing procedures
Appendix G	Safe use of radioactive materials
Appendix H	Spill procedures and action limits
Appendix I	Guidance for ordering and receiving radioactive material
Appendix J	Safely opening packages containing radioactive material
Appendix K	Area survey procedures
Appendix M	Information Required for Field Use of Byproduct Material
Appendix N	Radionuclide Storage and Usage Log

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

A senior partner, the president, director or chief executive officer must sign the application. Identify the title of the office held by the individual who signs the application.

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

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. See 641-39.4(35). An

application for an amendment must be filed either on IDPH Form 299-0514 or as a letter. The person indicated in Item 14/15 must sign the request. The appropriate fee must be included.

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

5. RENEWAL OF 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 the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material." Submit a signed copy of Section 5 of this appendix.

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program and a signed copy of Section 5 of this appendix.

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

- a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable; the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. RADIATION SAFETY OFFICER COMMITMENT

- a. Annual and Quarterly Review
 - (1) Annual review of the radiation safety program -- The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
 - (2) Quarterly review of occupational exposures -- The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of section 4 of this appendix.
- b. Education Responsibilities for ALARA Program

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

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

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
- (3) Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

d. Reviewing Instances of Deviation from Good ALARA Practices:

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

3. AUTHORIZED USERS COMMITMENT

a. New methods of Use Involving Potential Radiation Doses

- (1) The authorized user will consult the RSO during the planning stage before using radioactive materials for new uses.
- (2) The authorized user will review each planned use of radioactive materials to ensure that uses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

- (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
- (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

4. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES¹

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

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

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

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

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

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

- 5. SIGNATURE OF CERTIFYING OFFICIAL¹ Sign and submit as part of Appendix A.

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

Signature

Name (Print or type)

Title

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

APPENDIX B

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for RSO that was published in Appendix B to the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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 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. Ensure that exposure reports 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 the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three (3) years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation 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 the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material." 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 prior occupational training, board certification, etc have adequately covered safety instructions. 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 you 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.

Written instruction prepared and distributed to all personnel should include:

1. Availability, selection, and use of laboratory apparel and safety-related equipment and devices such as lab coats, gloves, and remote pipetting devices.
2. Limitations and conditions to be met in handling liquid or uncontained (unencapsulated, dispersible, or volatile) radioactive materials and special lab equipment to be used in working with these types of materials. Instructions should explain when operations with materials should

be confined to a radiochemical fume hood or glove box and should specify the use of appropriate shielding and remote handling equipment when energetic beta or gamma-emitting materials are to be used.

3. Performance of radiation survey and monitoring procedures for each area in which radioactive materials are to be used.
4. Safety precautions to be observed in movement of radioactive materials between buildings, rooms, and areas within rooms.
5. Safety requirements in storage of radioactive materials, including labeling of containers of radioactive materials and posting and securing areas where radioactive materials are to be stored. This should include the storage of contaminated laboratory equipment such as glassware.
6. Requirements for posting of areas in which radioactive materials are used.
7. The availability and use of personnel monitoring devices.
8. Waste disposal procedures to be followed, including limitations on the disposal of liquid or other dispersible waste to the sanitary sewer and procedures for the collection, storage, and disposal of other wastes.
9. Maintenance of appropriate records.
10. Good radiation safety practices (See Appendix G)
11. Emergency procedures to cover spills, fires, release or loss of material, or accidental contamination of personnel. These should include actions to be taken in order to prevent or limit contamination, telephone numbers of individuals to be notified, instructions for re-entry and recovery operations for contaminated facilities.
12. Procedures for picking up, receiving, and opening packages.
13. If material will be used in animals, instructions on handling, wastes, cleaning, and security.

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.1 and/or D.2) to the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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.

D.1 -- 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, 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.
6. Monitoring devices should be stored in a cool, dry place away from possibility of accidental exposure.

D.2 -- BIOASSAYS

FREQUENCY OF REQUIRED BIOASSAY MEASUREMENTS

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual
- Retention and excretion characteristics of the Radionuclides
- Sensitivity of the measurement technique

- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with 641-40.16(136C), which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10 per cent of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

ROUTINE MEASUREMENTS

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc) and the samples collected will vary according to the radionuclide and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is >0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than two hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program, because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

SPECIAL MONITORING

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination
- Entry into airborne radioactivity areas without appropriate exposure controls

- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity)
- Known or suspected incidents of a worker ingesting radioactive material
- Incidents that result in contamination of wounds or other skin absorption
- Evidence of damage to or failure of a respiratory protective device.

APPENDIX E

RADIOACTIVE MATERIALS USED IN ANIMALS

If radioactive materials will be used in animals, submit the following:

1. Specification of the facilities to be used to house the animals.
2. Instructions to be provided to animal caretakers for handling animals, animal wastes, and carcasses.
3. Instructions for cleaning and decontaminating animal cages.
4. Procedures for securing animal rooms when unattended by authorized users.

The following information is provided to assist you in responding to the above. You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the procedure published in Appendix E to IDPH Regulatory Guide for the use of radioactive materials in animals."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed procedures for your review that are appended as Appendix E" and submit your procedures.

A. RADIATION SAFETY PROCEDURES FOR THE CARE AND HANDLING OF ANIMALS ADMINISTERED RADIOACTIVE MATERIAL

1. Only individuals approved by IDPH shall be involved in the care and handling of animals that have been administered radioactive materials.
2. The door(s) to animal housing areas shall be locked at all times when animals are present. Only authorized personnel trained in radiation safety shall have access to these areas.
3. The door(s) to animal housing areas, and each cage containing a radioactive animal, shall be conspicuously posted with a "Caution Radioactive Material" sign.
4. Authorized personnel must record the appropriate information and sign the log near the door each time they enter or leave the animal housing area.
5. Personnel providing care to animals shall wear lab coats, disposable gloves (and boots, if appropriate), and whole body dosimeters (extremity dosimeters may also be required).
6. Disposable gloves and boots shall be removed at the entrance and placed in a radioactive waste container before leaving the housing area. Hands, feet, and clothing shall be checked for contamination at this time using a portable survey meter.
7. Animals shall be fed and watered using disposable dishes that will be placed, after use, in the radioactive waste container.
8. Animal excreta shall be collected daily, sealed in plastic bags, properly labeled, and frozen (if necessary). Excreta may not be disposed of as normal waste until the radiation levels from it have reached background.
9. Adequate precautions must be employed for the transfer of treated animals through unrestricted areas to prevent contamination of these areas by excreta.
10. In case of animal death, the carcass must be frozen and stored as radioactive waste until its radiation levels have reached background.
11. A radioactive contamination survey of the housing area shall be performed each day during which an animal is housed.

12. The animal housing area shall not be used for other purposes until surveys indicate that it is free of contamination.

B. RELEASE CRITERIA FOR ANIMALS DIAGNOSED OR TREATED WITH RADIOACTIVE MATERIAL

In accordance with the recommendations of NCRP Report No. 91 and the requirements of 641 Chapter 40, the total effective dose equivalent to any member of the general public from the diagnostic or therapeutic use of radioactive materials in animals shall be maintained "as low as reasonably achievable" (ALARA). In all cases, this should be less than 100 mrem. The total effective dose equivalent to any member of the public who is pregnant or under the age of 18 shall be maintained below 20 mrem. Toward these ends, the following criteria for release of animals administered radioactive material shall be established:

1. ANIMALS ADMINISTERED TECHNETIUM-99m

- a. Any small animal considered to be a pet that has been diagnosed using Technetium-99m shall not be released to its owner or any other member of the general public until radiation levels have reached natural background. The radiation levels shall be measured at the surface of the animal with an appropriate portable survey instrument. This will generally require that the animal be held for 24 to 48 hours after injection.
- b. Any small animal not considered to be a pet or any large animal which has been diagnosed using Technetium-99m should not be released to its owner or any other member of the public until radiation levels have reached natural background. The radiation levels shall be measured at the surface of the animal with an appropriate portable survey instrument. However, at the discretion of the attending veterinarian, the animal may be released provided the levels are below 2 mr/hr at the animal's surface. This will generally require that the animal be held for at least 24 hours after the time of injection.

2. ANIMALS ADMINISTERED IODINE-131

Any animal that has been treated with Iodine-131 shall not be released to its owner or any other member of the public until

- Maximum exposure rate of 5.0 mR/hour at 1 foot from the patient
- Three – day minimum stay post injection and
- Owner advised not to sleep with the patient for seven days post release.

C. WRITTEN INSTRUCTIONS FOR OWNERS OF ANIMALS TREATED WITH IODINE-131

The following information is provided to assist you in responding to the above. You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the procedure published in Appendix E to IDPH Regulatory Guide for the written instruction for owners of animals treated with Iodine-131"

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

APPENDIX F

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources. If you, or the 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 and/or F.2) to the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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, they should also be checked for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. 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 listed in 40.32. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with 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 records for five (5) years.

APPENDIX G

MODEL RULES FOR SAFE HANDLING OF RADIOACTIVE MATERIALS

In addition to 641-40.61

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix G to the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

If you prefer, you may develop your own rules for safe handling of radioactive materials for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Iowa Rules. Say on your application, "We have developed rules for the safe handling of radioactive materials for your review that are appended as Appendix G," and submit your model rules.

MODEL RULES

1. Protective clothing is to be worn at all times during the preparation, assay, and injection of radiopharmaceuticals. Wear long-sleeved laboratory coats, long pants, and closed toe and heel shoes in all areas where radioactive materials are being used. The protective clothing concept is for at least one protective layer over your skin in the event of a spill.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
5. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
6. If required, wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
7. If required, wear a finger exposure monitor during the preparation and use of radioactive materials and at all other appropriate times.
8. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
9. Never pipette by mouth.
10. Complete daily contamination surveys using wipes in areas of use and preparation; complete weekly wipe tests where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
11. After each use, survey with a radiation detection instrument the areas where radioactive material is prepared, used, and stored.
12. Always store sources, waste, and other radioactive material in labeled containers.
14. Store containers of liquid radioactive material in a secondary containment sufficient to hold the entire material if the liquid were to leak.
15. Use shielding for containers, sources, and waste as necessary to maintain exposures As Low As Reasonably Achievable.

APPENDIX H

MODEL SPILL PROCEDURES

In addition to 641-40.61(4)

You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the model spill procedure published in Appendix H to the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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

MODEL PROCEDURES

MINOR SPILLS OF LIQUIDS AND SOLIDS

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the Radiation Safety Officer (RSO).
6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

MAJOR SPILLS OF LIQUIDS AND SOLIDS

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing. Flush contaminated skin with lukewarm water. Wash affected areas with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the "Radioactive Spill Contamination Survey."

MAJOR SPILLS AND MINOR SPILLS

The decision to implement a major spill procedure depends on many incident-specific variables such as

- number of individuals affected,
- other hazards present,
- likelihood of spread of contamination,

- types of surfaces contaminated,
- radiotoxicity of the spilled material

For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

Table H-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparison of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values), 51 CFR 1092.
2. "Gamma Radiation Levels for One Curie of Some Radionuclides," Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.
3. National Council on Radiation Protection and Measurements. "Safe handling of Radioactive Materials," NCRP Report No. 30, paragraph 2.3 and Table 2, 1964.
4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 CFR 29712, Table 1, June 3, 1981.

Table H-1 may need to be modified before being used for guidance in a specific area.

TABLE H-1	
RELATIVE HAZARDS OF COMMON RADIONUCLIDES	
ESTIMATE THE AMOUNT OF RADIOACTIVITY SPILLED. INITIATE A MAJOR SPILL PROCEDURE BASED ON THE FOLLOWING DIVIDING LINE. SPILLS ABOVE THESE MILLICURIE AMOUNTS ARE CONSIDERED MAJOR, BELOW ARE CONSIDERED MINOR.	
RADIONUCLIDE	MILLICURIES
I-125, I-131, Co-60	1
P-32, Co-58, Fe-59, Se-75, Sr-85, In-111, I-123, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99m, Tl-201	100

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 the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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 the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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 one (1) meter. If it is in excess of 10 millirems per hour at three (3) feet (1 meter), stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or a "Yellow III" label is the approximate dose rate, in millirem per hour, at one (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/cm²
All other alpha-emitting radionuclides.....2.2 dpm/cm²

- f. Open the package with the following precautionary steps:
 - (1) Remove packing slip.
 - (2) Open outer package following the supplier's instructions, if provided.
 - (3) 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. (You should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) 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's 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 the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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.

Describe the type and frequency of radiation surveys that will be conducted in radioactive material use and storage areas, and in adjacent unrestricted areas. Explain which surveys are the responsibility of the authorized user and those that will be performed as part of your radiation safety audit program. Characterize laboratories and facilities according to the radiological hazard and indicate the types and frequencies of monitoring and surveys performed by designated staff.

TRAINING

Before allowing an individual to perform surveys, the RSO will ensure that he or she has sufficient training and experience to perform surveys independently.

Academic training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic using and measuring radioactivity
- Biological effects of radiation

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

FACILITIES AND EQUIPMENT

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cesium-137, Cobalt-60).

- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

AMBIENT RADIATION LEVEL SURVEYS

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 2.5 mrem/hr (0.025 mSv) or more (5 rem/year divided by 2,000 hr/year).
- 641-40.26(136C) requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year and the dose in any unrestricted area from external sources does not exceed 2 mrem (0.02 mSv) in any one hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. While the regulations do not specify a specific survey frequency, the licensee is required to ensure that the dose rate limits are not exceeded.

CONTAMINATION SURVEYS

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- After any spill or contamination event
- When procedures or processes have changed
- To evaluate the potential contamination of users and the immediate work area, at the end of the day or prior to leaving the area of use, when licensed material is used
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

CONTAMINATION SURVEY FREQUENCY

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and

quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in Appendix B of Chapter 40, then documented surveys should be performed at least daily.

Table I contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material it has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

TABLE I - SUGGESTED CONTAMINATION SURVEY FREQUENCY			
	< 0.1 ALI	> 0.1 ALI < 1.0	> 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

CONTAMINATION IN UNRESTRICTED AREAS

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table II.

TABLE II - ACCEPTABLE SURFACE CONTAMINATION LEVELS FOR EQUIPMENT			
Nuclide ^a	Average ^{b,c}	Maximum ^{b,d}	Removable ^{b,c}
I-125, I-129	1.7 Bq*/100 cm ² (100 dpm/100 cm ²)	5.0 Bq/100 cm ² (300 dpm/100 cm ²)	0.3 Bq/100 cm ² (20 dpm/100 cm ²)
I-126, I-131, I-133, Sr-90	16.7 Bq/100 cm ² (1,000 dp/100 cm ²)	50.0 Bq/100 cm ² (3,000 dpm/100 cm ²)	3.3 Bq/100 cm ² (200 dpm/100 cm ²)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq*/100 cm ² (5,000 dpm/100 cm ²)	250 Bq/100 cm ² (15,000 dpm/100 cm ²)	16.7 Bq/100 cm ² (1,000 dpm/100 cm ²)

^a Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

^b As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

^c Measurements of average contaminant should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each such object.

^d The maximum contamination level applies to an area of not more than 100 cm².

^e The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

1 Bq = 1 Disintegration per second

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, Table II provides the maximum acceptable residual levels for equipment and Table III provides screening values for building surface contamination. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm² is acceptable to indicate levels of removable contamination.

TABLE III - SCREENING VALUES FOR BUILDING SURFACE CONTAMINATION		
Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm ²)
Hydrogen-3	H-3	1.2x10 ⁸
Carbon-14	C-14	3.7x10 ⁶
Sodium-22	Na-22	9.5x10 ³
Sulfur-35	S-35	1.3x10 ⁷
Chlorine-36	Cl-36	5.0x10 ⁵
Manganese-54	Mn-54	3.2x10 ⁴
Iron-55	Fe-55	4.5x10 ⁶
Cobalt-60	Co-60	7.1x10 ³
Nickel-63	Ni-63	1.8x10 ⁶
Strontium-90	Sr-90	8.7x10 ³
Technetium-99	Tc-99	1.3x10 ⁶
Iodine-129	I-129	3.5x10 ⁴
Cesium-137	Cs-137	2.8x10 ⁴
Iridium-192	Ir-192	7.4x10 ⁴

Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using the US Nuclear Regulatory Commission's DandD Version 1.

Table III does not include screening values for radionuclides that emit alpha particles, or for soil contamination. Licensees are encouraged to use site-specific dose assessment based on actual site physical and environmental conditions.

Units are disintegrations per minute per 100 square centimeters (dpm/100 cm²). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 25 mrem/yr. (0.25 mSv/yr.) unrestricted release dose limit in 641-40.29(136C). For radionuclides in a mixture, the "sum of fractions" rule applies.

Table III was derived using the NRC DandD screening code, Version 1, and its default input parameters. Table III provides criteria that permit licensees to demonstrate compliance with the unrestricted release dose criterion in the License Termination Rule. The values correspond to screening "derived concentration guidelines" for each specific radionuclide based on the methodology. Sites with building surface contamination levels below those listed in Table III would be deemed acceptable for release for unrestricted use in accordance with the dose criteria, provided that residual radioactivity has been reduced to ALARA levels. The table is intended for use as criteria to facilitate license termination for many simple

routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in Table III, additional site-specific dose assessments may be necessary.

SURVEY RECORD REQUIREMENTS

Each survey record should include the following:

- A diagram of the area surveyed
- A list of items and equipment surveyed
- Specific locations on the survey diagram where wipe test was taken
- Ambient radiation levels with appropriate units
- Contamination levels with appropriate units
- Make and model number of instruments used
- Background levels
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

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 the IDPH Regulatory Guide for Research and Development, Laboratory, and Industrial Use of Small Quantities of By-Product Material."

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 radioactive waste is not created unnecessarily. 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 specific 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 DIS. 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 DIS 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.
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 sure that 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, and 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 DIS 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

INFORMATION REQUIRED FOR FIELD USE OF BYPRODUCT MATERIAL

10 CFR 51.22(c)(14)(v) identifies certain categorical exclusions for environmental assessments that includes an exclusion of radioactive material for research and development, and for educational purposes. However, this categorical exclusion does not encompass performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study, (e.g. tagging of animals or insects that remain in the wild). These type requests may require an environmental assessment. Field studies that do not deliberately release radioactive material into the environment, such as tagging of animals and penning them to prevent escape, may be eligible for a categorical exclusion.

The use of byproduct material in field uses will be considered if the licensee provides the following:

1. A complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.
2. A complete experiment protocol.
3. A description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment (if appropriate), and procedures for minimizing releases.
4. A description of the expected radiation dose to humans.
5. The written permission from the property owner to use radioactive materials at the proposed site.
6. A letter from the Department of Natural Resources (DNR) and any other appropriate regulatory authority indicating that they have reviewed your application and concur with your request.

REVISION	SECTION	DESCRIPTION
12/27/00	All	Format text. Changed address for Bureau of Radiological Health.
04/13/01	Appendix H	Revised and expanded Bioassay portion. Added Special Measurements section
04/13/01	Appendix K	Replaced text
04/13/01	All	Re-designated as Lab-01
06/06/01	All	Editorial Changes only
08/16/01	Appendix G	Deleted reference to syringe shields. Deleted words concerning movement of radioactive material via wheelchair or cart. Revised references to "flood sources" to "sources."
01/18/02	Section 7	Added information concerning inspections.
03/04/02	Appendix E	Added precautions for care of animals after release.
04/19/02	Appendix G	Added words concerning secondary containment for liquid containers.
04/19/02	Section 11.2	Expanded the guidance for inventory control.
07/01/02	Appendix N	Added model storage and usage log
03/13/03	Section 1.2	Replace the website address of the IDPH rules and publications.
12/07/04	Appendix G	Added requirement for long-sleeve laboratory coats.
07/01/05	All	Changed address for the Bureau of Radiological Health
01/16/07	Appendix E	Release criteria and precautions for care of animals after release (I-131)
09/07/10	Section 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.