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MINNESOTA DEPARTMENT OF HEALTH

REGULATORY GUIDE FOR LABORATORY USE OF RADIOACTIVE MATERIAL

Radioactive Materials Unit
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REGULATORY GUIDE FOR LABORATORY USE OF RADIOACTIVE MATERIAL

INTRODUCTION

This guide is designed to describe the type and extent of information needed by the Minnesota Department of Health (MDH) to evaluate an application for use of licensed radioactive material in laboratory, industrial, or research and development facilities. It also provides the user with a synopsis of the radioactive material regulations.

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

AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

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 radiological program to ensure the continued safe use of radioactive material. The RSO is also responsible for the day-to-day operations of the radiation safety program. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

FILING AN APPLICATION

You should apply for a license by completing the “Application for a Minnesota Radioactive Materials License.” Complete Items 1 through 4 on the form itself. For Items 5 through 11, submit the information on supplementary pages. Identify and key each sheet or document with the item number on the application. All typed pages, sketches, and, if possible, drawings should be on 8 1/2 X 11 inch paper to facilitate handling and review. If larger drawings are necessary, they should be folded to 8 1/2 X 11 inches. You should complete all items in the application in sufficient detail for MDH to determine that your equipment, facilities, training and experience, and radiation safety program is adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the MDH 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 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 MDH.

Submit one copy of your application to:

Radioactive Materials Unit
Minnesota Department of Health
625 Robert Street North
PO Box 64975
St. Paul, Minnesota 55164-0975

Retain one copy for yourself, as the license will be issued based on the statements and representations in your application, its supplements, and the requirements in the regulations. The statements and representations you make as if they were regulations will bind you.

The following comments apply to the indicated items on the Application for a Minnesota Radioactive Materials License.

Item 1: License Action Type

Check box A for a new license request.

Check box B for an amendment to an existing license and provide the license number. See "Amendments and Renewal of a License," sections of this document.

Check box C for a renewal of an existing license and provide the license number.

Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent.

Timely Notification of Transfer of Control
Licensees must provide full information and obtain MDH's prior written consent before transferring control of the license, directly or indirectly, or, as some licensees call it, "transferring the license." Transfers of control may be the results of mergers, contractual agreements, buyouts, or majority stock transfers. Although it is not MDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior MDH written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid MDH licenses.
- Materials are properly handled and secured.
- Persons using these materials are competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for final disposal of radiography devices.
- Public health and safety are not compromised by the use of such materials.

Item 3: Address(es) Where Licensed Material Will Be Used or Possessed

Applicants must provide a specific address for each location where radioactive material will be used, stored, or dispatched. Specify the street address, city, and state or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each permanent storage or use facility. A Post Office Box address is insufficient because MDH needs a specific address to allow an MDH inspector to find the use and/or storage location. In addition, the applicant should state whether a location will be used only for storage of sources and devices.

If a device will be used in a permanent installation, give the specific address of each location.

If operations will be conducted at temporary jobsites (i.e., locations where work is conducted for limited periods of time), specify "temporary jobsites anywhere in the Minnesota where MDH maintains jurisdiction."

Item 4: Person to Be Contacted About This Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer (RSO) or knowledgeable management official. The MDH will contact this individual if there are questions about the application.

Notify MDH if the contact person or telephone number changes. This notice is for information only and does not require a license amendment or a fee.

Items 5 through 11 should be submitted on separate sheets of paper.

Item 5: Radioactive Material

Unsealed and/or Sealed Radioactive Material

Each authorized radioisotope is listed on the MDH license by its element name, chemical and/or physical form, and the maximum possession limit. The applicant should list each requested radioisotope by its element name and its mass number [e.g., Carbon-14 (C-14)] in item 5. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not required. For volatile radioactive material, however, it is necessary to specify whether the requested radioisotope will be acquired in free (volatile) or bound (non-volatile) form, because additional safety precautions are required when handling and using free form volatile material. For example, when requesting authorization to use tritium (H-3) or Iodine-125 (I-125), the applicant must specify whether the material will be acquired in free form or bound form. If a radioisotope will be acquired in free and bound forms, separate possession limits for each form must be specified.

Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

The anticipated possession limit in Megabecquerels or gigabecquerels (millicuries or curies) for each radioisotope should also be specified. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. These requirements are discussed in the section on Financial Assurance and Decommissioning.

Applicants should determine if their proposed uses of licensed material are in excess of the quantities specified in 4731.3145. It is not necessary to submit an application to MDH for quantities of radioactive material that are covered by the exemption in 4731.3040, provided that they are received from entities that are licensed to distribute them. Similarly, certain prepackaged units (typically called kits) containing radioactive material for conducting *in vitro* clinical or laboratory tests, are distributed to persons who are generally licensed. Regulations related to possession and uses of such prepackaged kits under a general license are stated in 4731.3245. Persons eligible for this general license are limited to physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, and hospitals; however, these persons are required to register with MDH before acquiring or using these units, unless they already have an MDH license.

Certain devices containing sealed sources of radioactive material, such as Electron Capture Devices in Gas Chromatographs (ECDs in GCs), are authorized by the NRC or Agreement States for distribution to persons who are generally licensed as well as to persons who are specifically licensed. Generally licensed devices can be acquired by the users without obtaining a specific license from MDH. Distributors of such devices must provide users with appropriate information related to the acquisition, use, and transfer of these generally licensed devices.

A safety evaluation of sealed sources and devices is performed by the NRC or an Agreement State before authorizing a manufacturer or distributor to distribute them to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that MDH can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a license.

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device registry (SSDR) issued by the NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates without obtaining MDH's prior permission in a license amendment. To ensure that applicants use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer.

For unsealed materials, provide the element name with mass number, chemical and/or physical form, and maximum requested possession limit.

For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.

For sealed materials, identify each radionuclide (element name and mass number) that will be used and specify the maximum activity per source.

- Specify the maximum number of sources or total activity for each radionuclide.
- Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested.
- Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by the NRC or an Agreement State.
- Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by the NRC or by an Agreement State.

- Provide an Emergency Plan (if required).

Financial Assurance and Recordkeeping for Decommissioning

MDH wants to ensure that decommissioning will be carried out with minimum impact on the public, occupational health and safety, and the environment. MDH regulations requiring Financial Assurance or a Decommissioning Funding Plan are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and unrestricted use of the facilities is possible at the conclusion/termination of licensed activities. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available. Applicants are required to submit Financial Assurance or a Decommissioning Funding Plan when the possession of radioactive material with a half-life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit Financial Assurance or a Decommissioning Funding Plan are stated in 4731.3080.

More comprehensive guidance on determining the need for a Decommissioning Funding Plan or Financial Assurance is included in Appendix A. The Table below is a partial list of radioisotopes with half-lives greater than 120 days and their corresponding limits in excess of which Financial Assurance or a Decommissioning Funding Plan is required. Column 2 lists the corresponding possession limits of radioisotopes in unsealed form requiring Financial Assurance. Column 3 lists the corresponding possession limits of radioisotopes in unsealed form requiring the submittal of a Decommissioning Funding Plan DFP. These limits apply when only one of these radioisotopes is possessed.

Commonly Used Unsealed Licensed Materials
Requiring Financial Assurance/Decommissioning Funding Plan

RADIOISOTOPE	COLUMN 2 **LIMIT FOR FINANCIAL ASSURANCE (MILLICURIES)**	COLUMN 2 **LIMIT FOR DECOMMISSIONING FUNDING PLAN (MILLICURIES)**
Calcium-45	10	1,000
Carbon-14	100	10,000
Chlorine-36	10	1,000
Hydrogen-3	1,000	100,000
Zinc-65	10	1,000

Item 6: Purpose

Applicants should clearly specify the purpose for which each radioisotope will be used. The description should be detailed enough to allow MDH to determine the potential for radiation exposure to those working with radioactive materials and members of the public.

Applicants may use the format such as that shown below to provide the requested information.

Sample Format for Providing Information about Requested Radioisotopes

RADIOISOTOPE	CHEMICAL/PHYSICAL FORM	MAXIMUM POSSESSION LIMIT	PROPOSED USE
H-3	Unbound/volatile	100 millicuries	Labeling of compounds
H-3	Bound/non-volatile	100 millicuries	In vitro studies; studies in small lab animals
P-32	Any	30 millicuries	In vitro studies; labeling of compounds
I-125	Unbound/volatile	30 millicuries	Protein iodination
I-125	Bound/non-volatile	50 millicuries	In vitro studies; studies in small lab animals; calibration of instruments
Cs-137	Sealed source, Mfg. name/ model number	20 millicuries	Calibration of instruments

Applicants should clearly specify if the licensed material will be used in animal studies and/or tracer studies. Applicants should also state whether the studies will be limited to small animals (e.g., rats, mice) or may also include larger animals (e.g., pigs, dogs, horses).

Item 7: Individuals Responsible For Radiation Safety Program

Radiation Safety Officer (RSO)

The person responsible for implementing the radiation protection program is called the Radiation Safety Officer, or RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are described in Appendix B. MDH requires the name of the RSO on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

MDH believes that to demonstrate adequate training and experience, the RSO should have (1) as a minimum, a bachelor's degree, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles
- Characteristics of Ionizing Radiation
- Units of Radiation Dose and Quantities
- Radiation Detection Instrumentation
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of radioactive material to be used)
- MDH Regulatory Requirements and Standards
- Hands-on use of radioactive materials

The amount of the required training and experience depends upon the type, form, quantity and proposed use of the licensed material requested. Ultimately, the proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts.

The licensee should provide the name of the proposed RSO and information demonstrating the proposed RSO has obtained training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

It is important to notify MDH as soon as possible of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to MDH as part of an amendment request.

Authorized User (AU)

An Authorized User is a person whose training and experience have been reviewed and approved by MDH, who is named on the license, and who uses or directly supervises the use of licensed material. The Authorized User's primary responsibility is to ensure that radioactive materials are used safely and according to regulatory requirements. The Authorized User is also responsible to ensure that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

Authorized Users must have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of and access to licensed material, and respond appropriately to events or accidents involving licensed material.

MDH believes that to demonstrate adequate training and experience the Authorized User should have (1) a bachelor's degree or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of the proposed activities. Training should include the following subjects:

- Radiation Protection Principles
- Characteristics of Ionizing Radiation
- Units of Radiation Dose and Quantities
- Radiation Detection Instrumentation
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of radioactive material to be used)
- Hands-on Use of Radioactive Materials

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested, but it should cover the subjects stated.

An Authorized User is considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the Authorized User may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he/she is responsible for the safe use of radioactive material to assure that areas are not contaminated.

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, Authorized Users must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

Applicants should provide the name of each proposed Authorized User with the types and quantities of licensed material to be used and information demonstrating that each proposed Authorized User is qualified by training and experience to use the requested licensed materials. Applicants should not

submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)

Before beginning work with licensed material, individuals should receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Particular attention should be given to persons performing work with radioactive materials that may require special procedures, such as hot cell work, waste processing, and animal handling. Also, ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. The guidance in Appendix C may be used to develop a training program. The program should consider both the topics pertinent for each group of workers and the method and frequency of training. The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

The licensee should provide a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

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

Item 9: Facilities and Equipment

Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the radioactive materials.

Applicants may delay completing building projects and acquiring equipment until after the application review is completed, in case changes are required because of the application review. This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant may not possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

Applicants are reminded that records important to decommissioning include the following:

- As-built drawings and modifications of structures and equipment in restricted areas.
- As-built drawings and modifications of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination.
- Records of spills and unusual occurrences that may result in contamination of the facility or site.

These records are required to be maintained in an identifiable location. Facilities are required to meet MDH criteria before release. Therefore, careful facility design is important to prevent contamination, or

facilitate decontamination, reducing the costs needed for decommissioning. For further information, see the section entitled, "Financial Assurance and Record Keeping for Decommissioning."

If radioactive materials will be used with animals, include a description of the animal housing facilities.

Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, security, preparation and measurement of radioactive materials. A diagram should be submitted showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.

Item 10: Radiation Safety Program

You, as the licensee, are responsible for the conduct of your radiation safety program and for all actions of your employees. The elements of a radiation safety program are contained in Appendices. Review each appendix carefully. (Some of these appendices have been addressed in the proceeding text and need not be re-addressed.) Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate “not applicable.”

Audit Program

Appendix D contains a suggested audit program. Not all areas may be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to their activities or activities that have not occurred since the last audit. Audits are required to be conducted at least once every 12 months.

Currently, the MDH's emphasis in inspections is to perform actual observations of work in progress. As a part of your audit program, you should consider performing unannounced audits of radioactive material users to determine if the appropriate procedures are available and are being followed.

If an audit identifies violations of MDH requirements, the licensee should first evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. Certain identified problems or potential violations may require notification or a report to MDH. Licensees are encouraged to contact MDH for guidance if there is any uncertainty regarding a reporting requirement. MDH routinely reviews the licensee's records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. MDH can exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

Licensees should maintain records of these audits and other reviews of program content and implementation for three years from the date of the record. Records of these audits should include the following information: date of the audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records should be maintained for inspections by MDH.

Radiation Monitoring Instruments

Licensees shall possess or have access to calibrated radiation detection/measurement instruments or licensed services to perform, as necessary, the following:

- Package surveys
- Contamination surveys
- Sealed source leak tests
- Air sampling measurements
- Bioassay measurements
- Effluent release measurements
- Unrestricted area dose rate measurements

For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the survey instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters
- Portable or stationary dose rate or exposure rate meters
- Single or Multi-channel Analyzers
- Liquid Scintillation Counters (LSC)
- Gamma Counters
- Proportional Counters
- Solid State Detectors

The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (count rate, dose rate, etc.). Applications should include descriptions of the instrumentation available for use and instrumentation applicants intend to purchase before starting licensed activities. The description should include the type of instrument and probe and the instrument's intended purpose.

MDH requires that calibrations are performed by the instrument manufacturer or a person specifically authorized by MDH or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations should submit procedures for review. Information about instrument specifications and model calibration procedures are contained in the MDH Instrument Calibration Regulatory Guide.

The licensee should provide one of the following:[1]

- A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications.
- A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications. Additionally, we will implement the model survey meter calibration program published in MDH Instrument Calibration Regulatory Guide."
- A description of alternative procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration (including calibration frequency) of survey equipment will be performed."

All licensees have the option to upgrade survey instruments as necessary.

Material Receipt and Accountability

Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with 4731.2350. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

[1] Alternative responses will be reviewed by MDH staff.

Licensees need to arrange to receive radioactive packages when they are delivered or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee can pick up the package expeditiously.

In limited scope radiation safety programs, the RSO or his/her staff usually receives the incoming package directly from the carrier, and performs all verification, surveying, opening, and documentation for inventory. The package is then delivered to the Authorized User or the AU retrieves the package from the RSO. If the package is transported over public roads by the licensee, it must be repackaged and transported in accordance with DOT regulations.

If the package of licensed material is delivered to the licensed facility's receiving department (Receiving), individuals working in that department should be trained to do the following:

- Identify the package as radioactive by labeling and shipping papers.
- Segregate the package from other incoming items in a secured area pending further instruction from the RSO.
- Notify the RSO.

When notified that a package of licensed material has arrived, the RSO or his/her staff should retrieve the package and follow the safe opening procedures.

MDH rules state the requirements for monitoring packages containing licensed material. These requirements are described in the table below.

Package Monitoring Requirements

PACKAGE	CONTENTS	SURVEY TYPE	SURVEY TIME[1]
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level	As soon as practicable, but not later than three hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Greater Than Type A	Contamination Radiation Level	As soon as practicable, but not later than three hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than Type A	None	None
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less Than Type A	Contamination	As soon as practicable, but not later than three hours after receipt of package
Not Labeled	Licensed Material	None	None
Damaged	Licensed Material	Contamination Radiation Level	As soon as practicable, but not later than three hours after receipt of package

[1] Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has three hours after the beginning of the next workday to perform the required surveys.

Licensees are required to immediately notify MDH and the final delivery carrier by telephone, email, or facsimile, when removable radioactive surface contamination exceeds the limits of 4731.0415 or external radiation levels exceed the limits of 4731.0412.

Licensed materials must be tracked from receipt to disposal in order to ensure accountability and to ensure that possession limits listed on the license are not exceeded. Licensees frequently possess radioactive material that is generally licensed or distributed to them as an exempt quantity in addition to that which is specifically listed on their license. MDH recognizes that multiple authorizations can create some confusion. Therefore, a specific licensee always has the option of receiving and possessing radioactive materials that qualify for a general license by adding these to its specific license.

It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees must have in place accountability and control system for promptly detecting the loss of licensed material.

Licensees who use and/or possess sealed sources are required by license condition to perform inventories of sealed sources every six months. Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm that these sealed sources have not been disturbed at least every six months. Licensees are also required to conduct leak tests of sealed sources at six-month intervals (or at longer intervals as specified in the SSD Registration Certificate). Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.

To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside the normal channels, e.g., through the loan or other transfer of materials without purchase or through surplus. A model procedure for Ordering and Receiving Radioactive Material is included in Appendix F.

Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components including refrigerators and freezers will become contaminated. Removal of these items for maintenance, repair, or disposal should also be carefully controlled.

Licensees must maintain records of receipt, transfer, and disposal (as waste) of all licensed material. Other records such as transfer records could be linked to radioactive material inventory records. Receipt records should also document cases where excessive radiation levels or radioactive contamination were found on packages or containers of material received. These records should also describe the action taken.

Receipt, transfer, and disposal records typically contain the following information:

- Radionuclide and activity (in units of becquerels or curies), and date of measurement of radioactive material
- For each sealed source, manufacturer, model number, location, and, if needed for identification, serial number
- As appropriate, manufacturer and model number of device containing the sealed source

- Date of the transfer and name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number)
- For licensed materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.)

Applicants should provide a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced. Alternatively, applicants may make a statement that: "Physical inventories will be conducted at intervals not to exceed six months, to account for all sealed sources and devices received and possessed under the license."

Occupational Dose

If an adult (individual) is likely to receive in one year a dose greater than ten percent of any applicable limit, monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive before allowing the individual to receive the dose. This evaluation does not need to be made for every individual; evaluations can be made for employees with similar job functions or work areas.

If this prospective evaluation shows that the individual's dose is not likely to exceed ten percent of any applicable regulatory limit, there are no recordkeeping or reporting requirements. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. When determining the need for monitoring, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered, including any recordkeeping and reporting requirements. If an evaluation determines that monitoring was not required and a subsequent evaluation indicates that the 10 percent regulatory threshold may or will be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported (if required). These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a best estimate of the actual dose received.

If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter “Not Required” (NR) in the blocks on MDH Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter “Not Detectable” (ND).

If the prospective dose evaluation shows that the individual is likely to exceed ten percent of an applicable limit, monitoring is required. Recordkeeping of the results of monitoring performed regardless of the actual dose received is also required.

A common method for dose evaluation is to monitor workers' dose with whole body and extremity dosimetry (Optically Stimulated Dosimeters or thermoluminescent dosimeters, ring badge, etc.) provided by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved dosimetry service. Workers are typically monitored for a year or more to determine actual annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if there are changes to the licensee's program, such as procedures, frequency of use, quantity of licensed material used, isotopes used, etc.

The licensee should provide a description of the method for demonstrating compliance with the rules for monitoring exposures. Alternatively, the licensee should state that: "a prospective evaluation has been completed and that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits."

Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with MDH requirements (e.g., to respond to worker requests).

Safe Use of Radionuclides

Licensees are responsible for the security and safe use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. Licensees should develop and maintain written procedures to ensure safe use of licensed material. The procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

General Safety Procedures

The written procedures should include the following elements:

- Contamination controls
- Waste disposal practices
- Personnel and area monitoring (including limits)
- Use of protective clothing and equipment
- Record keeping requirements
- Reporting requirements
- Responsibilities
- Frequency of personnel monitoring
- Use of appropriate shielding
- Methods to avoid spread of contamination in the laboratory (e.g., frequent change of gloves)
- Methods to minimize exposure to the individual

Applicants should also develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

Licensees should determine if they have areas that require posting. In addition, containers of licensed material (including radioactive waste) must be labeled unless they meet the exemptions in 4731.2340.

Security Procedures

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about radioactive materials can not be exposed to or contaminated by the material. The area must also be secured so that radioactive material cannot be removed. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material, or to prevent persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include:

- Storage and use of licensed materials only in restricted areas.
- Limiting access to an entire facility or building or portion of the building only to radiation workers.
- Providing storage areas that can be locked to prevent access to the material.
- Implementing procedures that require a radiation worker to be with line of sight of the materials whenever licensed materials are in use.

Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may be required to security procedures at facilities which may have

unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment, and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, sabotage, fires, floods, etc., can adversely affect the safety of personnel and members of the public. It is therefore necessary to develop written procedures to minimize the impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of their role in an emergency with systematic instructions and clear direction of whom to contact.

Licensees should have readily available a sufficient number of appropriate and calibrated survey instruments. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Appendix G includes model emergency procedures. Applicants may adopt these procedures or develop their own incorporating the safety features included in these model procedures.

Collection of Bioassay Samples

The applicant must state that procedures for safe use, including security of materials, and emergencies have been developed, or will be developed before receipt of licensed material. Procedures may be revised only if 1) the changes are reviewed and approved by the licensee management and the RSO in writing; 2) the licensee staff is provided training in the revised procedures prior to implementation; and 3) the changes do not degrade the effectiveness of the program.

In the event of an emergency where an individual becomes contaminated and radioactive material is taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. Frequently, this estimate is made by performing a bioassay of the individual. Bioassays may be performed through direct methods, such as whole body counting or thyroid counting, where the radioactive material in the body can be directly measured using appropriate instruments. Bioassays may also be performed through indirect means by sampling urine or other excreta from the body, and calculating the intake from the amount of material detected in the samples, the time between suspected intake and sample collection, and knowledge of the rate of excretion of the compound and/or radionuclide from the body. While there are many ways to perform the calculations, including using computer models, the method of calculation is only as good as the quality of the samples and analyses performed. Because a dose estimate may be required, bioassay procedures for a suspected intake may differ from those in a routine bioassay-screening program, and your radiation safety program should include procedures and equipment for appropriate sample collection in an emergency. The following items should be considered in developing any procedures:

- Type of bioassay that must be performed (direct or indirect)
- Number of samples or data points to be collected
- Frequency of sampling (hourly, daily, weekly, etc.)

- Size of the sample to be collected (24-hour urine collection)
- Ease/difficulty of sample collection
- Need for written instructions to be provided to the sample collector, who may be the contaminated individual

Surveys

Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

Radiation surveys are used to detect and evaluate contamination of:

- Facilities
- Equipment
- Personnel (during use, transfer, or disposal of licensed material)
- Restricted and unrestricted areas

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

Surveys are required to evaluate a radiological hazard and when necessary for the licensee to comply with the regulations. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.
- Measurements of radioactive material concentrations in air for areas where unsealed radioactive materials are handled or processed, where operations could expose workers to the inhalation of radioactive material, or where licensed material could be released to unrestricted areas.
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer.
- Bioassays to determine the kinds, quantities, concentration, and the location of radioactive material in the human body. A bioassay can be made by direct measurement (*in vivo* counting) or by analysis and evaluation of material excreted or removed from the human body.
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above.

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program.

Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area.

Leak Testing

As a licensee, you must perform leak testing of sealed sources unless the sources are exempt from testing. The MDH 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 six-month intervals unless otherwise authorized by your license.

The following options are available for leak testing:

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 will report 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 name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix J 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 J or submit your own procedures.

Transportation

Packages shipped by licensees frequently meet the "Limited Quantity" criteria as described in 49 CFR 173.421, and therefore could be exempt from certain DOT requirements. If they are not exempted, however, licensed material, including radioactive waste, must be packaged and transported in accordance with MDH and DOT requirements if the transportation involves common carriers or the use of public highways. Licensees should develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Licensees should consider the safety of all individuals who may handle or may come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the package integrity is not compromised during transport, and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of 10 CFR 71.47, but are ALARA.

All domestic shipping papers and labels must be in SI units only *or* must be in SI units first with English units in parenthesis

No response is required for the application process. Transportation procedures will be reviewed during inspections.

Item 11: Waste Management

Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, unusable items contaminated with radioactive material, e.g., absorbent paper, gloves, etc. Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized to do so by MDH.

All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. MDH requires licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-storage (DIS)
- Release into sanitary sewerage
- Transfer to an authorized recipient
- Extended interim storage
- Disposal of waste as if it were not radioactive (specific wastes)
- Obtaining prior approval of MDH of any alternate method
- Release in effluents to unrestricted areas, other than into sanitary sewerage
- Incineration

Licensees may choose any one or more of these methods to dispose of their radioactive waste. Most facilities store or dispose of radioactive waste by a combination of the first four methods because of the types and amounts of licensed materials used by these facilities. Some of the radioactive waste may also include additional hazards, (e.g., biohazard or chemical hazard). Such waste is called mixed waste, and its storage and disposal must comply with all other applicable Federal, state, and local regulatory requirements.

Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require that licensees maintain all appropriate records of disposal of radioactive waste.

Disposal by Decay-In-Storage (DIS)

MDH has concluded that materials with half-lives of less than or equal to 120 days are appropriate for DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages before disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

Applicants should assure that adequate space and facilities are available for the storage of such waste. Licensees can minimize the need for storage space if the waste is segregated according to physical half-life. Waste containing radioisotopes of physical half-lives within a certain range may be stored in one container and allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container. Procedures for management of such waste should include methods of segregation, surveys before disposal, and maintenance of records of disposal. Records should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, and results of final survey before disposal as ordinary trash.

Release into Sanitary Sewerage
Although not a preferred method for disposal, MDH will authorize disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is easily dispersible biological material) in water.
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in 4731.2750, Subpart 7.
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 4731.2750, Subpart 7 cannot exceed unity.
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.

Licensees are responsible to demonstrate that licensed materials discharged into the public sewerage system are indeed readily soluble in water. Careful consideration should be given to the possibility of re-concentration of radioisotopes that are released into the sewer.

The regulations in 4731.2420 are not applicable for releases to a private sewerage treatment system, a septic system, or leach fields.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in 4731.2420 and do not exceed the monthly and annual limits specified in regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage.

Transfer to an Authorized Recipient
Licensees may transfer radioactive waste to an authorized recipient for disposal. It is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste before making any shipment. The waste must be packaged in approved containers for shipment, and each container must identify the radioisotopes and the amounts contained in the waste. Additionally, packages must comply with the requirements of the particular burial site's license and state requirements. Each shipment must comply with all applicable MDH and DOT requirements. In some cases, the waste handling contractor may provide guidance to the licensee for packaging and transportation requirements; however, the licensee is ultimately responsible for ensuring compliance with all applicable regulatory requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers and members of the public. The program should include adequate safety procedures to protect workers, members of the public, and the environment.

Disposal of Specific Waste as if it were Not Radioactive
The following radioactive wastes may be disposed of as non-radioactive waste:

- Liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 KBq (0.05 µCi) of H-3 or C-14 per gram of the medium.

- Animal carcasses or animal tissue containing no more than 1.85 KBq (0.05 µCi) of H-3 or C-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Applicants must maintain accurate records of these disposals.

Alternate Methods

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

Some licensees do not have an LLW disposal facility available to them and therefore must use on-site interim storage until such time that a facility becomes available. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort. The protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on-site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. Other than DIS, LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary.

The applicant should indicate the procedures for waste collection, storage and disposal by any of the authorized methods described in this section.

Item 12: License Fee

If this is an application for a new license, the full fee application must be included with this application. An application received without a fee or with an inadequate fee may be returned to you or delayed in processing. Fees for processed applications are not refundable. Make check or money order payable to the Minnesota Department of Health.

For license renewals, the fee is due on the date your license expires.

Item 13: 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 him/herself 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.

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. An application for an amendment must be filed either on MDH 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 MDH that the amendment has been approved.

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 MDH as provided for in paragraph 4731.0595. 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 MDH regulations that do not allow you to possess licensable material without a valid license.

IMPLEMENTATION

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

INSPECTIONS

MDH conducts initial inspections of new radiological programs between six and 12 months after licensed material is received and operations have begun. Subsequent routine inspections of licenses are scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency indicated in NRC Inspection Manual Chapter 2800.

APPENDIX A
GUIDANCE ON DECOMMISSIONING FUNDING PLAN AND FINANCIAL ASSURANCE

Table 1 and the Worksheet in Table 2 are used to determine the need for certification of financial assurance for decommissioning or a decommissioning funding plan. Table 1 is a listing of isotopes with a half-life of greater than or equal to 120 days. If the applicant proposes to use isotopes with a half-life greater than or equal to 120 days, divide the requested possession limit (in µCi) of the isotope by the value for that isotope in Table 1. If the material requested is in an unsealed form, use the value in the unsealed column. If the material requested is in a sealed form, use the value in the sealed column. Place the fraction in the proper column in Worksheet 2. Add the fractions in the column and place the total in the row labeled total (i.e., "sum of the ratios").

Table 1 - Isotopes with a Half-life Greater Than or Equal to 120 Days

ISOTOPE	UNSEALED (µCI)	SEALED (µCI)
Americium-241	10	1×10^{8}
Antimony-125	10000	1×10^{11}
Barium-133	10000	1×10^{11}
Cadmium-109	10000	1×10^{11}
Calcium-45	10000	1×10^{11}
Carbon-14	100000	1×10^{12}
Cerium-144	1000	1×10^{10}
Cesium-134	1000	1×10^{10}
Cesium-135	10000	1×10^{11}
Cesium-137	10000	1×10^{11}
Chlorine-36	10000	1×10^{11}
Cobalt-60	1000	1×10^{10}
Europium-152 13 yr	1000	1×10^{10}
Europium-154	1000	1×10^{10}
Europium-155	10000	1×10^{11}
Gadolinium-153	10000	1×10^{11}
Gold-198	100000	1×10^{12}
Hydrogen-3	1000000	1×10^{13}
Indium-115	10000	1×10^{11}
Iodine-129	100	1×10^{9}
Iron-55	100000	1×10^{12}
Krypton-85	100000	1×10^{12}
Manganese-54	10000	1×10^{11}
Nickel-59	100000	1×10^{12}
Nickel-63	10000	1×10^{11}
Niobium-93^{m}	10000	1×10^{11}
Platinum-193	100000	1×10^{12}
Polonium-210	100	1×10^{9}
Promethium-147	10000	1×10^{11}
Rubidium-87	10000	1×10^{11}

Ruthenium-106	1000	1×10^{10}
Silver-110^{m}	1000	1×10^{10}
Strontium-90	100	1×10^{9}
Technetium-97	100000	1×10^{12}
Technetium-99	10000	1×10^{11}
Thallium-204	10000	1×10^{11}
Thulium-170	10000	1×10^{11}
Thulium-171	10000	1×10^{11}
Tungsten-181	10000	1×10^{11}
Zinc-65	10000	1×10^{11}
Zirconium-93	10000	1×10^{11}
Any alpha emitting radionuclides not listed above with a half-life greater than or equal to 120 days.	10	1×10^{8}
Any radionuclide other than alpha emitting radionuclides not listed above with a half-life greater than or equal to 120 days.	100	1×10^{9}

Table 2 Sample Worksheet for Determining Need for a Decommissioning Funding Plan or Financial Assurance

ISOTOPE	UNSEALED RADIOACTIVE MATERIAL ACTIVITY (µCI) ÷ UNSEALED VALUE FROM TABLE 1	SEALED RADIOACTIVE MATERIAL ACTIVITY (µCI) ÷ SEALED VALUE FROM TABLE 1
Total		
Funds required		
	If 1.0, enter $0 If > 1.0 but 10.0, enter $150,000 If > 10.0, but 100.0, enter $750,000 If > 100.0, enter "DFP only"	If 1.0, enter $0 If > 1.0, enter $75,000

If the sum of the fractions is less than or equal to 1, the applicant does not need to submit certification of Financial Assurance or Decommissioning Funding Plan. If the sum of the fractions is greater than 1 but less than or equal to 100, the applicant will need to submit certification of Financial Assurance (in the amount shown above) or a Decommissioning Funding Plan. If the sum of the fractions is greater than 100, the applicant must submit a Decommissioning Funding Plan.

APPENDIX B
DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

The RSO's duties and responsibilities include ensuring radiological safety and compliance with MDH and DOT regulations and the conditions of the license. Typically, these duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of radioactive material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 4731.2090.
- Ensure security of radioactive material.
- Posting of documents as required by 4731.1010.
- Ensure that licensed material is transported in accordance with applicable MDH and DOT requirements.
- Ensure that radiation exposures are ALARA.
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with MDH and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.
- Immediately terminate any unsafe condition or activity that is found to be a threat to health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records of receipts, transfers, and surveys as required.
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all users are properly trained.
- Perform periodic audits of the radiation safety program to ensure that the licensee is complying with all applicable MDH regulations and the terms and conditions of the license (e.g., leak tests, inventories, use limited to trained, approved users, etc.). The audits should also review the efforts to achieve occupational doses and doses to members of the public are ALARA. The audit should also verify that the required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented and maintained for at least three years and provided to management for review; ensure that prompt action is taken to correct deficiencies.

- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or MDH limits are investigated and reported to MDH and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and up-to-date copies of MDH regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH during the licensing process.

APPENDIX C
MODEL TRAINING PROGRAM

This Appendix is intended only as a guide for developing a training program. Individuals working with radioisotopes may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be provided via a simple handout, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

Frequency of Training

- Before assuming duties with, or in the vicinity of, radioactive materials
- Whenever there is a significant change in duties, regulations, or terms of the license
- Annually (refresher training).

General Information

- Radiation safety
  - radiation vs. contamination
  - internal vs. external exposure
  - biological effects of radiation
  - ALARA concept
  - use of time, distance, and shielding to minimize exposure

- Regulatory issues
  - material control and accountability
  - personnel dosimetry
  - radiation safety program audits
  - transfer and disposal
  - record keeping
  - surveys
  - postings
  - labeling of containers
  - handling and reporting of incidents or events
  - licensing and inspection by MDH
  - need for complete and accurate information
  - employee protection
  - deliberate misconduct

Licensee-Specific Program Elements

- Authorized users and supervised users
- Ordering and receiving radioisotopes
- Applicable regulations and license conditions
- Areas where radioactive material is used or stored
- Potential hazards associated with radioactive material in each area where the individuals will work
- Appropriate radiation safety procedures
- Licensee's in-house work rules
- Each individual's obligation to report unsafe conditions to the RSO
- Appropriate response to spills, emergencies or other unsafe conditions
- Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable

- Locations where the licensee has 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 4731.1010.
- Emergency procedures:
  - RSO name and telephone number
  - immediate steps to prevent or control spread of contamination
  - clean-up instructions, decontamination
- Survey program:
  - survey instrument accessibility
  - who is responsible
  - types, contamination and area
  - frequency
  - levels of contamination
  - personnel, hands, shoes
  - records
- Waste
  - liquid
  - solids
  - sanitary sewer
  - burial (transfer to low level waste repository)
  - storage
  - decay-in-storage
  - waste storage surveys
  - incineration
  - records
- Dosimetry
  - whole body
  - extremities
  - lost or replacement badges and dose assessment
  - bioassay procedures
  - records
- Instrumentation
  - survey meters-use, calibration frequency, use of check sources
  - analytical instruments-gas chromatographs, liquid scintillation counters
- Procedures for receiving packages containing radioactive materials
  - normal
  - off-duty
  - notification of user and RSO
  - security
  - exposure levels
  - possession limit
  - receipt of damaged packages
- Procedures for opening and examining packages
  - leakage and contamination
  - monitoring packages
  - monitoring packing materials
  - gloves
  - transferring material to users
- Animal experiments
  - description of facilities
  - safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
  - security

- Sealed sources
  - leak test requirements
  - inventory requirements
  - exempt quantities
  - records
- Other topics, as applicable
- Question and answer period

Laboratory Safety and Use of Radioisotopes

Control procedures for obtaining permission to use radioactive materials at the facility; give limitations on quantity to be handled per user, allowed per experiment, etc.

- Protective clothing, laboratory apparel, and equipment.
- Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. As an example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or glove boxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma emitting licensed materials are handled.
- Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.
- Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.
- Decontamination procedures to use and whom to contact in case of an emergency.
- Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.
- Requirements for storage, labeling of containers, and identification of areas where licensed materials are used.
- Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.
- Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.
- Records to be maintained on use and disposal of licensed materials.
- Prohibition of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are used.

APPENDIX D
MODEL AUDIT PROGRAM

SAMPLE AUDIT PROGRAM

An audit is conducted, in part, to fulfill the requirements for an annual review of the content and implementation of the licensee's radiation protection program. It should also identify program weaknesses and allow licensees to take early corrective actions (before an MDH inspection). During an audit, the auditor needs to keep in mind not only the requirements of MDH's rules, but also the licensee's commitments in its applications and other correspondence with MDH. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

Section 1: Audit History. Enter the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

Section 2: Organization and Scope of Program. Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license.

Section 3: Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by 4731.1020. Be sure that users have received training and have a copy of the licensee's safe use and emergency procedures *before* being permitted to use radioactive material. Note whether refresher training is conducted in accordance with licensee commitments. Ensure that each worker has a copy of the licensee's procedures, and by interview and/or observation of selected workers that he/she can implement them**.**

Section 4: Audits. Verify that audits fulfill the requirements of 4731.2010, are conducted in accordance with licensee commitments, and are properly documented.

Section 5: Facilities. Verify that the licensee's facilities are as described in its license documents.

Section 6: Materials. Verify that the license authorizes the quantities and types of radioactive material that the licensee possesses.

Section 7: Leak Tests. Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.

Section 8: Inventories. Verify that inventories are conducted at least once every six months to account for all sources; inventory records should be maintained.

Section 9: Radiation Surveys. Verify that the licensee has appropriate, operable and calibrated survey instruments available, and that the instruments have been calibrated at the required frequency. Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas adjacent to use are within regulatory limits. Verify compliance with 4731.2090. Records of surveys must be retained for three years after the record is made.

Section 10: Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing radioactive material, received from others, are received, opened, and surveyed in accordance with 4731.2350. Ensure that transfers are performed in accordance with 4731.3105. Records of surveys, receipt, and transfer must be maintained.

Section 11: Transportation. Determine compliance with Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport (49 CFR 172.200, 201, 202, 203, 204 and 177.718).

Section 12: Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. Alternately, if personnel dosimetry is provided and required, verify that it complies with 4731.2200 and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 4731.2080. Check whether records are maintained as required.

Section 13: Auditor's Independent Measurements (If Made). The auditor should make independent survey measurements and compare the results with those made or used by the licensee.

Section 14: Notification and Reports. Verify compliance with the notification and reporting requirements.

Section 15: Posting and Labeling. Check for compliance with the posting and labeling requirements.

Section 16: Recordkeeping for Decommissioning. Check to determine compliance with 4731.3080.

Section 17: Bulletins and Information Notices. Check to determine if the licensee is receiving bulletins, information notices, etc., from MDH. Check whether the licensee took appropriate action in response to MDH mailings.

Section 18: Special License Conditions or Issues. Verify compliance with any special conditions on the licensee's license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

Section 19: Evaluation of Other Factors. Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

APPENDIX E
FACILITIES AND EQUIPMENT CONSIDERATIONS

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every applicant will need to address each topic in its application.

Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.

Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous to facilitate decontamination.

Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 4731.2750.

Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.

Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.

Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.

A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.

Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.

Remote handling tools, such as forceps or extension handles, should be used. In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.

Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.

Designated areas should be provided for coats and personal belongings to avoid contamination.

Areas with background radiation levels should be designated for personnel dosimetry storage.

Areas of use should be well-lit to avoid spills and other accidents that could result in contamination build-up.

Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.

The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.

If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed.

APPENDIX F
MATERIAL RECEIPT AND ACCOUNTABILITY

MODEL PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.

During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).

During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area and re-lock the door.

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals) as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name _____

Phone _____

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING LICENSED MATERIALS

For packages received under the specific license, authorized individuals shall implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed license possession limits.
- Monitor the external surfaces of a labeled package.
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again, check that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels before discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.

- Notify MDH and the final carrier by telephone, email, or facsimile when removable radioactive surface contamination exceeds the limits of 4731.0415 or external radiation levels exceed the limits of 4731.0412.

TRANSFER POLICY STATEMENTS

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or Authorized User's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with the applicable MDH, DOT, or U.S. Postal Service Regulations.

Gifts

On occasion, licensees may be offered licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with MDH requirements and the conditions of the license. In any case, the RSO should approve the gift before the transfer.

RADIONUCLIDE STORAGE AND USAGE LOG

Investigator:

Nuclide: _____ Chemical Name/Form: _____

Manufacturer/Supplier _____ Lot Number: _____

Initial Amount: _____ ☐ μCi ☐ mCi Date Received: _____

Storage Location: _____ Location of Use _____

DATE USED	AMOUNT (INDICATE UNITS)	SURVEY DATE	BACKGROUND (INDICATE UNITS)	MEASUREMENT (INDICATE UNITS)	SIGNATURE OR INITIALS

Date Consigned to Waste: _____

APPENDIX G
SAFE USE OF RADIOISOTOPES AND MODEL EMERGENCY PROCEDURES

GENERAL TOPICS FOR SAFE USE OF RADIOISOTOPES

Each laboratory or area where radioactive material is used or stored should have general rules so workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink or personal effects in areas where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

GENERAL SAFETY PROCEDURES TO HANDLE SPILLS

The name and telephone number of the RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:

- Disposable gloves
- Housekeeping gloves
- Disposable lab coats
- Disposable head coverings
- Disposable shoe covers
- Roll of absorbent paper with plastic backing
- Masking tape
- Plastic trash bags with twist ties
- "Radioactive Material" labeling tape
- Marking pen
- Pre-strung "Radioactive Material" labeling tags
- Box of Wipes
- Instructions for emergency procedures
- Clipboard with a copy of the Radioactive Spill Report Form for the facility
- Pencil
- Appropriate survey instruments including batteries (for survey meters).

MINOR SPILLS OF LIQUIDS AND SOLIDS

Instructions to Workers

- Notify persons in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled).
- Clean up the spill, wearing disposable gloves and using 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. Put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also, check hands, clothing, and shoes for contamination.
- Report the incident to the Radiation Safety Officer (RSO) promptly.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Follow up on the decontamination activities and document the results.
- As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
- If necessary, notify MDH.

MAJOR SPILLS OF LIQUIDS AND SOLIDS

Instructions to Workers

- Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.
- Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
- Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- Notify the RSO immediately.
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

- Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
- If necessary, notify MDH.

INCIDENTS INVOLVING RADIOACTIVE DUSTS, MISTS, FUMES, ORGANIC VAPORS, AND GASES

Instructions to Workers

- Notify all personnel to vacate the room immediately.
- Shut down ventilation system, if appropriate, to prevent the spread of contamination throughout system and other parts of facility.
- Vacate the room. Seal the area, if possible.
- Notify the RSO immediately.
- Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
- Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO.
- Promptly report suspected inhalations and ingestions of licensed material to the RSO.
- Decontaminate the area only when advised and/or supervised by the RSO.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

Reminders to RSO

- Supervise decontamination activities.
- Perform air sample surveys in the area before permitting resumption of work with licensed materials.
- Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.
- Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material.
- Determine cause and corrective actions needed; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident.
- If necessary, notify MDH.

MINOR FIRES

Instructions to Workers

- Immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards or radiation hazards are not present.
- Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO).
- Once the fire is out, isolate the area to prevent the spread of possible contamination.
- Survey all persons involved in combating the fire for possible contamination.
- Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.

- In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Supervise decontamination activities.
- If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
- Consult with fire safety officials to assure that there are no other possibilities of another fire starting.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident.
- If necessary, notify MDH.

FIRES, EXPLOSIONS, OR MAJOR EMERGENCIES

Instructions to Workers

- Notify all persons in the area to leave immediately.
- Notify the fire department.
- Notify the RSO and other facility safety personnel.
- Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc.
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Allow no one to return to work in the area unless approved by the RSO.
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Coordinate activities with facility's industrial hygienist or environmental health & safety office, and with local fire department.
- Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.
- Once the fire is extinguished, do not allow the firefighters to enter the radiation area until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.
- Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.
- Supervise decontamination activities.
- Consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident.
- If necessary, notify MDH.

Copies of emergency procedures should be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

APPENDIX H
SAFE HANDLING OF RADIOACTIVE MATERIALS

You may use the following model rules as they appear here, stating on your application, "We will establish and implement the model safety rules published in Appendix H to the MDH Regulatory Guide for Research and Development, Laboratory and Industrial Use of Small Quantities of Radioactive 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 Minnesota Rules. Say on your application, "We have developed rules for the safe handling of radioactive materials for your review that are appended as Appendix H," and submit your model rules.

MODEL RULES

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Monitor your hands for contamination in a low-background area with an appropriate survey instrument after each procedure and before leaving the area.
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
- 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.
- If required, wear a finger exposure monitor during the preparation and use of radioactive materials and at all other appropriate times.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- 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.
- After each use, survey with a radiation detection instrument the areas where radioactive material is prepared, used, and stored.
- Always store sources, waste, and other radioactive material in labeled containers.
- Store containers of liquid radioactive material in a secondary containment sufficient to hold the entire material if the liquid were to leak.
- Use shielding for containers, sources, and waste as necessary to maintain exposures As Low As Reasonably Achievable.

APPENDIX I
RADIATION SAFETY SURVEY TOPICS

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

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 instrument use
- Mathematics and basic calculations 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 0.025 mSv (2.5 mrem/hr) or more (50 mSv/year divided by 2,000 hr/year).

The total effective dose equivalent to an individual member of the public from the licensed operation should not exceed 1 mSv (0.1 rem) in a year. The dose in any unrestricted area from external sources should not exceed 0.02 mSv (2 mrem) 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 4731.2750, then documented surveys should be performed at least daily.

The following table indicates the 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 greater than the required survey frequency, then it is considered not in use.

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**		

ALTERNATE SURVEY FREQUENCY

An example alternate survey frequency is described below. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of Iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for Iodine-131 is Group 1, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

Licensees should survey daily at the end of use to monitor the spread of contamination from radionuclides not listed in the following table.

Grouping of Radioisotopes for Alternate Survey Frequency						
Group 1	Co-60	Cs-134	Cs-137	Eu-152 (13 y)	Eu-154	I-125
	I-126	I-131	I-133	Ir-192	Sr-90	Tl-204
Group 2	Au-198	C-14	Co-57	Co-58	Cr-51	Dy-165
	Eu-152	Eu-155	F-18	Fe-59	Gd-153	Hg-197
	In-115m	Lu-177	Mo-99	Na-24	P-32	Pd-103
	Rh-105	S-35	Se-75	Sm-153	Sn-113	Sr-85
	Tc-99	Tl-201	Y-90	Yb-175		
Group 3	Cs-134 ^{m}	H-3	In-113 ^{m}	0-15	Rb-87	Rh-103^{m}
	Tc-99 ^{m}	Xe-133				

Classification of Laboratories for Alternate Survey Frequency			
Survey Frequency Category			
Group	**Low**	**Medium**	**High**
Group 1	<1 mCi	1 mCi to 10 mCi	>10 mCi
Group 2	<100 mCi	100 mCi to 1 Ci	>1 Ci
Group 3	<10 Ci	10 Ci to 100 Ci	>100 Ci

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day.

Proportional fractions are to be used for more than one isotope.

Modifying Factors for Alternate Survey Frequency	
Modifying Factors	**Factors**
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of non-occupational persons (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

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 the following table.

Acceptable Surface Contamination Levels for Equipment			
Nuclide[a]	**Average[b, c]**	**Maximum[b, d]**	**Removable[b, e]**
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/100cm^2 (1,000 dpm/100 cm^2)	50.0 Bq/100cm^2(3,000 dpm/100 cm^2)	3.3 Bq/100cm^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 1 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 cm^2.

[e] The amount of removable radioactive material per 100 cm^2 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.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the table above provides the maximum acceptable residual levels for equipment. The following table provides screening values for building surface contamination. To the extent practical, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before equipment or facilities 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 cm^2 is acceptable to indicate levels of removable contamination.

Screening Values for Building Surface Contamination[1]		
Radionuclide	**Symbol**	**Screening levels for unrestricted release (dpm/100 cm^2)**
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Manganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Iridium-192	Ir-192	7.4×10^4

[1] 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 percent 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 DandD Version 1.

The table for Screening Values for Building Surface Contamination does not include screening values for radionuclides that emit alpha particles, or for soil contamination. The MDH staff is assessing current screening approaches for sites with alpha emitters and for soil contamination. For such sites, licensees are encouraged to use, in the interim period, 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 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in 4731.2110. For radionuclides in a mixture, the sum of fractions rule applies.

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.

AIR MONITORING IN THE WORKPLACE

Air sampling can be used to do the following:

- Determine whether the confinement of radioactive materials is effective
- Measure airborne radioactive material concentrations in the workplace
- Estimate worker intakes of radioactive material
- Determine posting requirements
- Determine what protective equipment and measures are appropriate
- Warn of significantly elevated levels of airborne radioactive materials.
- If bioassay measurements are used to determine worker doses, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program may eliminate need for bioassays.

AIRBORNE EFFLUENT RELEASE MONITORING

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

For release points where monitoring is not practical, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur anytime unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or ten percent of the permissible air effluent concentrations found on column 1 of Table 2 in 4731.2750, whichever is greater.

BIOASSAY MONITORING

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential, 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 ten percent ALI criterion is consistent with 4731.2210, which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed ten percent 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 is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 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, a termination bioassay measurement should be made.

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 J
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 state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix J to the MDH Regulatory Guide for Research and Development, Laboratory and Industrial Use of Small Quantities of Radioactive 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 Minnesota Rules. Say on your application, "We have developed a leak test procedure for your review that is appended as Appendix J" and submit your leak test procedure.

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.

MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive. 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 microcuries for beta or gamma emitters or 0.001 microcuries 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 MDH 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 these records for five (5) years.

APPENDIX K
CONSIDERATIONS FOR LABORATORY ANIMAL AND VETERINARY MEDICINE USES

This Appendix provides additional information on the use of radioactive materials in laboratory animals, in animals used for research in the environment, and by veterinarians.

LABORATORY ANIMALS

Personnel Training

Before allowing an individual to care for animals used in studies with or treated with licensed material, the Radiation Safety Officer (RSO), Authorized User (AU), and/or veterinarian must ensure that he or she has sufficient training and experience to maintain doses ALARA, control contamination, handle waste appropriately, etc.

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

- Principles and practices of radiation protection.
- Radioactivity measurements, monitoring techniques, and using instruments.
- Mathematics and calculations basic to using and measuring radioactivity.
- Biological effects of radiation.
- Appropriate on-the-job-training should consist of:
    - Observing authorized personnel using survey equipment, using proper contamination control techniques, and proper disposal of radioactive material.
    - Using survey equipment, proper contamination control techniques, and proper disposal of radioactive material procedures under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material.

Contamination Control and Waste Handling

In order to minimize the spread of contamination, animals used in studies with or treated with licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages shall be secured to prevent unauthorized access to the animals. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, and eye protection, as appropriate.

Special care should be observed when cleaning the cage or stall. The cage or stall, the bedding, and waste from the animal may contain radioactive material. Any radioactive material should be properly disposed of as described in "Waste Management" section.

Disposal of animal carcasses that contain radioactive material require special procedures. Animal carcasses that contain less than 1.85 KBq/gram (0.05 microcuries/gram) of Carbon-14 or Hydrogen-3 may be disposed of by the same method as non-radioactive animal carcasses. Animal carcasses that contain radioactive material with a half-life of less than 120 days may be allowed to decay-in-storage in a freezer designated for radioactive material. Animal carcasses must be held for a minimum of 10 half-lives of the longest-lived isotope. After 10 half-lives, the animal carcasses may be disposed as non-radioactive if radiation surveys (performed in a low background area and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background.

Animals Used for Research in the Environment
Before a researcher releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the researcher will ensure that the dose that members of the public will receive from the animal is within limits of 4731.2090. The total effective dose equivalent to an individual member of the public from the licensed operation should not exceed 1 mSv (0.1 rem) in a year. The dose in any unrestricted area from external sources should not exceed 0.02 mSv (0.002 rem) in any one hour. Further, the researcher may be required to perform an assessment of the impact the radioactive material will have on the environment.

VETERINARY USE

Personnel Training
MDH believes that to demonstrate adequate training and experience, the veterinarian should have training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation protection principles
- Characteristics of ionizing radiation
- Units of radiation dose and quantities
- Radiation detection instrumentation
- Biological hazards of exposure to radiation (appropriate to the types and forms of radioactive material to be used)
- Hands-on use of radioactive materials

The length of the training (usually 40 hours) will depend upon the type, form, quantity and proposed use of the licensed material requested, but training shall cover the subjects stated.

Release of Animals
Before a veterinarian releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the veterinarian must ensure that the dose that members of the public (including the animal's caretaker) will receive from the animal is within limits of 4731.2090. This rule requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Furthermore, licensees should provide instructions to the animal's caretaker to keep doses ALARA.

Instructions to Animal Caretaker upon Release
The instructions given for release should be specific to the type of treatment given, such as permanent implants or radioiodine therapy, and may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

Sample Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Other Unsealed Materials
Radiopharmaceutical instructions to the caretaker should include the following topics:

- Maintaining animal’s distance from people.

- Minimizing time in public places (e.g., walks on public sidewalk, parks, beaches, grooming salon).
- Precautions to reduce the spread of radioactive contamination, including animal excreta (which may need to be held for decay).
- The length of time each of the precautions should be in effect.

Sample Radiopharmaceutical Instructions

The animal has been treated with radioactive material and still possesses a low level of radioactivity. The present level of radioactivity is below the regulatory agency level necessary for isolating the animal from humans. Because some radioactivity will be present for the next few days, it is necessary that the following safety precautions be exercised for _____ days:

1. The animal should be kept inside or in its cage/stall following hospital discharge.
2. The animal should not be permitted to have prolonged contact with children under the age of 12 for _____ days following hospital discharge. Close contact should be limited to less than _____ minutes per day.
3. Pregnant women should avoid *any* contact with the animal or its urine and/or feces for at least _____ days after discharge.
4. Family members should not be permitted to sleep with the animal for _____ days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next _____ day(s) to no more than _____ minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period.
5. Use a plastic litter pan liners and a scoopable litter for cats.
6. Disposable gloves should be worn whenever changing the litter box for the next _____ days after discharge.
7. Wash hands after contact with the animal or the litter.
8. Call to discuss any other radiation safety concerns.

Sample Instructions to Caretakers of Animals Implanted with Sealed Sources

A small radioactive source has been placed (implanted) inside the animal. The source is actually many small metallic pellets or seeds, which are each about 1/4" to 1/3" long, similar in size and shape to a grain of rice. The following precautions should be taken for _____ days to minimize exposure to radiation to humans from the source inside the animal:

- Maintain a distance of _____ feet.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle pet.
- Avoid taking the animal on public transportation.
- Examine any bandages that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If a seed or pellet has fallen out, do the following:
    - Do not handle it with fingers. Use something like a spoon or tweezers to place it in a jar or other container that can be closed with a lid.
    - Place the container with the seed or pellet in a location away from people.
    - Telephone _____ at _____.

APPENDIX L
US DEPARTMENT OF TRANSPORTATION TRAINING REQUIREMENTS

The following information summarizes The Department of Transportation training requirements and provides a reference to other DOT regulations.

The *Federal Hazardous Materials Transportation Law* requires the training of all hazardous material (HAZMAT) employees. "Hazardous material" means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce. The training requirements are to increase a HAZMAT employee's safety awareness. As such, training is considered an essential element in reducing hazardous material incidents. As it pertains to a medical facility, a HAZMAT employee is any person who directly affects hazardous material transportation safety including a person who:

- loads, unloads, or handles hazardous material;
- marks packages for use in the transportation of hazardous material;
- prepares hazardous material for transportation;
- is responsible for safety of transporting hazardous material; or
- operates a vehicle used to transport hazardous material.

Each employer must train, test, certify, and retain records of current training for each HAZMAT employee to ensure knowledge of hazardous materials and the Hazardous Material Regulations as well as to ensure that the employee can perform assigned HAZMAT functions properly. (See 49 CFR 172.700 through 172.704.) HAZMAT training must include:

- general awareness/familiarization
- function-specific;
- safety;
- security awareness;
- In-depth security training, if a security plan is required; and
- driver training (for each HAZMAT employee who will operate a motor vehicle).

Initial training
A new employee, or an employee who changes job functions, may perform HAZMAT job functions before completing training, provided:

- the employee does so under the direct supervision of a properly trained and knowledgeable HAZMAT employee; and
- the HAZMAT training is completed within 90 days of employment of change in job function.

Recurrent Training
Training is required at least once every three years. The three-year period begins on the actual date of training. Relevant training received from a previous employer or source may be used to satisfy the requirements provided a current record of training is obtained from the previous employer or other sources.

Training records
Training records must include the following information:

- HAZMAT employee's name;

- completion date of most recent training;
- training materials (copy, description, or location);
- name and address of HAZMAT training; and
- certification that the HAZMAT employee has been trained and tested.

49 CFR References

Licensed material must be transported in accordance with DOT regulations. The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101: Purpose and use of hazardous materials table;
- Shipping Papers 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;
- Package Marking 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;
- Emergency Response Information 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Shippers – General Requirements for Shipments and Packaging 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements for U.S.
- NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and
- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping papers, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

For additional transportation information, licensees may consult DOT's "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials" or contact the DOT at <http://www.dot.gov>.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION