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# MINNESOTA DEPARTMENT OF HEALTH



## AGREEMENT STATE APPLICATION Volume IV

The logo is circular with a black border. Inside, there is a stylized animal head (possibly a moose or bear) facing right. The text "Radioactive Materials Group" is written along the top inner edge, "Minnesota Department of Health" along the bottom inner edge, and "RMG" in the center.	<p><b>Radiation Control Unit</b> <b>Asbestos, Lead, Indoor Air &amp; Radiation Section</b> <b>Division of Environmental Health</b> <b>Minnesota Department of Health</b></p>
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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR BROAD SCOPE LICENSES

	<p style="text-align: center;"><b>Radiation Control Unit</b> <b>Asbestos, Lead, Indoor Air &amp; Radiation Section</b> <b>Division of Environmental Health</b> <b>Minnesota Department of Health</b></p>
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## MDH REGULATORY GUIDE FOR BROAD SCOPE LICENSES

### PURPOSE

This document provides guidance to an applicant in preparing a broad scope license application and describes the criteria used by Minnesota Department of Health (MDH) staff when evaluating the application. The applicant for a limited scope license generally must submit to the MDH for review and approval the specific training and experience of each proposed user and the facilities and equipment available to support each proposed use. However, the applicant for a broad scope license normally must submit to the MDH, for review and approval, a description of the internal review process and criteria that will be used to approve users and uses. As opposed to limited scope licenses, which typically identify specific isotopes that may be possessed, the broad scope license generally authorizes the possession and use of a wide range of radioactive materials.

Because MDH grants significant decision making authority to broad scope licensees through the license, a broad scope license is not normally issued to a new licensee. An applicant for a broad scope license typically has several years of experience operating under a limited scope license and a good regulatory performance history. This document is intended to provide the additional guidance required by the experienced limited scope licensee to prepare an application for a broad scope license. Guidance related to specific program areas, which may not apply to all broad scope licensees, is not included in this document.

Type A licenses of broad scope are typically the largest licensed programs and encompass a broad range of uses. Type A broad scope licensees use a Radiation Safety Committee (RSC), Radiation Safety Officer (RSO), and criteria developed and submitted by the licensee and approved by MDH during the licensing process, to review and approve all uses and users under the license. The requirements for issuance of a Type A broad scope license are described in 4731.3530. An applicant for a Type A broad scope license must establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

- Establishment of an RSC
- Appointment of a qualified RSO
- Establishment of appropriate administrative procedures to assure:
  - Control of procurement and use of radioactive material.
  - Completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures.
  - Review, approval, and recording by the RSC of safety evaluations of proposed uses.

Type B broad scope licensed programs are normally smaller and less diverse than Type A broad scope programs. Type B broad scope licensees use an RSO and criteria developed and submitted by the licensee and approved by MDH during the licensing process, to review and approve all uses and users under the license. Because the RSO reviews and approves all uses and users under the license, and not a full RSC as established for Type A broad scope programs, the types and quantities of radioactive material authorized by the Type B broad scope license are limited to those described in 4731.3580, Schedule A, Column I. While the quantities of individual radionuclides described may be large, the Unity Rule further restricts total license possession limits. Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the RSO. The requirements for issuance of a Type B broad scope license are described in 4731.3540.

An applicant for a Type B broad scope license must also establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including the following:

- Appointment of a qualified RSO
- Establishment of appropriate administrative procedures to assure
  - Control of procurement and use of radioactive material.
  - Completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures.
  - Review, approval, and recording by the RSO of safety evaluations of proposed uses.

Type C broad scope licenses are typically issued to institutions that do not require significant quantities of radioactive material but need the flexibility to possess a variety of different radioactive materials. Users of licensed material under these programs are approved by the licensee based on training and experience criteria 4731.3550. The types and quantities of radioactive material authorized by the Type C broad scope license are limited to those described in 4731.3580, Schedule A, Column II, again, considering the Unity Rule. While not required to appoint an RSO, the licensee must establish administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. This should include the appointment of someone responsible for the day-to-day operation of the Radiation Safety Program, such as an RSO.

Except for activities specifically excluded from broad scope licenses by 4731.3570, a Type A broad scope license can include any licensed material the applicant needs and for which it qualifies. An application for a Type A broad scope license can include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the radioactive material to be possessed. However, applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of radioactive material under the Type A broad scope license (e.g., use of source material in sub-critical assemblies and special nuclear material in cardiac pacemakers).

Type B and Type C licensees who require materials not specified, or in excess of those quantities, in Schedule A will need to: (1) develop Type A broad scope programs, which would require a license amendment; or (2) carry these additional materials under a separate specific license of limited scope. Licensees are reminded that changes to the specific license of limited scope require an amendment to the license.

In practice, MDH attempts to reduce the administrative burden for licensees without reducing the safety standards or lessening the licensing requirements for training, experience, facilities, and equipment. Both the MDH and the licensee benefit from the reduction in license amendments that might otherwise be needed to change authorized radionuclides, quantities, or names of individuals who may use or supervise the use of radioactive material. A broad scope licensee is authorized to implement administrative changes, such as changing the dosimetry provider, without amendment of the license. Through license condition, MDH will provide even greater flexibility to Type A broad scope licensees who have developed an adequate structure for the oversight of the radiation safety program.

Administrative changes or revisions to procedures must be reviewed and approved by the RSC before implementation. They must also satisfy regulatory requirements, not change existing license conditions, and not decrease the effectiveness of the Radiation Safety Program. Type A broad scope licensees and applicants for Type A broad scope license will be authorized to implement administrative changes and to revise procedures previously approved by MDH without amendment provided they specify the duties and responsibilities of management, the Radiation Safety Committee (RSC), and the Radiation Safety Officer (RSO). Those duties must include

1. Review and approval of program and procedural changes by the RSC.
2. Implementation of program and procedural changes.
3. Audit of licensed operations to determine compliance.

4. Taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence. See the license condition below.

For Type A broad scope applicants or licensees requesting this additional flexibility, a clear description of the process for procedure and program review and approval must be provided. Applicants must describe how specific changes will be documented. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered before the approval of each change.

#### License Condition

##### Type A Broad Scope License Condition Used to Grant Additional Flexibility:

Notwithstanding the requirements of License Condition Number (insert number of license condition that incorporates the licensee's application and letters into the document), the licensee is authorized to make program changes and changes to procedures specifically identified in the (application dated or letter dated), which were previously approved by the Commissioner and incorporated into the license, without prior Commissioner approval, as long as:

- The proposed revision is documented, reviewed, and approved by the licensee's radiation safety committee in accordance with established procedures prior to implementation;
- The revised program is in accordance with regulatory requirements, will not change license conditions, and will not decrease the effectiveness of the radiation safety program;
- The licensee's staff is trained in the revised procedures prior to implementation; and

The licensee's audit program evaluates the effectiveness of the change and its implementation.

The guidance that follows in this document specifies that Type A broad scope licensees who have developed an adequate structure for the oversight of the radiation safety program may be granted the flexibility to make program changes and revise procedures in the areas of:

- Training for individuals working in or frequenting restricted areas
- Audit program
- Radiation monitoring instruments
- Material receipt and accountability
- Occupational dose
- Safe use of radionuclides and emergency procedures
- Surveys

#### 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.

## **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 this 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 Group  
Minnesota Department of Health  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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. 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) At Which 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will not be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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 both free and bound forms, then 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 abilities 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 Recordkeeping for 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 MDH 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 MDH 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 MDH 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 MDH 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 MDH 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.

The Table below is a partial list of radioisotopes of  $T_{1/2} > 120$  days with their corresponding limits in excess of which Financial Assurance or a Decommissioning Funding Plan is required. Radioisotopes of

$T_{1/2} > 120$  days are listed in column 1. 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	LIMIT FOR FINANCIAL ASSURANCE (MILLICURIES)	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

Licensees who possess radioactive materials in excess of the quantities listed in 4731.3150 must provide with the application either of the following:

- An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid.
- An emergency response plan for responding to a release.

Applicants for a Type B or Type C broad scope license should request any chemical or physical form of radioactive material specified in 4731.3580, Schedule A. The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in 4731.3580, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined by calculating the ratio of the quantity possessed to the applicable quantity specified in 4731.3580, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity. The possession limit for a Type C broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in Schedule A, Column II. If two or more radionuclides are possessed, the sum of the ratios determined in the same manner as discussed above for all radionuclides possessed under the license shall not exceed unity.

Applicants for a Type A broad scope license should request any form of radioactive material with atomic numbers from 1 through 84. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. The applicant should separately list individual radionuclides needed in much larger quantities or in much smaller quantities than that described in the atomic number 1 - 84 request. The maximum quantities of nuclides with atomic numbers above 84 should be listed separately. A separate listing should also be submitted for sealed sources needed in larger quantities than that described in the atomic number 1 - 84 request. 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 a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license.

Possession requests should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications.

#### **Item 6: Purpose(s) For Which Licensed Material Will Be Used**

The applicant should describe in general terms the purposes for which the licensed material will be used. New applicants should describe why a broad scope license is needed rather than amendments to an existing limited scope license. The uses should be consistent with prior licensed activities. Sufficient information should be provided to enable the reviewer to have a clear understanding of each use and to determine the potential for radiation exposure of workers and members of the public. The information provided regarding purpose of use is understood by the MDH staff as a self-imposed limitation contained within the application. If a broad scope licensee desires to initiate a use other than those described in its application and committed to in its license, the licensee must submit an amendment to the license to modify or expand the purpose.

Unless specifically authorized by other parts of the regulations, persons licensed under broad scope licenses will not do any of the following:

- Conduct tracer studies in the environment involving the direct release of radioactive material (applies to field users).
- Receive, acquire, own, possess, use, transfer, or import devices containing  $3.7 \times 10^{15}$  becquerels (Bq) (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials.
- Add or cause the addition of radioactive material to any food or other product designated for ingestion or inhalation by, or application to, a human being.

#### **Item 7: Individuals Responsible For Radiation Safety Program**

Executive management, the Radiation Safety Committee (RSC), the Radiation Safety Officer (RSO), and his or her staff work as a team to oversee the broad scope program. Each plays a critical role within its area of responsibility. The roles and responsibilities of executive management, the RSC, the RSO, and the radiation safety office staff are discussed in the sections that follow.

##### ***Executive Management***

Executive management is the individual at the senior management level who is responsible for oversight of the facility's radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program. MDH expects executive management to be knowledgeable of the program.

Due to the various structures of different organizations, MDH recognizes that executive management may need to delegate certain responsibilities to other managers for the day-to-day oversight of the program. For example, a large company may have several licenses issued to it for different facilities or for different activities. In this case, a company may choose to establish a senior level manager with responsibility for all of the licenses issued to that company, with the day-to-day responsibility for each license designated to the facility senior manager or program area senior manager. There are numerous ways in which an applicant may wish to structure its management oversight to meet the needs of the organization. However, there must still be one level of management, as the licensee's representative, with ultimate responsibility for the radiation safety program.

In a Type A broad scope program, executive management or her/his delegate is a vital member of the RSC and should attend Committee meetings. In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program to ensure all activities complies with regulatory requirements and the conditions of the license, and that activities are being conducted in a safe manner.

The licensee should consider several factors when selecting executive management for the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the RSC (for Type A broad scope programs), and the RSO, particularly in the event of an emergency. Executive management must have the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations and conditions of the license.

Executive management is involved in selecting the chairperson and members of the RSC (for Type A broad scope) and the RSO (for Type A and Type B broad scope), and defines the role, duties and responsibilities of each. Executive management should support the RSC and the RSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising radiation safety concerns. Authority will be enhanced if authorized users clearly understand that there is strong management support for, and participation in, the licensed program. Many problems can be avoided if management takes proactive steps before radiation safety problems escalate. Individuals should understand management's expectations regarding internal enforcement of program requirements and the consequences for non-compliance.

The applicant must describe administrative controls and provisions relating to organization and management and management review necessary to assure safe operations. It is recommended that the applicant submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).

#### ***Radiation Safety Committee***

An applicant for a Type A broad scope license must establish a RSC. The RSC works with executive management and the RSO in implementing the radiation safety program, and will be involved in establishing policies and procedures for managing the radiation safety program. The RSC, through the executive management, must have the authority and flexibility necessary so that it may effectively fulfill its role in managing the radiation safety program. The RSC for a Type A broad scope program is composed of such persons as the RSO, executive management, and persons trained and experienced in the safe use of radioactive materials. Each area of use under the license should be represented on the RSC.

A chairperson for the committee should be selected. There are several factors to consider when selecting a chairperson for the RSC. An individual with knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of their position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO should not be appointed as the chairperson of the Committee, since the RSO is responsible for the day-to-day operation of the radiation safety program and may be too closely involved with the licensed activities to be objective.

The RSC should establish a quorum for RSC meetings. A quorum consisting of the chairperson of the committee (or his/her designee), the RSO, the executive management (or his/her alternate), a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion.

The meeting frequency for RSC meetings for broad scope programs is not specified in MDH rules. The RSC should meet as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures and the regulations. For most programs, quarterly RSC meetings are needed to adequately oversee the program.

The RSC should maintain minutes of its meetings. The minutes should include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions and recommendations, and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes should also include information related to the annual audit review.

#### ***Radiation Safety Committee's Duties and Responsibilities***

The committee is responsible for reviewing personnel dosimetry data, discussing the results of required radiation surveys, and any significant incidents, including spills, contamination, misadministrations, etc. The RSC is also required to review the program for maintaining doses ALARA and providing any necessary recommendations to ensure doses are ALARA. The overall compliance status for authorized users should be thoroughly reviewed. The RSC, working with the executive management, shares responsibility with the RSO for conducting periodic audits of the radiation safety program. Additionally, the Committee reviews any consultant's audit findings and acts upon those findings. The RSC also reviews the results of the annual audit of the radiation safety program. Possible trends should be analyzed, and suggestions for timely and corrective action should be made. Problems should be clearly defined and remain open for future review. An assessment of the effectiveness of corrective actions is also helpful in deterring or eliminating future problems and violations.

One of the primary responsibilities of the RSC for a broad scope program is to evaluate new users and new uses of radioactive material. The RSC needs to consider all available information in making decisions. This includes evaluating the training and experience of applicants who request authorization to use radioactive material at the facility, using criteria developed by the RSC. The RSC members should be aware of the regulatory training and experience criteria that apply to each type of use at their institution. The criteria developed by the committee should include such things as the requester's training and experience, the proposed facilities, the protocol for using radioactive material to ensure that all procedures are in accordance with good radiation safety practices, and waste disposal.

For Type A broad scope licensees or applicants for a Type A broad scope license who desire the flexibility to make administrative changes as previously discussed, the RSC, along with executive management and the RSO, will review and approve program and procedural changes in accordance with criteria developed and approved by the RSC. The criteria for reviewing and approving such changes should include provisions for training staff before implementing new procedures and ensuring that the proposed changes will not degrade the effectiveness of the currently approved program. The audit program should include an evaluation process that will assure that changes have been properly implemented. Audits should also determine the effectiveness of changes made in achieving program goals.

Applicants for a Type A broad scope license should submit the following:

- Description of the duties and responsibilities of the RSC.
- Criteria used for selecting members of the RSC, including membership and the number of members constituting a quorum. Members should be indicated by position title, rather than by name.
  
- Criteria used by the RSC and RSO for approving new users and new uses.

In addition, applicants for a Type A broad scope license who are requesting the flexibility to make some program changes and revise some procedures previously approved by the MDH without amendment of the license should submit the following:

- A description of the duties and responsibilities of the RSC, including:
  - Review and approval of permitted program and procedural changes prior to implementation;
    - Implementation of program and procedural changes;

- Audit of licensed operations to determine compliance; and
  - Taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.
- A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation should state the reason for the change and summarize the radiation safety matters that were considered before approval of the change.

***Radiation Safety Officer (RSO)***

Each Type A and Type B program in which radioactive materials are used must appoint an RSO who is responsible for radiation safety and compliance with the regulations for the use of radioactive material. Each Type C broad scope program should appoint an individual who is responsible for the day-to-day operation of the radiation safety program. In a Type A broad scope license, the RSO is a member of the RSC and works closely with the RSC and executive management in implementing the radiation safety program. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of radioactive material and the authority to terminate any activity in which health and safety appear to be compromised without consulting with executive management or the RSC, if required. The applicant should submit a "Radiation Safety Officer Delegation of Authority" signed by executive management. Appendix B contains a model "Delegation of Authority" that is acceptable to MDH.

In a Type A broad scope licensed program, the RSO typically performs a preliminary review of proposed new uses and users before formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses in a Type A broad scope license. The task of reviewing and approving proposed uses and users in a Type B broad scope licensed program is the responsibility of the RSO. In a Type C broad scope program, individuals are qualified as users if they meet the training and experience criteria described in 4731.3550 B. While no licensee Committee or individual is required by regulation to make the determination that an individual is qualified to use the material possessed under the Type C broad scope license, or that a particular use of radioactive material is safe, licensee management is ultimately responsible for assuring safe operations.

The RSO performs audits of all areas of use and individuals who are authorized to use radioactive material to ensure work is done in accordance with the license, regulations, and user permit conditions. Specific duties and responsibilities of the RSO include:

- Monitoring and surveys of all areas in which radioactive material is used
- Oversight of ordering, receipt, surveys, and delivery of radioactive material
- Packaging, labeling, surveys, etc., of all shipments of radioactive material leaving the institution.
- Personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits
- Training of all personnel
- Waste disposal program
- Inventory and leak testing of sealed sources
- Decontamination
- Investigating any incidents and responding to any emergencies
- Maintaining all required records

The responsibilities of the RSO may not be transferred to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals; however, the responsibility for these tasks and duties lies with the RSO. MDH does recognize that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods for

professional conferences, vacation, or illness. However, this should not occur for extended or indefinite periods. Consideration should also be given to how this individual would be contacted in the event of an emergency.

When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with radioactive materials under his or her responsibility. MDH recognizes that an RSO cannot be an expert in all areas that might be involved in a broad scope program. The RSO should be qualified by training and experience to perform the duties required for the position. Executive management should ensure that enough time is allocated to the individual selected as the RSO to carry out the responsibilities of the position.

For Type A and Type B applicants:

- Submit the name of the proposed RSO.
- Describe the training and experience for the proposed RSO that demonstrate the individual is qualified to perform the duties required under the license.
- Submit a statement delineating the RSO's duties and responsibilities.
- Submit a Radiation Safety Officer Delegation of Authority signed by the licensee's executive management.

For Type B applicants, submit the criteria used by the RSO to approve of new users and uses of radioactive material.

For Type C applicants, submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program, e.g., the RSO, who will be contacted if there are further questions about this application, and who is duly authorized to act for the applicant or licensee.

Applicants should provide specific information about the proposed RSO's training and experience that is 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. This only serves to slow down the review process.

It is important to notify MDH as soon as possible, typically within 30 days, 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. Applicants should review the regulations for specific program areas, such as medical uses, that have specific requirements regarding changes in the RSO.

#### ***Radiation Safety Staff***

The licensee should provide the RSO with a sufficient staff of professional and administrative support personnel. The number of staff and their qualifications will vary depending on the scope of the program. For small programs, the RSO may not require any assistance. Licensees should evaluate the licensed program and ensure that the RSO has adequate resources to effectively manage the program.

If staff a radiation safety staff has been established, submit an organization chart and the a description of the training and experience for the assigned individuals.

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

The licensee, in determining which individuals are subject to the training requirements of 4731.1020, must consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. Many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, hospital technologist, or environmental services worker at their facility to receive in a year an occupational dose in excess of 1 mSv (100 mrem). However, these individuals and others could reasonably be expected to receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Practical, site-specific training should be provided for all individuals before beginning work with or in the vicinity of licensed material. Periodic refresher training should also be provided. Topics covered should, at a minimum, include those described in 4731.1020 Subpart 1. The training may take any form. Many licensees utilize videotapes or interactive online or offline computer programs to provide training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual who is familiar with the licensee's program.

Retraining should be performed whenever there is a change in duties or the work environment and at a frequency sufficient to ensure that all staff are adequately trained. The applicant should also be aware of additional specific training requirements that may apply to their licensed program.

Submit a description of the radiation safety training program developed for each group of workers, including topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training. In addition, if the application is for a Type A broad scope license, describe the process that will be used to revise and implement your submitted training program.

### **Item 9: Facilities and Equipment**

Applicants for all broad scope licenses need to 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 types and quantities of radioactive materials to be used. Facilities can include fences or exclusion areas that are between the source and the maximally exposed member of the public. An example of equipment designed to control exposure is a vial that contains licensed material. Taking these protective measures not only reduces the exposure from the source but may also limit access to the source. The licensee should list and describe these measures for the following purposes:

- To show compliance with a regulation.
- To demonstrate the use of the material will be within the ALARA concept.
- To meet emergency response requirements.

Licensees should consider controlling exposures through available engineering options, as well as through limiting the releases of effluents to the environment. The licensee should describe all facilities and equipment essential to achieving these goals. The licensee will also need to describe the criteria that will be used by the RSC and/or RSO to review and approve of proposed facilities. Facilities and equipment used for special applications where the impact upon workers or the public could be significant if radioactive material were released accidentally need to be specifically described. These would include,

for example, room irradiators, specialized iodination/tritiation facilities, alpha laboratories, radioactive waste processing facilities (including incinerators, compactors, liquid reclamation processors, etc.), radioactive waste storage facilities (including decay-in-storage locations), individual laboratories processing 3.7 gigabecquerels (GBq) (100 millicuries) or more of radioactive materials per experiment or process, nuclear pharmacies, specially designed therapy rooms, and sealed source storage areas. Significant modifications affecting facilities and equipment should have prior RSO review and RSC approval before commencement of such modifications.

Also, note that if radioactive materials will be used in or on animals, a description of the animal handling and housing facilities will need to be discussed.

In your discussion of the criteria used to evaluate your facilities and equipment, you should include a discussion on how a laboratory or facility classification scheme relates to toxicity and quantity of radioactive material and your facility and equipment requirements. Applicants may consider the development of such a classification scheme since it can be correlated with all aspects of the radiation safety program. Each applicant's scheme should be based upon the types and quantities of radioactive material anticipated to be used. The criteria used to develop the classification scheme should be provided to each RSC member for use when evaluating requests to use licensed materials.

Appendix C provides the radionuclide toxicity and laboratory classification information excerpted from IAEA, which is acceptable to the MDH staff. This table is not all-inclusive and is meant to be used as an example only. Based on chemical/physical form, need and quantities, your classification scheme may differ from that of the IAEA excerpt. Your application will need to describe the minimum facilities and equipment requirements for each laboratory classification.

Appendix D provides additional guidance regarding facilities and equipment used to handle radioactive materials in a laboratory setting.

Describe the criteria your RSC and/or RSO will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). Your description will need to include your method of classifying laboratories based on type, toxicity and quantity of radioactive material being requested. Sample diagrams should be provided. Each classification scheme must take into consideration shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems including pertinent airflow rates, pressures, filtration equipment and monitoring systems. For special application facilities, such as those facilities described above, you will need to specify their locations (i.e. buildings and room numbers) and special considerations that your RSC and/or RSO will use in authorizing radioactive material use. Also, describe your procedures for control, review, and approval of significant facilities or equipment modifications.

## **Item 10: Radiation Safety Program**

### ***Management and Radiation Safety Committee Audits***

The application for a Type A, B, or C broad scope license should discuss executive management oversight of the licensed program and the mechanisms they will use to ensure that they are aware of MDH regulations, the provisions of the license, and the compliance status of the institution's licensed program. This oversight may include independent audits of the program, frequent meetings with the RSC and/or RSO, and periodic tours of selected facility areas.

In a Type A broad scope program, the RSC assists executive management in performing this oversight function. Detailed written procedures should be developed and implemented for the operation of the RSC to ensure that appropriate oversight is provided. The RSC should be fully aware of the operations and

activities of the radiation safety staff. The RSC should conduct periodic interactive management audits and evaluations of the radiation safety program's performance, including non-conformance reports, corrective action, status reports and audits, incident investigation reports, ALARA program development and implementation, effluent releases, qualification and radiological safety training, and performance of the RSO. Results of the RSC's audit and program reviews should be reported to executive management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with MDH regulations and license conditions.

Appendix E contains a model audit program that is acceptable to MDH for use in the review of most non-medical broad scope programs.

Licensees are required to review the radiation program content and implementation periodically (at least annually).

### ***Internal Audits***

The application should describe the audit mechanism implemented by the RSO and her or his staff, or other individual who is responsible for the day-to-day operation of the licensed program, to determine user compliance with MDH regulations, the terms and conditions of the MDH license, the requirements of the RSC or RSO-approved permits, and good health physics practices. The audit program should include routine unannounced inspections of each user's facility and practices to supplement and audit the routine monitoring performed by the user. Facility inspections should include:

- Review of user inventory and survey records.
- Evaluation of user and technician training through discussion and observation of work practices.
- Performance of independent surveys of user work areas.
- Evaluation of compliance with MDH regulations, the conditions of the license, the RSC/RSO permit and safety manual requirements.
- Provision for performance-based instruction to users and technical-level staff.

The types and frequencies of monitoring performed by the RSO should be indicated. The intervals of surveys and audits should be frequent enough to ensure close communications and proper surveillance of individual radioactive material users. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high use facilities and users of volatile radioactive materials may be audited weekly or biweekly, intermediate use facilities may be audited monthly, and low-level facilities may be audited quarterly).

If an audit identifies violations of MDH requirements, the licensee should evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. Licensees are encouraged to contact MDH for guidance if there is any uncertainty regarding a reporting requirement. MDH routinely reviews licensees' 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.

The MDH's emphasis in inspections is for applicants to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of radioactive material users to determine if, for example, safe use of radionuclide procedures and emergency procedures are available and are being followed.

### ***Recordkeeping***

Licensees maintain records of audits and other reviews of program content and implementation for three years from the date of the record. Records of audits should include the 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 must be maintained for inspection by the MDH.

Describe the mechanisms used by executive management to ensure that adequate oversight of the program is exercised. In addition, if you are upgrading your limited scope license to a Type A broad scope license or you are renewing your Type A broad scope license, describe the RSC's involvement in these oversight mechanisms.

Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with MDH regulations, the terms and conditions of the MDH license, the requirements of the RSC or RSO-approved permits, and good health physics practices.

Describe the process you will use to revise and implement your audit program.

### ***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, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations shall 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:<sup>1</sup>

- 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 equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed.

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

#### ***Material Receipt and Accountability***

Applicants for a broad scope license are required to establish appropriate administrative controls and provisions that are necessary to assure safe operations, including procedures to assure the control of procurement and use of radioactive material. Administrative procedures must assure that only authorized individuals receive radioactive materials and that individuals receive only the types and quantities of radioactive material they are authorized to receive.

Applicants for a broad scope license are strongly encouraged to develop an administrative procedure to control procurement and use of radioactive material that emphasizes centralized purchasing and receipt. MDH has found centralized purchasing and receipt to be effective in controlling licensed materials entering the licensed institution through normal commercial channels, particularly for larger institutions. Procedures must also be established to control licensed materials obtained outside of the normal channels, e.g., through the loan or transfer of materials without purchase or through surplus.

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.

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 AU, 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.

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<sup>1</sup> Alternative responses will be reviewed by MDH staff.

- Notify the RSO.

When notified by Receiving 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**

<b>PACKAGE</b>	<b>CONTENTS</b>	<b>SURVEY TYPE</b>	<b>SURVEY TIME<sup>2</sup></b>
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 3 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 3 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 3 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 3 hours after receipt of package

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 when 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 and, 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 an 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

<sup>2</sup> 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.

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.

Applicants for a broad scope license are required to establish appropriate administrative controls and provisions relating to material control and accounting that are necessary to assure safe operations. Licensees use various methods to account for receipt, use, transfer, disposal, and radioactive decay of unsealed licensed material (e.g., computer programs, manual ledgers, log books, etc.). These methods help to assure that licensee and individual authorized user possession limits are not exceeded. Licensees who possess sealed sources are required to perform periodic inventories. The frequency of these inventories is normally established by license condition as every six months; however, regulation may specify a different inventory frequency (e.g., sealed sources used for medical therapy are required to be inventoried every 3 months).

Licensed material is considered to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier in accordance with procedures established by the licensee. If through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory being in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact the MDH regional office and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

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 G.

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 and 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 state 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 ten 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 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 (OSDs, TLDs, film, 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 unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of ten 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).

### ***Public Dose***

Public dose is defined as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material

and released from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on whether the individual is in a restricted area, a controlled area, or an unrestricted area when the dose is received.

There are both external exposure components and internal exposure components of public dose. The licensee should review all possible internal and external exposure pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b). The extent and frequency of monitoring will depend upon the nature of the licensee's operations, potential releases, exposures and pathways to cause public dose or environmental contamination. Licensees must maintain survey and monitoring records that demonstrate compliance with the dose limits for members of the public until the Commissioner terminates the license.

### ***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
- Recordkeeping 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 the radioactive material cannot be stolen. 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 the following:

- 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 within the 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 H 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***

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.

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.

### **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 or 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. In addition, 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 kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix J.1 or submit your own procedures.

For Option 3, indicate how the test sample will be taken. Specify the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for these measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application. Commit to Appendix 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 parentheses.

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

### **Appendices**

Review each of the following appendices carefully. Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate "not applicable."

Appendix A	Use of Radioactive Material in Field Studies
Appendix B	Model Delegation of Authority for Radiation Safety Officer
Appendix C	Radionuclides Classified According to Relative Toxicity
Appendix D	Facilities and Equipment Considerations
Appendix E	Audit Program
Appendix F	Instrument Specifications
Appendix G	Material Receipt and Accountability
Appendix H	Safe Use of Radioisotopes and Model Emergency Procedures
Appendix I	Radiation Surveys
Appendix J	Leak Testing Sealed Sources
Appendix K	Considerations for Laboratory Animal and Veterinary Medicine Uses
Appendix L	Model Waste Management Procedures

### **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 chose 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.

### ***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, Table 3.
- 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, Table 3 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 Ci) 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 Ci) 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.

#### ***Incineration***

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of 4731.2430. Applicants proposing incineration should be aware that a notice in the Federal Register may be required before disposal of ash as ordinary waste can be approved. However, approval of incineration does not require notice in the Federal Register if the ash is disposed as radioactive waste or transferred to a specific licensee. A model procedure for incineration of waste is described in Appendix L of this guidance document.

Applicants who are considering disposal of radioactive material by incineration should review the NRC Regulatory Guide 8.37, "ALARA Levels for Effluents From Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

#### ***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.

### ***Waste Volume Reduction***

Waste volume reduction operations that could create a radiological hazard to licensee employees or the general public must be described in detail in the application. A model procedure for waste compaction is described in Appendix L of this guidance document.

### **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

MDH recognizes that effective management of the radiation safety program is vital to achieving safe and compliant operations. MDH believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. MDH also believes that effective management will result in increased safety and compliance.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations.
- Completeness and accuracy of the radiation safety records and all information provided to MDH.
- Knowledge about the contents of the license and application.
- Compliance with current MDH and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures.
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained.
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program.
- Obtaining MDH's prior written consent before transferring control of the license.
- Notifying MDH in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

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

If the senior partner, president, director, or chief executive officer wishes another person other than himself or 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 by-product 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 twelve months after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the MDH Radioactive Materials Fee Schedule. (For example, the routine inspection for a licensee with Irradiated Gemstones would be scheduled four years after the initial inspection.)

## TERMINATION OF ACTIVITIES

Before a licensee can decide whether it must notify MDH, the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release according to MDH requirements. A licensee's determination that a facility is not contaminated is subject to verification by MDH inspection.

The permanent cessation of principal activities in an individual room or laboratory may require the licensee to notify MDH if no other licensed activities are being performed in the building. This also applies to buildings that were approved by the broad scope licensee as locations of use but not specifically named on the broad scope license.

The following are acceptable license termination screening values of common radionuclides for building surface contamination.

**Acceptable License Termination Screening Values  
of Common Radionuclides for Building Surface Contamination**

RADIONUCLIDE	SYMBOL	ACCEPTABLE SCREENING LEVELS*
Hydrogen-3 (tritium)	<sup>3</sup> H	1.2 x 10 <sup>8</sup>
Carbon-14	<sup>14</sup> C	3.7 x 10 <sup>6</sup>
Sodium-22	<sup>22</sup> Na	9.5 x 10 <sup>3</sup>
Sulfur-35	<sup>35</sup> S	1.3 x 10 <sup>7</sup>
Chlorine-36	<sup>36</sup> Cl	5.0 x 10 <sup>5</sup>
Manganese-54	<sup>54</sup> Mn	3.2 x 10 <sup>4</sup>
Iron-55	<sup>55</sup> Fe	4.5 x 10 <sup>6</sup>
Cobalt-60	<sup>60</sup> Co	7.1 x 10 <sup>3</sup>
Nickel-63	<sup>63</sup> Ni	1.8 x 10 <sup>6</sup>
Strontium-90	<sup>90</sup> Sr	8.7 x 10 <sup>6</sup>
Technetium-99	<sup>99</sup> Tc	1.3 x 10 <sup>6</sup>
Iodine-129	<sup>129</sup> I	3.5 x 10 <sup>4</sup>
Cesium-137	<sup>137</sup> Cs	2.8 x 10 <sup>4</sup>
Iridium-192	<sup>192</sup> Ir	7.4 x 10 <sup>4</sup>

\* Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using D and D Version 1, based on site-specific re-suspension factor. For Unrestricted Release (dpm/100 cm<sup>2</sup>). Units are disintegrations per minute per 100 square centimeters (dpm/100 cm<sup>2</sup>). 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. For radionuclides in a mixture, the "sum of fractions" rule applies.

When the license expires, or at the time the licensee ceases operations, and any necessary decommissioning activities must be undertaken, information must be submitted.

**APPENDIX A**  
**THE USE OF RADIOACTIVE MATERIAL IN FIELD STUDIES**

Field studies in which licensed material is deliberately released directly into the environment for purposes of the study (e.g., tagging of animals or insects that remain in the wild) may require an environmental report filed by the applicant and an environmental assessment by MDH. If the licensee desires to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies, please provide the following information:

- A complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.
- A complete experimental protocol.
- A description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment (if appropriate) and procedures for minimizing releases.
- A description of the expected radiation dose to humans.
- Written permission from the property owner to use radioactive materials at the proposed site.
- A letter from the appropriate state health authorities indicating that they have reviewed your application and concur with the request.

**APPENDIX B**  
**MODEL DELEGATION OF AUTHORITY FOR RADIATION SAFETY OFFICER**

Memorandum To:           All Employees

From:                        Chief Executive Officer

Subject:                    Delegation of Authority for Radiation Safety Officer

\_\_\_\_\_ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radioactive material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of radioactive material in which health and safety may be compromised or may result in non-compliance with the Minnesota Department of Health (MDH) requirements.

**APPENDIX C**  
**RADIONUCLIDES CLASSIFIED ACCORDING TO RELATIVE TOXICITY<sup>3</sup>**

These tables are *not* all-inclusive and are meant to be used as an example only. Based on chemical/physical form, need, and quantities, your classification scheme may differ from that of the IAEA excerpt.

**Radionuclides Classified According to Relative Radiotoxicity**

<b>Group 1: Very High Radiotoxicity</b>	<sup>210</sup> Pb	<sup>226</sup> Ra	<sup>227</sup> Th	<sup>233</sup> U	<sup>243</sup> Am	<sup>249</sup> Cf			
	<sup>210</sup> Po	<sup>228</sup> Ra	<sup>231</sup> Pa	<sup>238</sup> Pu	<sup>244</sup> Cm				
<b>Group 2: High Radiotoxicity</b>	<sup>22</sup> Na	<sup>56</sup> Co	<sup>95</sup> Zr	<sup>125</sup> Sb	<sup>131</sup> I	<sup>181</sup> Hf	<sup>228</sup> Ac		
	<sup>36</sup> Cl	<sup>60</sup> Co	<sup>125</sup> I	<sup>192</sup> Ir	<sup>144</sup> Ce	<sup>207</sup> Bi			
<b>Group 3: Moderate Radiotoxicity</b>	<sup>7</sup> Be	<sup>48</sup> Sc	<sup>65</sup> Zn	<sup>91</sup> Sr	<sup>103</sup> Ru	<sup>125m</sup> Te	<sup>140</sup> La	<sup>153</sup> Gd	<sup>187</sup> W
	<sup>14</sup> C	<sup>48</sup> V	<sup>69m</sup> Zn	<sup>90</sup> Y	<sup>32</sup> P	<sup>35</sup> S	<sup>51</sup> Cr	<sup>24</sup> Na	<sup>198</sup> Au
<b>Group 4: Low Radiotoxicity</b>	<sup>3</sup> H	<sup>58m</sup> Co	<sup>71</sup> Ge	<sup>87</sup> Rb	<sup>103m</sup> Rh	<sup>125</sup> Cs	<sup>232</sup> Th		
	<sup>15</sup> O	<sup>85</sup> Kr	<sup>99m</sup> Tc	<sup>97</sup> Nb	<sup>131m</sup> Xe	<sup>191m</sup> Os			

**Limitations on Activities in Various Types of Working Place or Laboratory**

RADIOTOXICITY OF RADIONUCLIDES	MINIMUM QUANTITY	TYPE OF WORKING PLACE OR LABORATORY REQUIRED		
		Type C	Type B	Type A
1. Very high	0.1 (3.7 kBq)	<10 Ci (<370 kBq)	10 Ci (370 kBq)	10 Ci or more (>370 kBq)
2. High	1.0 (37 kBq)	<100 Ci (<3.7 MBq)	100 Ci (3.7 MBq)	100 Ci or more (>3.7 MBq)
3. Moderate	10 (370 kBq)	<1 mCi (<37 MBq)	1 mCi - 1 Ci (37 MBq - 37 GBq)	1 Ci or more (>37 GBq)
4. Low	100 (3.7 MBq)	<10 mCi (<370 MBq)	10 mCi - 10 Ci (370 MBq - 370 GBq)	10 Ci or more (>370 GBq)

<sup>3</sup> Excerpted from (IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition"

## APPENDIX D 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, unsealed volatile licensed materials, and 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 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 the 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 E 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, before being permitted to use radioactive material, the user has received training and has a copy of the licensee's safe use and emergency procedures. 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 4731.2020, 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, NMSS Newsletters, 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 F  
INSTRUMENT SPECIFICATIONS**

The specifications in the following table will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities.

**Typical Survey Instruments<sup>1</sup>  
(Instruments used to measure radiological conditions at licensed facilities)**

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
<i>Detectors</i>	<i>Radiation</i>	<i>Energy Range</i>	<i>Efficiency</i>
Exposure Rate Meters	Gamma, X-ray	R-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
Nal Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
<i>Detectors</i>	<i>Radiation</i>	<i>Energy Range</i>	<i>Efficiency</i>
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Table from The Health Physics & Radiological Health Handbook, Revised Edition, edited by Bernard Shleien, 1992 (except for \* items).

**APPENDIX G  
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 Users 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.



## APPENDIX H 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 that 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 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 I RADIATION SURVEYS**

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 (or for Type C broad scopes, the individual designated as responsible for the day-to-day operation of the radiation safety program) 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 calculations basic using and measuring radioactivity.
- Biological effects of radiation.
- Appropriate on-the-job-training consists of the following:
  - Observing authorized personnel using survey equipment, collecting samples, and analyzing samples.
  - Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

### **Facilities and Equipment**

To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.

A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cesium-137, Cobalt-60).

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

### **Ambient Radiation Level Surveys**

Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 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.

Table 1 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material in use at the 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.

**Table 1 - 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 - Classification of Laboratories

### Survey Frequency Category

GROUP	LOW	MEDIUM	HIGH
1	< 370 kBq (10 Ci)	370 kBq (10 Ci) to 37 MBq (1 mCi)	> 37 MBq (1 mCi)
2	< 37 MBq (1 mCi)	37 MBq (1 mCi) to 3.7 GBq (100 mCi)	> 3.7 GBq (100 mCi)
3	< 3.7 GBq (100 mCi)	3.7 GBq (100 mCi) to 370 GBq (10 Ci)	> 370 GBq (10 Ci)
4	< 370 GBq (10 Ci)	370 GBq (10 Ci) to 37 TBq (1000 Ci)	> 37 TBq (1000 Ci)

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

### Survey Frequency Category Modifiers

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	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

The object is to determine how often to survey the laboratory. To do this, multiply the activity range 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.

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.

### Isotope Groups

<b>Group 1</b>	Pb-210	Po-210	Ra-223	Ra-226	Ra-228	Ac-227	Th-227	Th-228	Th-230	
	Pa-231	U-230	U-232	U-233	U-234	Np-237	Pu-238	Pu-239	Pu-240	
	Pu-241	Pu-242	Am-241	Am-243	Cm-242	Cm-243	Cm-244	Cm-245		
	Cm-246	Cf-249	Cf-250	Cf-252						
<b>Group 2</b>	Na-22	Cl-36	Ca-45	Sc-46	Mn-54	Co-56	Co-60	Sr-89	Sr-90	Y-91
	Zr-95	Ru-106	Ag-110 <sup>m</sup>	Cd-115 <sup>m</sup>	In-114 <sup>m</sup>	Sb-124	Sb-125	Te-127 <sup>m</sup>	Te-129 <sup>m</sup>	
	I-124	I-125	I-126	I-131	I-133	Cs-134	Cs-137	Ba-140	Ce-144	Eu-152
	Eu-154	Tb-160	Tm-170	Hf-181	Ta-182	Ir-192	Tl-204	Bi-207	Bi-210	
	At-211	Pb-212	Ra-224	Ac-228	Pa-230	Th-234	U-236	Bk-249		

<b>Group 3</b>	Be-7	C-14	F-18	Na-24	C1-38	Si-31	P-32	P-33	S-35	Ar-41	K-42
	K-43	Ca-47	Sc-47	Sc-48	V-48	Cr-51	Mn-52	Mn-56	Fe-52	Fe-55	
	Fe-59	Co-57	Co-58	Ni-63	Ni-65	Cu-64	Zn-65	Zn-69 <sup>m</sup>	Ga-72	As-73	
	As-74	As-76	As-77	Se-75	Br-82	Kr-85 <sup>m</sup>	Kr-87	Rb-86	Sr-85	Sr-91	
	Y-90	Y-92	Y-93	Zr-97	Nb-93 <sup>m</sup>	Nb-95	Mo-99	Tc-96	Tc-97 <sup>m</sup>	Tc-97	
	Tc-99	Ru-97	Ru-103	Ru-105	Rh-105	Pd-103	Pd-109	Ag-105	Ag-111		
	Cd-109	Cd-115	In-115 <sup>m</sup>	Sn-113	Sn-125	Sb-122	Te-125 <sup>m</sup>	Te-127	Te-129		
	Te-131 <sup>m</sup>	Te-132	I-130	I-132	I-134	I-135	Xe-135	Cs-131	Cs-136	Ba-131	
	La-140	Ce-141	Ce-143	Pr-142	Pr-143	Nd-147	Nd-149	Pm-147	Pm-149		
	Sm-151	Sm-153	Eu-152	Eu-155	Gd-153	Gd-159	Dy-165	Dy-166	Ho-166		
	Er-169	Er-171 (9.2 hr)	Tm-171,	Yb-175	Lu-177	W-181	W-185	W-187			
	Re-183	Re-186	Re-188	Os-185	Os-191	Os-193	Ir-190	Ir-194	Pt-191		
	Pt-193	Pt-197									
	Au-196	Au-198	Au-199	Hg-197	Hg-197 <sup>m</sup>	Hg-203	Tl-200	Tl-201	Tl-202		
	Pb-203	Bi-206	Bi-212	Rn-220	Rn-222	Th-231	Pa-233	Np-239			
	<b>Group 4</b>	H-3	O-15	Ar-37	Co-58 <sup>m</sup>	Ni-59	Zn-69	Ge-71	Kr-85	Sr-85 <sup>m</sup>	Rb-87
		Y-91 <sup>m</sup>	Zr-93	Nb-97	Tc-96 <sup>m</sup>	Tc-99 <sup>m</sup>	Rh-103 <sup>m</sup>	In-113 <sup>m</sup>	I-129	Xe-131 <sup>m</sup>	
		Xe-133	Cs-134 <sup>m</sup>	Cs-135	Sm-147	Re-187	Os-191 <sup>m</sup>	Pt-193 <sup>m</sup>	Pt-197 <sup>m</sup>		
		Th-232	Th-Nat	U-235	U-238	U-Nat					

#### 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.

**Table 2 - Acceptable Surface Contamination Levels for Equipment**

<b>NUCLIDE<sup>A</sup></b>	<b>AVERAGE<sup>B, C</sup></b>	<b>MAXIMUM<sup>B, D</sup></b>	<b>REMOVABLE<sup>B, E</sup></b>
I-125, I-129	1.7 Bq/100 cm <sup>2</sup> (100 dpm/100 cm <sup>2</sup> )	5.0 Bq/100 cm <sup>2</sup> (300 dpm/100 cm <sup>2</sup> )	0.3 Bq/100 cm <sup>2</sup> (20 dpm/100 cm <sup>2</sup> )
I-126, I-131, I-133, Sr-90	16.7 Bq/100cm <sup>2</sup> (1,000 dpm/100 cm <sup>2</sup> )	50.0 Bq/100cm <sup>2</sup> (3,000 dpm/100 cm <sup>2</sup> )	3.3 Bq/100cm <sup>2</sup> (200 dpm/100 cm <sup>2</sup> )
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 <sup>2</sup> (5,000 dpm/100 cm <sup>2</sup> )	250 Bq/100 cm <sup>2</sup> (15,000 dpm/100 cm <sup>2</sup> )	16.7 Bq/100 cm <sup>2</sup> (1,000 dpm/100 cm <sup>2</sup> )
<p><sup>a</sup> 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.</p> <p><sup>b</sup> 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.</p> <p><sup>c</sup> 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.</p> <p><sup>d</sup> The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup>.</p> <p><sup>e</sup> The amount of removable radioactive material per 100 cm<sup>2</sup> 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.</p>			

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, Table 2 provides the maximum acceptable residual levels for equipment and Table 3 provides screening values for building surface contamination. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before 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<sup>2</sup> is acceptable to indicate levels of removable contamination.

**Table 3 - Screening Values for Building Surface Contamination<sup>1</sup>**

<b>RADIONUCLIDE</b>	<b>SYMBOL</b>	<b>SCREENING LEVELS FOR UNRESTRICTED RELEASE (DPM/100 CM<sup>2</sup>)</b>
Hydrogen-3 (Tritium)	H-3	1.2 x 10 <sup>8</sup>
Carbon-14	C-14	3.7 x 10 <sup>6</sup>
Sodium-22	Na-22	9.5 x 10 <sup>3</sup>
Sulfur-35	S-35	1.3 x 10 <sup>7</sup>
Chlorine-36	Cl-36	5.0 x 10 <sup>5</sup>
Manganese-54	Mn-54	3.2 x 10 <sup>4</sup>
Iron-55	Fe-55	4.5 x 10 <sup>6</sup>
Cobalt-60	Co-60	7.1 x 10 <sup>3</sup>
Nickel-63	Ni-63	1.8 x 10 <sup>6</sup>
Strontium-90	Sr-90	8.7 x 10 <sup>3</sup>
Technetium-99	Tc-99	1.3 x 10 <sup>6</sup>
Iodine-129	I-129	3.5 x 10 <sup>4</sup>
Cesium-137	Cs-137	2.8 x 10 <sup>4</sup>
Iridium-192	Ir-192	7.4 x 10 <sup>4</sup>

<sup>1</sup> 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.

Table 3 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 cm<sup>2</sup>). 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 for which monitoring is not practicable, 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 and the physical and chemical characteristics of the radioactive material, and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual
- Retention and excretion characteristics of the radionuclides
- Sensitivity of the measurement technique
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 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 that was published in Appendix (J.1 and/or J.2)."

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.1 and/or J.2)," and submit your leak test procedure.

### J.1 MODEL PROCEDURE FOR TAKING TEST SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, they should also be checked for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

### J.2 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 microcurie 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 microcuries 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 three 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.

### ***Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Sealed 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***

This 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 his 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 MODEL WASTE MANAGEMENT PROCEDURES

### General Guidelines

All radioactivity labels must be defaced or removed from containers and packages before disposal into ordinary non-radioactive waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

Remind workers that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.

Occasionally monitor all procedures to ensure that unnecessary waste is not being produced. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs. Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.

Housekeeping staff should be provided with adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

### Model Procedure for Disposal by Decay-in-Storage (DIS)

Applicants should assure that adequate space and facilities are available for the storage of waste for DIS. Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

1. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
2. Short-lived waste should be segregated from long-lived waste.
3. Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
4. Liquid and solid wastes must be stored separately.
5. When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
6. The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives. Persons performing surveys should be aware of the potential for measurable radiation.
7. The contents of the container should be allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container.

8. Prior to disposal as ordinary trash, each container should be monitored as follows:
  - a. Check the radiation detection survey meter for proper operation.
  - b. Survey the contents of each container in a low background area.
  - c. Remove any shielding from around the container.
  - d. Monitor all surfaces of the container.
  - e. Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e. surface readings are indistinguishable from background.
  - f. If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.
  
9. If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

All radiation labels must be defaced or removed from containers and packages before disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, if the following is done:

- Waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility.
- Labels are removed from the waste barrels/containers.
- The waste is incinerated, not placed in a landfill.
- The waste disposal firm is cautioned not to open the container before incineration.

#### **Model Procedure for Disposal of Liquids Into Sanitary Sewerage**

Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.

Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.

Calculate the amount of each radioisotope that can be discharged by using the information from prior similar discharges and the information in 4731.2750.

Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in 4731.2750, Table 3 (records for individual users/laboratories).

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, Table 3 must not exceed unity.

The total quantity of licensed material released into the sanitary sewerage system in a year must not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.

Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.

Liquid waste should be discharged only via designated sinks or toilets. Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.

Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces. Decontaminate as appropriate.

Decontaminate all areas or surfaces if found to be contaminated.

For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and its quantity and concentration that is released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

### **Model Procedure for Incineration**

These guidelines apply to noncommercial waste disposal, i.e., incineration of a licensee's own waste. You do not need specific MDH approval in order to incinerate certain categories of radioactive waste. For example, 4731.2440 provides that tritium and Carbon-14 in low level concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After you review your program and confirm that you have waste that requires specific MDH approval for incineration, please provide the following information:

- Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.
- Describe the waste that is proposed to be incinerated, to include:
  - The chemical and/or physical form of the waste containing licensed material.
  - A description of how the waste is segregated, packaged and labeled for transfer from the generation site to the incinerator.
  - The name of the radioisotope.
  - Concentration of radioactivity averaged over the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated.
  - The total radioactivity of each isotope per burn and the total number of burns per year.
- Describe procedures for ensuring that these frequencies and activities will not be exceeded.
- Describe the procedures for packaging, handling, securing and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.
- Describe your method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe your procedures for collection, handling and disposal of the ash residue.
- Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable regulations.
- Describe the characteristics of the incinerator and site location, including height of the stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital), and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that are present.
- State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined.

- Describe any stack monitoring that is planned.
- Provide a copy of the written safety analysis that demonstrates the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 4731.2000.
- Provide a written commitment that the applicant has coordinated with appropriate State and local authorities and that such permits and other authorizations as may be necessary have been obtained.
- Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding regulatory limits will be disposed of.

### **Model Procedure for Compaction**

The following information should be provided from licensees who propose to compact waste:

- Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs, etc.).
- Describe the type, quantities, and concentrations of waste to be compacted.
- Provide an analysis of the potential for airborne release of radioactive material during compaction activities.
- State the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors.
- Include a description of the procedures for monitoring filter blockage and exchange.
- Discuss the methods used to monitor worker breathing zones and/or exhaust systems.
- Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.
- Discuss the instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling un-compacted waste, and examining containers for defects.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including:

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### Security Plan

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

## **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one or more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

## **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.

- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.
- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.

- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.
- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS

The logo is circular with a stylized animal head (possibly a moose or bear) in the center. The text "Radioactive Materials Group" is written along the top inner edge, and "Minnesota Department of Health" is written along the bottom inner edge. The letters "RMG" are at the bottom.	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

**REGULATORY GUIDE FOR CALIBRATING  
RADIATION SURVEY AND MONITORING INSTRUMENTS**

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## **MDH REGULATORY GUIDE FOR CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS**

### **PURPOSE**

This guide identifies the information needed by the MDH to evaluate an application for a "Calibrating Radiation Survey and Monitoring Instruments" license and to describe the radioactive material regulations.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing a radiation safety program. You should carefully study this guide and all the regulations identified in the 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.

### **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. Appendix A provides an outline for a licensee's ALARA program.

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.

### **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 propriety information to the public or substantial delays in processing your application.

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

Submit one copy of your application to:

Radioactive Materials Unit  
Minnesota Department of Health  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section of this document.

Check box C for a renewal of an existing license and provide 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) At Which Licensed Material Will Be Used or Possessed**

Applicants must provide a specific address for each location where radioactive material will be used or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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**

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

If the use of sealed or plated sources is being considered, specify the isotope, manufacturer, and model number of each sealed source or plated source. You should consult with your proposed supplier for information to be sure that your sources and devices conform to the sealed source and device designations registered with the US Nuclear Regulatory Commission (NRC) or an Agreement State.

Also list any survey meter or calibration source not exempted under 4731.3040.

Example:

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

NOTE: It is the practice of MDH to provide flexibility in the number of identical sealed source/device combinations you may want to possess at any one time. Therefore, it is not necessary for you to specify the number of identical source/device combinations. You will need to amend your license before you obtain any source other than those listed in Item 6.

#### Item 6: Purpose(s) For Which Licensed Material Will Be Used

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

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

#### Item 7: Individual(s) Responsible for Radiation Safety Program

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.

##### ***Radiation Safety Officer (RSO)***

The person responsible for the radiation protection program is called the Radiation Safety Officer (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. MDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO<sup>1</sup>. The duties of the RSO are outlined in Appendix B.

Radiation Safety Officers (RSOs) must have adequate training and experience. The licensee should provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.

Additional training is required for RSOs of programs that perform non-routine operations. This includes repairs involving or potentially affecting components related to the radiological safety of the calibration equipment (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)

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<sup>1</sup> It is important to notify MDH, as soon as possible, of changes in the designation of the RSO.

and any other activities during which personnel could receive radiation doses exceeding MDH limits (e.g., installation, initial radiation survey, or relocation).

As an alternative, the licensee should state that:

- a. Before obtaining licensed materials, the proposed RSO will have successfully completed training. Provide an outline of the course content or describe the training.
- b. The new RSO will receive training within a specified time after being appointed. Provide an outline of the course content or describe the training.

### ***Authorized Users***

An authorized user (AU) is a person whose training and experience meet MDH criteria and who uses or directly supervises the use of licensed material. Authorized users must ensure the proper use, security, and routine maintenance of devices containing licensed material. Therefore, they must attend the formal training and instruction or receive equivalent training and instruction.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that the AU has sufficient training and experience to perform independent survey instrument calibrations. Classroom 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 calculations basic to using and measuring radioactivity
- Biological effects of radiation

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

- Observing authorized personnel performing survey instrument calibration.
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

### **Item 8: Training for Individuals Working In or Frequenting Restricted Areas**

Individuals who, in the course of employment, are likely to receive occupational doses of radiation in excess of 100 mrem (1 mSv) in a year must receive training. The extent of this training must be commensurate with potential radiological health protection problems present in the work place. A model training program is included in Appendix C.

Licensee personnel who work in the vicinity of a device but do not use equipment containing sources (ancillary staff) are not required to have radiation safety training as long as they are not likely to receive 100 mrem (1 mSv) in a year. However, to minimize potential radiation exposure when ancillary staff are working in the vicinity of a device, it is prudent for them to work under the supervision and in the physical presence of an AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the device and the meaning of the radiation symbol. They should be instructed not to touch the equipment and to keep away from it as much as their work permits.

Some ancillary staff, although not likely to receive doses over 100 mrem, should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments near the equipment, to ensure the control and security of licensed material.

Submit the training program for individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 100 mrem (1 mSv) in a year (occupationally exposed workers) and ancillary personnel.

#### **Item 9: Facilities and Equipment**

Calibration equipment normally has engineering features to protect the user from unnecessary radiation exposure. An application will be approved if, among other things, the applicant has equipment and facilities that are adequate to protect health and to minimize danger to life or property. Therefore, you should provide a sketch or description of the proposed location of each device containing radioactive equipment within your facility. Note the following:

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

Sketches and descriptions should show the relationship of material use areas to any adjoining unrestricted areas (e.g., offices, rest rooms, or cafeterias).

In addition, the following precautions should be observed:

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry. Additional information on monitoring is in Appendix D.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

## **Item 10: Radiation Safety Program**

### ***Surveys***

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

- (1) type of instrument
- (2) type of radiation detected
- (3) sensitivity range
- (4) specific use
- (5) calibration interval

Survey instruments should be calibrated at least annually and following servicing.

The following is an example:

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

### ***Operating and Emergency Procedures***

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

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

### ***Annual Audit of Radiation Safety Program***

Annually licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure the following:

- Compliance with MDH and DOT regulations (as applicable), and the terms and conditions of the license.
- Occupational doses and doses to members of the public are ALARA.
- Records of audits and other reviews of program content are maintained for three years.

Currently the MDH's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of calibration equipment users to determine if, for example, Operating and Emergency Procedures are available and are being followed, etc. It is essential that once identified, problems are corrected comprehensively and in a timely manner.

MDH will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If the licensee identifies violations and these steps are taken, the MDH will normally exercise discretion and may elect not to cite a violation. MDH's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for three years from the date of the record. These audit records should include the following:

- date of audit
- name of person(s) who conducted the audit
- persons contacted by the auditor(s)
- areas audited
- audit findings
- corrective actions
- follow-up

The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, and should not be submitted in the license application.

### ***Leak Testing of Sealed Sources***

As a licensee, you must perform leak tests to ensure that sources are not leaking. MDH requires tests to determine if there is any leakage from the sealed sources in the devices. Normally, leak tests should be performed at six-month intervals. Some sealed source/device combinations have been authorized for a leak test interval of three years. Information about sealed source/device combinations that have three-year leak test intervals may be obtained from suppliers and manufacturers.

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. Use a commercial leak test kit. You take the smears and send them to the kit supplier, who will report the results to you.
3. Perform the entire leak test sequence yourself, including taking the smears and their measurements.

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

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

For Option 3, describe the procedure for taking the sample and the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used: hand-held survey meters will not normally be considered adequate for measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application. Commit to Appendix E or submit your own procedures.

### ***Inventories***

State that you will conduct inventories at intervals not to exceed six months, to account for all sealed sources and devices received and possessed under your license. You should maintain records of the inventories for at least three years from the date of the inventory. The records should include the radionuclide and amount of material in each source, the manufacturer's name, the model number and serial number of each device, the location of each device, and the date of inventory.

### ***Appendices***

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

- Appendix B Duties and Responsibilities of the RSO
- Appendix C Model Training Program
- Appendix D Personnel Exposure Monitoring Program
- Appendix E Leak Testing Sealed Sources
- Appendix F Calibrating Survey Instruments
- Appendix G Certificate of Instrument Calibration
- Appendix H Guidance for Ordering and Receiving Radioactive Material
- Appendix I Safely Opening Packages Containing Radioactive Material
- Appendix J Area Surveys
- Appendix K Waste Disposal
- Appendix L Calibration Equipment Required
- Appendix M Maintenance of Quality of Calibration

### **Item 11: Waste Management**

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

### **Item 12: License Fees**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

### **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 signed by the delegated person and must include the appropriate amendment fee.

*The licensee may not place into effect any amendment until the licensee has received written verification from the 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 MDH has taken the final action on the application. 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**  
**MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA**

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix A to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments." Submit the signed commitment in Section 6 of this appendix.

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in Section 6 of this appendix.

**ALARA PROGRAM**

**1. Management Commitment**

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

**2. Review of Proposed Users and Uses**

- a. The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- b. When considering the use of radioactive material, the RSC will review efforts of the applicant to maintain exposure ALARA.
- c. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- d. The RSC will delegate authority for enforcement of an ALARA program to the RSO.

- e. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- f. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- g. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

**Table A-1 – Investigational Levels**

	Investigational Levels (mrems per month)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

- h. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

**3. RADIATION SAFETY OFFICER COMMITMENT**

- a. Annual and Quarterly Review
  - The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
  - The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.
- b. Education Responsibilities for ALARA Program
  - The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.
- c. Cooperative Efforts for Development of ALARA Procedures
  - Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
  - The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
  - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- d. Reviewing Instances of Deviation from Good ALARA Practices:
- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
- e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

#### **4. AUTHORIZED USERS COMMITMENT**

- a. New methods of Use Involving Potential Radiation Doses
- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
  - The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
- b. Authorized User's Responsibility to Supervised Individuals
- The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
  - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

#### **5. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES<sup>1</sup>**

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table A-1. These levels apply to the exposure of individual workers.

The RSO will review and record on MDH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table A-1:

- a. Personnel dose less than Investigational Level I

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<sup>1</sup> MDH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table A-1 values for the investigational Level I.
- b. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II
- The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality. This review will be recorded in the Committee minutes.
- c. Personnel dose equal to or greater than Investigational Level II
- The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's "Occupational Exposure Record for Monitoring Period" and "Cumulative Occupational Exposure History," or its equivalent.
- d. Re-establishment of investigational levels to levels above those listed in Table I
- In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

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

**6. SIGNATURE OF CERTIFYING OFFICIAL<sup>1</sup>** Sign and submit as part of Appendix A.

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

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (Print or type)

\_\_\_\_\_  
Title

<sup>1</sup> The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

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

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for RSO published in Appendix B to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota rules. State on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

**MODEL PROCEDURE**

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include but are not limited to the following:

1. Ensure that licensed material possessed by the licensee is limited to the types, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained, are designated by the RSO, have received refresher training at least annually, and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Ensure that personnel monitoring devices are used as required, and reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to make certain that
  - a. The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained, approved users).
  - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA.
  - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
7. Ensure that results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).

9. Ensure that all incidents, accidents, and personnel exposure to radiation more than ALARA levels or 4731 limits are investigated and reported to MDH within the required time limits.
10. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
11. Ensure that licensed material is disposed of properly.
12. Ensure that the facility has up-to-date copies of MDH regulations, completes a review of new or amended MDH regulations, and revises licensee procedures to comply with MDH regulations.
13. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

**APPENDIX C**  
**MODEL TRAINING PROGRAM**  
In addition to 4731.1020

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may state on your application, "We will establish and implement the model training program published as Appendix C to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments." You may use methods of training that best suit your facility's needs, such as lectures, video presentations, or demonstrations.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of 4731.1020. State on your application, "We have developed a training program for your review that is appended as Appendix C." Be sure to include the groups of workers, the method of their training, and the frequency of training.

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

**MODEL PROGRAM**

Personnel to be instructed:

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

Frequency of instruction:

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

Instruction for individuals will include the following subjects in addition to 4731.1020:

1. Applicable regulations and license conditions.
2. Licensee's in-house work rules.
3. Locations where the licensees have posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 4731.1010.

Training will also include a question and answer period. Records will be kept with information regarding the date of the program, subjects covered, and attendees.

**APPENDIX D  
MODEL PERSONNEL EXPOSURE MONITORING PROGRAM**

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may state on your application, "We will establish and implement the model personnel exposure monitoring program published in Appendix D to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of 4731.2020. State on your application, "We have developed an exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.

If personnel monitoring will not be used, you should submit calculations or documentation from radiation surveys that demonstrate that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 4731.2020.

**MODEL PROGRAM FOR EXTERNAL EXPOSURE**

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

## **APPENDIX E LEAK TESTING SEALED SOURCES**

You may use the following model procedure to leak test sealed sources. If you or a contractor follow the model procedure you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix E to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

You may provide leak test analysis as a service. If you wish to analyze leak tests for other licensees, you should indicate in your application that you will be doing so. You may use the model procedure to analyze test samples. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix E to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix (E.1 and/or E.2)," and submit your leak test procedure.

### **E.1 MODEL PROCEDURE FOR TAKING TEST SAMPLES**

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, you should also check for radon leakage. 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.

### **E.2 MODEL PROCEDURE FOR ANALYZING TEST SAMPLES**

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries (185 Bq) for beta or gamma emitting radionuclides. For alpha emitting radionuclides, select an instrument that is sufficiently sensitive to detect 0.001 microcuries (37 Bq). 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 sodium-iodide crystal with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive. For alpha emitting radionuclides, a zinc-sulfide scintillation detector with a ratemeter or scaler is appropriate.

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. Wipes of alpha emitting radionuclides should be dry and the exposed, single layer of the wipe material should face the detector.
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 microcuries or greater for beta or gamma emitting radionuclides or 0.001 microcuries for alpha emitting radionuclides, notify the RSO. The source must be withdrawn from use to be repaired or disposed 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 records for three years.

## **APPENDIX F CALIBRATING SURVEY INSTRUMENTS**

You may use the following guidance to calibrate survey instruments. If you follow all the guidance, you may state on your application, "We will establish and implement the model procedure for calibrating survey instruments published in Appendix F to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If your procedure does not follow the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota rules. State on your application, "We have developed a survey instrument calibration procedure for your review that is appended as Appendix F," and append your survey instrument calibration procedure.

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

### **PRE-CALIBRATION**

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

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

### **MODEL PROCEDURE FOR PRIMARY CALIBRATION**

1. The source must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
4. The source should be of sufficient strength to give an exposure rate of about 30 mr/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cesium-137 or 21 millicuries of Cobalt-60.
5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record must be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than ten percent. A correction chart or graph must be conspicuously attached to the instrument if the difference is greater than ten percent. Any instrument with an exposure rate that differs from the calculated exposure rate by more than 20 percent must be repaired and cannot be considered calibrated.
8. Three kinds of scales are frequently used on survey meters:
  - a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be separated by at least 50 percent of scale rating.
  - b. Meters that have a multi-decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.
  - c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.
9. Readings above 1,000 mr/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained and should be retained for three years. The description of the calibration will include the following:
  - a. The owner or user of the instrument.
  - b. A description of the instrument that includes
    - manufacturer
    - model number
    - serial number
    - type of detector
    -
  - c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure.
  - d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument.

- e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument).
  - f. The angle between the radiation flux field and the detector. For external cylindrical GM or ionization-type detectors, this will usually be parallel or perpendicular indicating photons traveling either parallel or perpendicular to the central axis of the detector. For instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument.
  - g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure.
  - h. The apparent exposure rate from the check source.
  - i. The name of the person who performed the calibration and the date on which the calibration was performed.
12. The following information will be attached to the instrument as a calibration sticker or tag:
- a. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument).
  - b. The apparent exposure rate from the check source.
  - c. The name of the person who performed the calibration and the date on which the calibration was performed.
  - d. For each scale or decade, one of the following *as appropriate*:
    - (1) The average correction factor;
    - (2) A graph or graphs from which the correction factor for each scale or decade may be deduced; or
    - (3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
13. To check reproducibility, the instrument should be exposed to a radiation field three or more times under identical conditions. The readings obtained should normally not deviate from the mean value by more than  $\pm 10$  percent.
14. The response of an instrument may vary as a function of such parameters as energy, temperature, pressure, humidity, and source/detector geometry. Primary calibration should be accomplished with known values of these parameters and under the conditions specified by the manufacturer. Any of these parameters may be fixed to the condition in which the instrument is to be used routinely, and notation will be made of these values.
15. Readout Scale and Linearity Calibration and Adjustment:
- a. Linear Readout Instruments
    - (1) Linear instruments usually have a scale selection switch. If controls are provided for each scale, adjustment of each shall be made according to the manufacturer's specifications or at the midpoint of each scale. If only one control is provided, adjustment shall be made
      - at the point specified by the manufacturer,

- near the midpoint of the middle scale, or
  - near the midpoint of a scale that is particularly important to the user's requirements.
  -
- (2) After adjustment, calibration shall be checked near the ends of each scale (approximately 20 percent and 80 percent of full scale). After an adjustment has been completed, instrument readings shall be within  $\pm 10$  percent of known radiation values at these two points. However, readings between 10 and 20 percent are acceptable if a calibration chart or graph is prepared and attached to the instrument.
- b. Logarithmic readout instruments
    - (1) These instruments commonly have a single readout scale spanning several decades with two or more adjustments. The instrument should be adjusted for each scale according to the manufacturer's specifications, or, alternatively, at points of particular importance to the user.
    - (2) As a minimum, calibration shall be performed at one point near the midpoint of each decade after adjustment. Instrument readings shall be within  $\pm 10$  percent of known radiation values at these points. Readings between 10 and 20 percent are acceptable if a calibration chart or graph is prepared and attached to the instrument.
  - c. Digital readout instruments
 

These may have manual scale switching (auto ranging) or no scale switching. For instruments with either manual or automatic scale switching, the calibration shall be performed according to 15.a. above. For instruments without scale switching, the calibration shall be performed as in 15.b. above.

## MODEL PROCEDURES FOR SPECIAL CONDITIONS

1. If the instrument is to be used under conditions that vary significantly from those for which the instrument is designed, the instrument should be adjusted, calibrated, and used only for the special conditions. (Examples of such conditions are radiation energy, temperature and pressure, and source/detector geometry). When an instrument is calibrated for special conditions, an identification label shall be attached, in addition to any required calibration labels, to indicate its restriction to the special use. If the instrument is also to be used within its design limits, the adjustments made during primary calibration shall remain the same and instrument readings for the special conditions shall be corrected using correction factors obtained from appropriate tables or graphs. Only one parameter should be varied at a time during calibration for the special conditions, but the interrelationships of the variables should be known.
2. Radiation Energy
  - a. Calibration shall be performed with a standard source or source-providing radiation fields similar to those in which the instrument will be used. Where instruments will be used in radiation fields of widely differing energies, the response of the instrument at several energies over the energy range shall be determined.
  - b. The response of the instrument to various energies of radiation shall be
    - (1) plotted as a function of energy, or otherwise called out;
    - (2) normalized to the response to a specific energy obtained during primary calibration; and
    - (3) provided with the instrument.

This type of graph is commonly called an energy dependence or spectral sensitivity curve.

**3. Temperature, Pressure, and Humidity**

- a. Instruments to be used outside the manufacturer's recommended temperature range or at temperatures that differ by more than 30 degrees from the calibration temperature shall be calibrated over the temperature range at which they will be used. Care should be taken to ensure that instruments are not exposed to temperatures that will damage the detector or electronic components.
- b. If the manufacturer has not stated operating limits for humidity or atmospheric pressures, the instruments shall be calibrated at the approximate humidity or pressure expected to be encountered in use. Care should be taken to ensure that an instrument is not damaged by exceeding its pressure or humidity limits.

**4. Detector Directional Dependence**

If an instrument is to be used in a detector orientation relative to the source that is different from that used during primary calibration, correction factors should be developed.

**DISCRIMINATION AGAINST UNWANTED RADIATION**

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

**PERIODIC PERFORMANCE TEST**

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

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

**PRIMARY CALIBRATION FREQUENCY**

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

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

**CALIBRATION FREQUENCY FOR SPECIAL CONDITIONS**

Calibration for special conditions need be performed only once unless

- (1) the instrument is modified or physically altered,
- (2) the special conditions are changed, or
- (3) the primary calibration is altered, providing that the conditions above are met.

#### **PERFORMANCE TEST FREQUENCY**

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

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

## **APPENDIX G CERTIFICATE OF INSTRUMENT CALIBRATION**

The following guidance may be used to develop a procedure for the certificate of instrument calibration to be given to the customer with each calibrated instrument. If you use this procedure, you may state on your application, "We will establish and implement the model procedure for instrument calibration certificates as published in Appendix G to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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

### **MODEL PROCEDURE**

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

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

**APPENDIX H**  
**GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL**  
In addition to 4731.2350

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may state on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material published in Appendix H to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 4731.2350. State on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix H," and submit your procedure.

**MODEL GUIDANCE**

1. The Radiation Safety Officer (RSO) or a designee must ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. For routinely used materials:
    - (1) Written records identifying the authorized user or department, isotope, chemical form, activity, and supplier
    - (2) Verification that material received was ordered by an authorized user.
  - b. For occasionally used materials (e.g., therapeutic dosages):
    - (1) The authorized user who will perform the procedure will make a written request to confirm that the material received is what was ordered.
    - (2) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.
4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

**SAMPLE MEMORANDUM**

**MEMO TO:** Chief of Security

**FROM:** Radiation Safety Officer

**SUBJECT:** Receipt of Packages Containing Radioactive Material

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

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

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

\_\_\_\_\_, at \_\_\_\_\_  
Name Home Telephone

**APPENDIX I  
SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix I to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix I," and submit your procedure. The response should address the requirements of 4731.2350.

**MODEL PROCEDURE**

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination in accordance with 4731.2350.
2. The following procedures for opening each package will be followed:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
  - c. Measure the exposure rate from the package at one (1) meter and at the package surface. If it is more than 10 millirem per hour at three (3) feet (1 meter), stop and notify the RSO. (The transport index noted on packages with Yellow II or Yellow III labels is the approximate dose rate, in millirem per hour, at one (1) meter from the package surface).
  - d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with White I labels should be less than 0.5 millirem per hour on the external surface of the package.
  - e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

Beta-gamma-emitting radionuclides; all radionuclides with half-lives less than ten days.....	22 dpm/cm <sup>2</sup>
All other alpha-emitting radionuclides.....	2.2 dpm/cm <sup>2</sup>
  - f. Open the package with the following precautionary steps:
    - (1) Remove packing slip.
    - (2) Open outer package following the supplier's instructions, if provided.
    - (3) Verify that the contents match the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

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

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

i. Monitor the packing material and the empty packages for contamination with a survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding it.

j. Make a record of the receipt.

3. For packages received under the general license, the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure that the material received is the material that was ordered.

## **APPENDIX J AREA SURVEYS**

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix J to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

You may develop your own procedure for review. State on your application, "We have developed survey procedures for your review that are appended as Appendix J" and submit your survey procedures.

### **MODEL PROCEDURE**

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

### **AMBIENT DOSE RATE SURVEYS**

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

2. Survey areas: unrestricted

Quarterly surveys should be completed in areas

- adjacent to restricted areas,
- through which radioactive materials are transferred, and
- where radioactive material is temporarily stored before shipment.

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

### **REMOVABLE CONTAMINATION SURVEYS**

1. Survey Areas: unrestricted

In any area where the potential for spreading contamination is likely to occur, (in cafeterias and snack bars, or on furniture and equipment), survey at least quarterly. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be

taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200 dpm/100 cm<sup>2</sup> for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).
3. Immediately notify the RSO if you find levels that exceed the established action levels. See Table J-1 below for guidance in establishing your action levels.

## RECORDS

1. Records must include the information in required for normal package receipt as well as actions taken in the case of excessive dose rates or contamination and follow-up survey information.
2. The RSO will review and initial the record at least monthly and promptly in those cases in which action levels were exceeded.

**Table J-1**

<b>RECOMMENDED ACTION LEVELS IN DPM/100 CM<sup>2</sup> FOR SURFACE CONTAMINATION</b>		
	<b>P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198</b>	<b>Cr-51, Co-57, Ga-67, Tc-99<sup>m</sup>, Hg-197, Tl-201</b>
<b>1. Unrestricted areas, personal clothing</b>	<b>200</b>	<b>2,000</b>
<b>2. Restricted areas, protective clothing used only in restricted areas, skin</b>	<b>2,000</b>	<b>20,000</b>

## **APPENDIX K WASTE DISPOSAL**

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for waste disposal published in Appendix K to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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

### **OVERVIEW**

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. Nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See 4731.2410 through 4731.2450.)

### **GENERAL GUIDANCE**

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

### **MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES**

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

1. Regulations for disposal in the sanitary sewer appear in 4731.2420. There are monthly limits based on the total sanitary sewerage release of your facility. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and the sink or toilet at which the material was released.
2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in 4731.2750(4). These limits normally apply at the boundary of the restricted area. Make a

record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and the vent site at which the material was released.

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

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

Short-lived material (with physical half-life less than 120 days) may be disposed of by decay-in-storage. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all decay-in-storage waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the decay-in-storage area.
3. Decay the material for at least ten half-lives. If the material is not segregated by isotope, decay the material for at least ten half-lives of the longest-lived radionuclide.
4. Before disposal as in-house waste, monitor each container as follows:
  - a. Check your radiation detection survey meter for proper operation.
  - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
  - c. Remove any shielding from around the container.
  - d. Monitor all surfaces of each container.
  - e. Discard as in-house waste only those containers with radiation levels that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be that sure no radiation labels are visible.
  - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99<sup>m</sup> generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

### **MODEL PROCEDURE FOR TRANSFER FOR BURIAL**

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

### **MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE**

Waste from in vitro kits that are generally licensed pursuant to 4731.3245 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

## APPENDIX L REQUIRED CALIBRATION EQUIPMENT

The following general guidance and procedure may be used for the requirements for calibration equipment. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for the requirements for calibration equipment published in Appendix L to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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

### MODEL PROCEDURE

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

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

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

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

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

1. the source instrument geometry is well understood and easily reproduced, or
2. the instrument response to this radiation is well understood and is not critically dependent on instrument adjustment. For example, the use of a photon source to check instruments sensitive to beta radiation may be acceptable; the use of a photon source to check a detector utilizing a  $\text{BF}_3$  response to neutrons is not acceptable.

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

## APPENDIX M MAINTAINING QUALITY OF CALIBRATION

The following general guidance and procedures may be used for the maintaining quality of calibration. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for the maintenance of quality of calibration published in Appendix M to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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

### MODEL PROCEDURE

#### *Radiation Field*

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

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

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

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

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

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

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

#### *Calibration Facility*

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

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

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

*Other*

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

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

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### **Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

#### **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one of more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

#### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

#### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR DIAGNOSTIC AND THERAPEUTIC MEDICAL PROCEDURES

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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# **REGULATORY GUIDE FOR MEDICAL USE OF RADIOACTIVE MATERIAL IN DIAGNOSTIC AND THERAPEUTIC PROCEDURES**

## **INTRODUCTION**

The Minnesota Department of Health (MDH) regulates the intentional internal or external administration of radioactive material and the radiation produced by the material itself, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Radioactive Materials Rules, Chapter 4731.4400.

MDH usually issues a single radioactive material license to cover the radioisotope program. However, separate licenses must be obtained for the following:

- Gamma stereotactic radiosurgery devices (gamma knives)
- High, medium, and low dose rate afterloaders
- Irradiators
- Nuclear powered pacemakers
- Teletherapy devices

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the regulations identified in 4731.4400 through 4731.4527 before completing 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

This guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for a medical use license and to describe the radioactive material regulations for medical use. Separate guidance has been developed to meet the specific needs of a teletherapy applicant.

## **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.

## **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 this 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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 Materials and Item 6: Purpose**

Radioactive material for medical use is divided into types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may state, "As needed" in the "Amount" column as shown. For implant material, express the total amount in millicuries (mCi). If you plan to have an eye applicator, list it as a separate item and note its total activity in mCi.

For 4731.4432, 4433, and 4434 use, the applicant should define the purpose of use by stating the applicable section and the description of the applicable modality (e.g., any uptake dilution and excretion procedure for which a written directive is not required). The use of unsealed radioactive material in therapy (4731.4440) involves administering a radioactive material, either orally or by injection, to treat or palliate a particular disease. The most common form of use of unsealed radioactive material for therapy is the treatment of hyperthyroidism with Iodine-131 (I-131), sodium iodide. Other therapeutic procedures include, for example, ablation of thyroid cancer metastasis, treatment of malignant effusions, treatment of polycythemia vera and leukemia, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. References to particular diagnostic or treatment modalities in this section are intended to be examples and are not intended to imply that licensees are limited to these uses.

**Table 1**

<b>RADIOACTIVE MATERIAL</b>	<b>AMOUNT</b>	<b>PURPOSE</b>
5.a Material in 4731.4432	As needed	6.a Medical use
5.b Material in 4731.4433	As needed	6.b Medical use
5.c Material in 4731.4434	As needed	6.c Medical Use
5.d Material in 4731.4440	mCi	6.d Medical use
5.e Implant and Material in 4731.4450	mCi	6.e Medical use

(Note: Broad Scope medical use applicants may request "Any radioactive material with atomic numbers 3 through 84 for medical use.")

If you need other items, make a separate line entry for each isotope. Each line entry must identify the radionuclide, the physical form, maximum amount available for use expressed in millicuries, and the purpose for which the material will be used.

**For sealed sources used in devices:** An applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registration (SSDR) Certificate. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the licensed activity limit prior to installation in the device.

For use of brachytherapy sources (4731.4450), the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (i.e., 10 CFR 35.400). If a source is to be used in a device, applicants may need to define the purpose of use by describing the manufacturer's name and model number of the device. The licensee should relate the sealed sources listed in Item 5 to the devices described in this item. In manual brachytherapy several types of treatments are available. These may include, for example:

- Interstitial Treatment of Cancer
- Eye Plaque Implants. (This is considered interstitial, not topical, treatment.)

- Intracavitary Treatment of Cancer<sup>1</sup>
- Topical (Surface) Applications

For use of sealed sources for diagnosis (4731.4460), the applicant should define the purpose of use by describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR.

For use of a sealed source in a remote afterloader, teletherapy unit, or a gamma stereotactic radiosurgery unit (4731.4463), the applicant should define the purpose of use (e.g., teletherapy, remote afterloading, GSR) and describing the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (e.g., for use in a Manufacturer's Name and Unit Type, Model xxxx radiation therapy unit for the treatment of humans). The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that an additional source is requested to be stored in its shipping container incident to source replacement.

Applicants must apply for authorization to use radioactive material, or radiation therefrom, in medical applications under other medical uses of radioactive material or radiation from radioactive material when 4731.4463 does not cover the type of use. When applying for use under the provisions of 4731.4403, applicants should describe the purpose of use and submit the information required under Section 4731.4403, review regulatory requirements in other parts of the medical uses rules, and use them as a guide on how to determine what should be included in an application. It is anticipated that many of the uses of radioactive material under the provisions of 4731.4403 may involve research or product development; thus, applicants should ensure review and compliance with 4731.4401, "Provisions for the protection of human research subjects." Use of radioactive material in a source or device after approval by the U.S. Food and Drug Administration, e.g., under an IDE (investigational device exemption) or an IND (investigational new drug exemption), does not relieve individuals of the responsibility to obtain a license to use the radioactive material in medicine.

*Remote afterloading and teletherapy devices should not be included in this application. Special requirements for these devices are included in separate guides available upon request from the MDH.*

**Calibration, Transmission, and Reference Sources:** For calibration, transmission, and reference sources covered in 4731.4423, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 4731.4400 for medical use of radioactive material.

#### **Item 7: Individual Users Responsible for the Radiation Safety Program**

Responsible individuals are the authorized users and the Radiation Safety Officer (RSO). 4731.4411 requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience. 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.

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<sup>1</sup> For purposes of sealed source and device (SSDR) evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.

### **Authorized Users For Medical Uses**

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiation dosage or dose and how it is to be administered.
3. Actual use or direction of technologists or other paramedical personnel in the use of radioactive material.
4. Interpretation of diagnostic procedures and the evaluation of therapy procedures.

Applicants must meet recentness of training requirements as described in 4731.4415. Authorized user applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Technologists, therapists, or other personnel may use radioactive material for medical use under an authorized user's supervision in accordance with 4731.4407, "Supervised Individuals."

There is no MDH requirement that an authorized user must render an interpretation of a diagnostic image or results of a therapeutic procedure. MDH recognizes that the authorized user may or may not be the physician who interprets such studies. Additionally, MDH rules do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

All training for users of high dose rate afterloader units must comply with the specifications in 4731.4479.

### **Authorized Users For Non-Medical Use**

List the full name of each individual proposed as an authorized user for non-medical use. Submit a complete description of the person's training and experience in non-medical use areas.

For *in-vitro* and animal research (or other uses that do not involve the intentional exposure of humans), the list of proposed authorized users should include those individuals who will actually be responsible for the use of the requested radioactive material. Indicate which user will be involved with which use by reference to Items 5 and 6 of the application. Those authorized users may direct the use of the radioactive material by technologists or other individuals for the requested use.

### **Radiation Safety Officer (RSO)**

Radiation Safety Officers must have adequate training and experience. The training and experience requirements for the RSO are described in 4731.4411 and allow for the following four training pathways:

- Certification by one of the professional boards recognized by MDH, the NRC or another Agreement State.
- Didactic training, work experience, and preceptor statement as described in 4731.4411(B).
- Identification on the license as an Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO.

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 4731.4405, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities to ensure that radioactive materials are used in a safe manner. MDH requires the name of the RSO on the license, and an agreement in writing from the RSO to

ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. MDH has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 4731.4405.

### ***RSO Responsibilities***

Some of the typical duties and responsibilities of Radiation Safety Officers include ensuring the following:

- Unsafe activities involving licensed materials are stopped
- Radiation exposures are ALARA
- Material accountability and disposal
- Interaction with MDH
- Timely and accurate reporting and maintenance of appropriate records
- Annual program audits
- Proper use and routine maintenance
- Personnel training
- Investigation of incidents involving radioactive material (e.g., medical events)

Appendix B contains a detailed list of typical duties and responsibilities of the RSO. Applicants are reminded of recency of training requirements. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the following:

- Name of the proposed RSO.
- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

One of the following is also needed:

- Copy of the certifications for the boards recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.
- Description of the training and experience specified in 10 CFR 35.900(b).
- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.

In addition, provide both of the following:

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

### ***Authorized Nuclear Pharmacist (ANP)***

At many licensed medical facilities, an Authorized Nuclear Pharmacist is directly involved with the preparation and administration of radiopharmaceuticals.

Technologists, or other personnel, may prepare radioactive material for medical use under an ANP's supervision in accordance with 4731.4407, "Supervision." (Preparation of radioactive material for medical use may also be performed under the supervision of a physician who is an authorized user.)

Applicants are reminded of recentness of training requirements described in 4731.4415. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, nuclear pharmacist applicants must have had related continuing education and experience since initially completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the name of the proposed ANP and one of the following:

- Previous license number or a copy of the license (if issued by the NRC an Agreement State) on which the individual was specifically named ANP.
- Copy of the certification(s) for the radiopharmacy board(s) identified in 4731.4413 or 4731.4491.
- Description of the training and experience demonstrating that the proposed Authorized Nuclear Pharmacist is qualified by training and experience.

Also provide the following:

- Written certification, signed by a preceptor Authorized Nuclear Pharmacist that the above training and experience has been satisfactorily completed and that a level of competency sufficient to
  - function independently as an Authorized Nuclear Pharmacist (4731.4413), or
  - independently operate a nuclear pharmacy (4731.4491).
- If applicable, submit a description of recent related continuing education and experience as required by 4731.4415.

#### ***Authorized Medical Physicist (AMP)***

At many licensed medical facilities conducting radiation therapy treatments, an Authorized Medical Physicist is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in 4731.4415. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the name of the proposed AMP and one of the following:

- Previous license number or a copy of the license (if issued by the NRC an Agreement State) on which the individual was specifically named as an Authorized Medical Physicist for the units requested.
- Copy of the certification(s) for the board(s) recognized by NRC in 4731.4412 or 4731.4490.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4490 for the units requested.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4412 for the units requested.

Also provide one of the following:

- Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized Medical Physicist has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

#### **Item 8: Training For Individuals Working In or Frequenting Restricted Areas**

Describe your training program for individuals who work with or near radioactive material. Include the training for individuals who handle non-medical radioactive materials.

#### **Item 9: Facilities And Equipment**

Applications will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta emitters.

Applicants must describe the proposed facilities and equipment. The facility diagram should include the room or rooms and adjacent areas where radioactive material is prepared, used, administered, and stored that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

For use of unsealed radioactive material for uptake, dilution, or excretion, or for imaging and localization (4731.4432 or 4731.4433), applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described.

For radiopharmaceutical therapy and manual brachytherapy (4731.4440 and 4731.4450), applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under 4731.4427. The discussion should include a description of shielding, if applicable.

For a remote afterloader, teletherapy unit, or gamma knife (4731.4463), the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram.

Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy patient's room or a therapy treatment room.

The applicant should demonstrate that the dose limits for individual members of the public (4731.2090) will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.
- Requesting prior MDH authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements will be met. The applicant must demonstrate the need for and the expected duration of operations that will

result in an individual dose in excess of the limits. A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA must be developed.

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by MDH. If applicants elect to use portable shielding they should commit to having administrative procedures to control configuration management to maintain dose within regulatory limits.

If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided. A written description should be submitted for simple changes.

For teletherapy units, it may be necessary to restrict use of the unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. The licensee should specify the electrical, mechanical, or other physical means (rather than administrative controls) used to limit movement or rotation of the unit (e.g., electrical or mechanical stops).

#### ***Annotated Drawings***

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used.
- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored.
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003.
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

#### ***Radiation Monitoring Instruments***

All licensees should possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

The radiation protection program that licensees are required to develop, document, and implement in accordance with 4731.2010 must include provisions for survey instrument calibration (4731.2200). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, since it is not expected that a survey be conducted each time such a procedure is performed. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

Qualified personnel must perform survey meter calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an MDH (or equivalent NRC or Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration.

Provide one or both of the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."
- A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 4731.2200 and that meet the requirements of 4731.4421." Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing."

Also provide both of the following:

- A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
Short Scientific, Inc.	LGD-310	1 - 100000 cpm

- A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

***Dose Calibrator and Other Equipment Used To Measure Dosages of Unsealed Radioactive Material***

As described in 4731.4422, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or a nuclear pharmacy and does not split, combine, or otherwise modify unit dosages, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.
- If the licensee performs direct measurements of dosages in accordance with 4731.4422 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

#### **Item 10: Radiation Safety Program**

The elements of a radiation safety program are contained in Appendices A through R. 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."

Appendix A	Model Program for Maintaining Occupational Radiation Exposure ALARA
Appendix B	Duties and Responsibilities of the Radiation Safety Officer
Appendix C	Calibrating Dose Calibrators
Appendix D	Personnel Exposure Monitoring Program
Appendix E	Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority
Appendix F	Leak Testing Sealed Sources
Appendix G	Safe Use of Radiopharmaceuticals
Appendix H	Spill Procedures
Appendix I	Ordering and Receiving Radioactive Material
Appendix J	Safely Opening Packages Containing Radioactive Material
Appendix K	Records of Radioactive Material Use
Appendix L	Area Surveys
Appendix M	Monitoring, Calculating, and Controlling Air Concentrations
Appendix N	Radiation Safety During Radiopharmaceutical Therapy
Appendix O	Radiation Safety During Implant Therapy
Appendix P	Waste Disposal
Appendix Q	Medical Use of Strontium-90 Eye Applicators
Appendix R	Model Annual Audit Checklist

#### ***Sealed Source Inventories***

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

- Model number of each source
- Serial number if one has been assigned
- Identity of each source radionuclide
- Estimated activity

- Location of each source
- Date of inventory
- Initials or name of individual performing the inventory
- Signature of the Radiation Safety Officer

#### ***Annual Audit of the Radiation Safety Program***

4731.2010 requires that licensees review at least annually the radiation protection program content and implementation. Currently the MDH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that problems are promptly and comprehensibly corrected. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

The MDH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with MDH rules.

A model audit program is included in this Regulatory Guide.

#### **Item 11: Waste Management**

Submit your procedures for waste disposal, including a procedure for all material listed in Item 5. See Appendix R for more information on these procedures.

#### **Item 12: License Fees**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

## AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

## RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of radioactive material are capable of complying with MDH rules. This guide provides one set of methods approved by 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**  
**MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA**

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix A to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures." Submit the signed commitment in Section 6 of this appendix.

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in Section 6 of this appendix.

**ALARA PROGRAM**

**1. Management Commitment**

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

**2. Review of Proposed Users and Uses**

- a. The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- b. When considering the use of radioactive material, the RSC will review efforts of the applicant to maintain exposure ALARA.
- c. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- d. The RSC will delegate authority for enforcement of an ALARA program to the RSO.

- e. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- f. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- g. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

**Table A-1 – Investigational Levels**

	Investigational Levels (mrems per month)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

- h. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

**3. Radiation Safety Officer Commitment**

**a. Annual and Quarterly Review**

- The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
- The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.

**b. Education Responsibilities for ALARA Program**

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

**c. Cooperative Efforts for Development of ALARA Procedures**

- Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
- The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
  - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- d. Reviewing Instances of Deviation from Good ALARA Practices:
- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
- e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

**4. Authorized Users Commitment**

- a. New methods of Use Involving Potential Radiation Doses
- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
  - The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
- b. Authorized User's Responsibility to Supervised Individuals
- The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
  - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

**5. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses<sup>1</sup>**

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table A-1. These levels apply to the exposure of individual workers.

The RSO will review and record on MDH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table A-1:

- a. Personnel dose less than Investigational Level I

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<sup>1</sup> MDH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table A-1 values for the investigational Level I.
- b. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II
- The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality. This review will be recorded in the Committee minutes.
- c. Personnel dose equal to or greater than Investigational Level II
- The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's "Occupational Exposure Record for Monitoring Period" and "Cumulative Occupational Exposure History," or its equivalent.
- d. Re-establishment of investigational levels to levels above those listed in Table I
- In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

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

**6. Signature of Certifying Official<sup>1</sup>** Sign and submit as part of Appendix A.

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

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (Print or type)

\_\_\_\_\_  
Title

<sup>1</sup> The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

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

You may use the following model guidelines to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for RSO that was published in Appendix B to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

You may develop your own guidelines for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. State on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

**MODEL PROCEDURE**

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
  - a. The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
  - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
  - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).

9. Ensure that all incidents, accidents, and personnel exposure to radiation exceeding ALARA levels or limits in 4731 are investigated and reported to MDH within the required time limits.
10. Ensure that fume hood flow rates are tested at appropriate intervals and that employees use hoods in accordance with the safe use of radiopharmaceuticals.
11. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
12. Ensure that licensed material is disposed of properly.
13. Ensure that the facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.
14. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

## APPENDIX C CALIBRATING DOSE CALIBRATORS

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you or the contractor follow the model procedure, you may state on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you develop your own dose calibrator calibration procedure for review, you should carefully review all the features in the model procedure. State on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as Appendix C," and submit your dose calibrator calibration procedure.

### MODEL PROCEDURE

Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of  $\pm 5$  are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

#### 1. Constancy

Constancy means reproducibility in measuring a source over a long period. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

- a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
- b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.
- c. Either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
- d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
- e. Establish an action level at which the individual performing the test will automatically notify the supervision of the suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds  $\pm 10$  percent.

2. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

#### 3. Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99<sup>m</sup> whose activity is at least as large as the maximum activity normally assayed.

### **DECAY METHOD**

- a. Assay the Tc-99<sup>m</sup> syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time (to the nearest minute), and net activity. This first assay should be done in the morning at a regular time, for example, 8 a.m.
- b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity used. For dose calibrators with a range selection switch, select the range you would normally use for the measurement.
- c. Convert the recorded time and date to hours elapsed.
- d. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.
- e. Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  $(A_{\text{observed}} - A_{\text{line}})/A_{\text{line}} = \text{deviation}$ .

### **SHIELD METHOD**

If you decide to use a set of sleeves to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the "sleeves" must be performed each time the dose calibrator is returned from repair.

Follow the manufacturer's instructions when performing the linearity test.

#### **4. Geometry independence**

Geometry means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

- a. In a small beaker or vial, mix 2.0 cc of a solution of Tc-99<sup>m</sup> with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
- b. Draw 0.5 cc of the Tc-99<sup>m</sup> solution into the syringes and assay. Record the volume and millicuries.
- c. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- d. Repeat the process until you have assayed a 2.0 - cc volume.
- e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- f. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure

to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

- g. To test the geometry dependence of a 30-cc glass vial, draw 1.0 cc of the Tc-99<sup>m</sup> solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
- h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries indicated.
- i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
- j. Select as a standard the volume closest to that normally used for mixing radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- k. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure to label the table or graph, note the date of the test, and indicate the model number and serial number of the calibrator.

#### 5. Accuracy

Accuracy means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier. The supplier must compare that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. Consider using at least one reference source whose activity is within the range of activities normally assayed.

- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for three determinations.
- b. Average the three determinations. The average value should be within five (5) percent of the certified activity of the reference source, mathematically corrected for decay.
- c. Repeat the procedure for other calibrated reference sources.
- d. If the average value does not agree, within five (5) percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.
- e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values.

6. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

## **APPENDIX D PERSONNEL EXPOSURE MONITORING PROGRAM**

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may state on your application, "We will establish and implement the model personnel exposure monitoring program published in Appendix D.1 and/or D.2 to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program. State on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.

### **D.1. MODEL PROGRAM FOR EXTERNAL EXPOSURE**

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor.
4. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

### **D.2. MODEL PROGRAM FOR INTERNAL EXPOSURE**

Medical personnel who administer substantial doses of radioiodine to patients may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Historically, bioassays for medical personnel have been required only in cases of administration to hospitalized patients because these are the patients receiving substantial doses of radiopharmaceuticals. This in turn meant that the medical personnel who prepared or administered the dosages to these patients handled substantial amounts of radioactive material, and therefore were at greatest risk for intakes. Patients who did not need to be confined after administration of radiopharmaceuticals were generally those patients who received relatively small dosages of these materials. The preparation or administration of these smaller dosages posed a relatively lower risk to the medical personnel involved.

The change in the criteria for release of patients who have been administered radiopharmaceuticals may involve the administration of relatively large dosages of radioactive materials without requiring patient

confinement. Bioassays are only applicable to the administration of radiopharmaceuticals at levels that require hospitalization. It may be possible for medical personnel to prepare or administer substantial doses of radiopharmaceuticals without meeting the requirement to perform a bioassay.

Although licensees may no longer be tied to a bioassay program because of the new patient release criteria, they remain subject to the requirements of 4731.2210, "Conditions requiring individual monitoring of external and internal occupational dose." This requires the licensee to monitor all occupationally exposed personnel who may receive, in one (1) year, an intake in excess of the applicable ALI in 4731.2750.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed ten percent of the limit in the year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For medical licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay. Baseline surveys should be completed for all individuals likely to require future monitoring.

**APPENDIX E  
RADIATION SAFETY COMMITTEE CHARTER AND  
RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY**

You may use the following text as it appears here, stating on your application, "We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that is published in Appendix E to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures ". Include the signed Delegation of Authority shown on the following page.

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text. State on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as Appendix E," and submit your charter and Delegation of Authority shown on the following page.

**MANAGEMENT**

1. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing, as adjunct members, representatives from security, physical plant, housekeeping, and other departments. Adjunct members should abstain from balloting on radiation safety questions.
2. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

**MODEL CHARTER CHARGE**

The Committee shall:

1. Ensure that licensed material will be used safely. This includes review, as necessary, of training programs, equipment, facility, supplies, and procedures.
2. Ensure that licensed material is used in compliance with MDH regulations and the institutional license.
3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program.
4. Establish a table of investigational levels for individual occupational radiation exposures.
5. Identify program problems and solutions.

**RESPONSIBILITIES**

The committee shall:

1. Be familiar with all pertinent MDH regulations, the license application, the license, and the amendments. Ensure that the radioactive material license is amended, if required, before making any changes in facilities, equipment, policies, procedures, and personnel.
2. Review the RSO's summary report of the radiation safety program at least annually. The review should be sufficient to determine that all activities are being conducted safely, in accordance with MDH regulations and the conditions of the license, and consistent with the ALARA program and

philosophy. The review should include an examination of records, reports from the RSO, results of MDH inspections, written safety procedures, and the adequacy of the management control system.

3. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
4. Support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
5. Perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 of Appendix A are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.
6. Delegate authority to the Radiation Safety Officer (RSO) by submitting the following as part of Appendix E:

**MODEL DELEGATION OF AUTHORITY**

MEMO TO: All Employees  
FROM: Chief Executive Officer  
SUBJECT: Delegation of Authority

\_\_\_\_\_ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; ensuring compliance with regulations; and maintaining ALARA. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

**SIGNATURE OF CERTIFYING OFFICIAL<sup>1</sup>**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (Print or type)

\_\_\_\_\_  
Title

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

## **APPENDIX F LEAK TESTING SEALED SOURCES**

As a licensee, you must perform leak testing of sealed sources. The MDH requires tests to determine whether or not there is any leakage from the radioactive source. The leak test should be performed at six-month intervals unless otherwise authorized by your license. You may use the following model procedure to leak test sealed sources. If you follow the model procedure you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources that was published in Appendix (F.1 and/or F.2) to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix F," and submit your leak test procedure.

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 send 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 kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix F.1 or submit your own procedures.

For Option 3, describe the procedure for taking the test sample. Identify 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 the minimum sensitivity for the instrument used for analysis and 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.

### **F.1 MODEL PROCEDURE FOR TAKING TEST SAMPLES (Option 2)**

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 greater 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, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
- c. For the teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or crosshairs. Wipe the primary and secondary collimators and trimmers.
- d. If you are testing radium sources, you should also check for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

## **F.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES**

(Option 3)

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries. 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 check source that is the same isotope and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries 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 records for three years.

## APPENDIX G SAFE USE OF RADIOPHARMACEUTICALS

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 G to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model. State on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Appendix G," and submit your model rules for the safe use of radiopharmaceuticals.

### MODEL RULES

1. Wear long-sleeved laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Before leaving the restricted area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins or infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve so syringe shields can still be used).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. 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.
8. Wear a finger exposure monitor while handling radioactive material including during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and while in contact with patients that have been administered radiopharmaceuticals.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe-test radioactive material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
12. With a radiation survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation.
14. A log should be used to record additional information such as:
  - The total prepared activity
  - Specific activity (in mCi/cc) at a specified time
  - Total volume prepared
  - The measured activity of each patient dosage
  - Any other appropriate information
15. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
16. Assay each patient dosage in the dose calibrator before administration. Only use a dosage that differs by more than ten percent of the prescribed dosage with approval of an authorized user (except for prescribed dosages of less than 10 microcuries). When measuring the dosage, the radioactivity that adheres to the syringe wall or remains in the needle does not need to be considered.
17. Check the patient's name, the prescribed radionuclide, and the dosage before administering.
18. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
19. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

## **APPENDIX H SPILL PROCEDURES**

You may use the following model procedures as they appear here, stating on your application, "We will establish and implement the model spill procedure published in Appendix H to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

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

### **MODEL PROCEDURES**

#### ***MINOR SPILLS OF LIQUIDS AND SOLIDS***

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector meter. Check the area around the spill. Also, check your hands, clothing, and shoes for contamination.
5. The RSO will review the radioactive spill contamination survey records for trends.

#### ***MAJOR SPILLS OF LIQUIDS AND SOLIDS***

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

#### ***DISCUSSION OF MAJOR SPILLS AND MINOR SPILLS***

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the

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

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major. Spills of the amounts shown below are considered minor.

**Table H-1 – Relative Hazards of Common Radionuclides**

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.	
<b>RADIONUCLIDE</b>	<b>MILLICURIES</b>
Co-60, Sr-89, I-125, I-131	1
F-18, P-32, Co-58, Fe-59, Se-75, Sr-85, Y-90, In-111, I-123, Sm-153, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99 <sup>m</sup> , Tl-201	100

## **APPENDIX I ORDERING AND RECEIVING RADIOACTIVE MATERIAL**

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may state on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix I to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 4731.2350. State on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix I," and submit your procedure.

### **MODEL GUIDANCE**

1. The Radiation Safety Officer (RSO) or a designee must ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. For routinely used materials:
    - (1) Written records identifying the authorized user or department, isotope, chemical form, activity, and supplier.
    - (2) Verification that material received was ordered by an authorized user.
  - b. For occasionally used materials (e.g., therapeutic dosages):
    - (1) The authorized user who will perform the procedure will make a written request to confirm that the material received is what was ordered.
    - (2) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.
4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

**SAMPLE MEMORANDUM**

**MEMO TO:** Chief of Security

**FROM:** Radiation Safety Officer

**SUBJECT:** Receipt of Packages Containing Radioactive Material

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

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

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

\_\_\_\_\_, at \_\_\_\_\_.  
Name Home Telephone

Radiation Safety Officer: \_\_\_\_\_

Chief of Nuclear Medicine: \_\_\_\_\_

Chief of Nuclear Medicine Technologist: \_\_\_\_\_

Nuclear Medicine Technologist on call  
(Call page operator at extension \_\_\_\_\_)

Nuclear Medicine Physician on call  
(Call page operator at extension \_\_\_\_\_)

**APPENDIX J**  
**SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**  
In addition to 4731.2350

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix J to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion 4731.2350. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix J," and submit your procedure.

**MODEL PROCEDURE**

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination in accordance with 4731.2350.
2. The following procedures for opening each package will be followed:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
  - c. Measure the exposure rate from the package at one (1) meter and at the package surface. If it is more than 10 millirem per hour at three (3) feet (1 meter), stop and notify the RSO. (The transport index noted on packages with Yellow II or Yellow III labels is the approximate dose rate, in millirem per hour, at one (1) meter from the package surface).
  - d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with White I labels should be less than 0.5 millirem per hour on the external surface of the package.
  - e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

Beta-gamma-emitting radionuclides; all radionuclides with half-lives less than ten days.....	22 dpm/cm <sup>2</sup>
All other alpha-emitting radionuclides.....	2.2 dpm/cm <sup>2</sup>
  - f. Open the package with the following precautionary steps:
    - (1) Remove packing slip.
    - (2) Open outer package following the supplier's instructions, if provided.
    - (3) Verify that the contents match the packing slip.
    - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
    - (5) If anything is other than expected, stop and notify the RSO.

- g. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument [for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter] should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.
  - h. Check the user request to ensure that the material received is the material that was ordered.
  - i. Monitor the packing material and the empty packages for contamination with a survey meter before discarding.

    - (1) If contaminated, treat this material as radioactive waste.
    - (2) If not contaminated, remove or obliterate the radiation labels before discarding it.
  - j. Make a record of the receipt.
3. For packages received under the general license, the following procedure for opening each package will be followed.
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - b. Check to ensure that the material received is the material that was ordered.

## APPENDIX K RECORDS OF RADIOACTIVE MATERIAL USE

### GENERAL

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does *not* have to replicate entries. For example, if you prepare a multi-dose vial for use one day, you do not have to record the date each time you draw a dose from it. If you take thirty Ir-192 seeds that are 0.5 millicuries each, you do not have to list each seed individually.

### RECORDS OF UNIT DOSAGE USE

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedures in the model procedure. Indicate on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as Appendix K" and submit your unit dosage record procedure.

### **MODEL PROCEDURE**

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt
4. Supplier
5. Lot number or control number, if assigned, and expiration date
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time
7. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual)
  - b. Measured activity in millicuries or microcuries and date and time of assay and administration
  - c. Patient name and identification number if one has been assigned
8. If discarded, the date and method of disposal
9. Initials of the individual who performed the assay

Maintain these records for three (3) years.

### RECORDS OF MULTI-DOSE VIAL USE

You may use the following model procedure to keep a record of multi-dose vial use. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for a multi-dose vial record system that was published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own multi-dose vial record system for review. If you do so, you should consider for inclusion all the features in the model system. State on your application, "We have developed

a procedure for a multi-dose vial record system for your review that is submitted as Appendix K\* and submit your multi-dose vial record procedure.

#### **MODEL PROCEDURE**

For each multi-dose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt or preparation
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml)
5. Supplier or kit manufacturer
6. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual)
  - b. Date and time dosage was drawn and measured
  - c. Calculated volume that is needed for the prescribed dosage
  - d. Measured activity in millicuries or microcuries
  - e. Patient name and identification number if one has been assigned
7. If discarded, the method of disposal and date
8. Initials of the individual who performed the assay

Maintain these records for three (3) years.

#### **MEASURING AND RECORDING MOLYBDENUM CONCENTRATION**

Each licensee who uses a technetium generator to prepare radiopharmaceuticals must complete a test for molybdenum concentration. This measurement is usually made with a dose calibrator. Licensees may not distribute or administer radiopharmaceuticals that contain more than 0.15 microcuries of Mo-99 per millicurie of Tc-99<sup>m</sup> at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect.

The model procedure for measuring molybdenum concentration is based on the use of a molybdenum breakthrough pig. Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert the measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99<sup>m</sup> generator elution. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that is published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider the inclusion of all the features in the model procedure. State on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as Appendix K," and submit your procedure for measuring and recording molybdenum concentration.

#### **MODEL PROCEDURE**

Each time a generator is eluted, record the following information:

1. Date the generator was received.
2. Product of the measured Mo-99 activity and the correction factor. This is noted by the manufacturer.

Maintain these records for three (3) years.

An action level of 0.07 allows for the decay of the Tc-99<sup>m</sup> throughout the day of use. It is assumed that the material will be used within six (6) hours, at which time the concentration of Mo-99 to Tc-99<sup>m</sup> would have doubled.

## **INVENTORY OF IMPLANT SOURCES**

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own procedure for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system. State in your application, "We have developed a procedure for keeping an inventory of implant sources for your review that is appended as Appendix K." Submit your procedure for keeping an inventory and use record for implant sources.

### **MODEL PROCEDURES**

1. Use a locking installed cabinet or safe to store all implant sources.
2. Make a list of names of those individuals you allow to handle the implant sources and have them initial beside their names.
3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.
4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
5. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Make appropriate records.
6. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

## APPENDIX L AREA SURVEYS

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix L to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure. State on your application, "We have developed survey procedures for your review that are appended as Appendix L," and submit your survey procedures.

### MODEL PROCEDURE

#### AMBIENT DOSE RATE SURVEYS

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

Quarterly surveys should be accomplished in areas

  - Adjacent to restricted areas
  - Through which radioactive materials are transferred
  - Where radioactive material is temporarily stored before shipment

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

#### REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas:

In any area where the potential for spreading contamination is likely to occur (e.g., cafeterias, snack bars, furniture and equipment), survey at least *quarterly*. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.
2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200-dpm/100 cm<sup>2</sup> for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).
3. Immediately notify the RSO if you find levels that exceed the established action levels. Recommended removable surface contamination action levels are published in NRC Regulatory

Guide 8.23, "Radiation Safety Surveys at Medical Institutions" or see Table N-1 below for guidance in establishing your action levels.

**RECORDS**

1. Records must contain the following:
  - The date of the survey.
  - A sketch of each area surveyed.
  - Action levels established for each area.
  - The measured dose rate at several points in each area expressed in millirem (microSievert) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters.
  - The serial number and the model number of the instrument used to make the survey or analyze the samples.
  - The initials of the individual who performed the survey.
  
2. In those cases in which radiation or contamination action levels were exceeded, a follow-up survey should be completed and recorded. The RSO should promptly review and sign survey records that document the results of any actions implemented to corrective the excessive radiation or contamination levels.
  
3. Maintain these records for three (3) years.

**Recommended Action Levels**

RECOMMENDED ACTION LEVELS IN DPM/100 CM <sup>2</sup> FOR SURFACE CONTAMINATION		
	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99 <sup>m</sup> , Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

**APPENDIX M  
MONITORING, CALCULATING, AND CONTROLLING  
AIR CONCENTRATIONS**

**WORKER DOSE FROM NOBLE GASES**

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

You may respond by stating, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you are not monitoring trap effluent, you must estimate worker dose by calculation. If you exhaust spent gas to the atmosphere, you must also estimate worker dose by calculation. It is not necessary to submit the calculations, but you should keep them for MDH review during inspections. If you will follow the model procedure for calculating worker dose from noble gases, you may respond by stating, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix M of the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If none of the above applies, you may develop your own procedure for review. State on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as Appendix M," and append your procedure for monitoring worker dose from noble gases.

**WORKER DOSE FROM AEROSOLS**

You may respond by stating, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for MDH review during inspections.) If you follow the model procedure below for calculating worker dose from aerosols, you may respond by saying "We will follow the model procedure for calculating worker dose from aerosol concentrations that is appended as Appendix M.2." Submit your procedure for monitoring worker dose from aerosols.

**M.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS**

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, OSD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the derived air concentration (DAC) for Xenon-133 (or other gas to be used) to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of five (5) rem (50 mSv) and divide this number by five (5) rem.

- a. This yields the fraction of the dose limit of five (5) rem that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in 4731.2750.
  - b. If the highest annual external dose is 2 rem, and the listed DAC value for Xenon-133 is  $1E-4$  mCi/ml, then the modified DAC value should be based on 3 rem that could still be incurred from internal exposure.
3. The following calculations must be made:
- a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
  - b. The estimated activity released to the restricted areas.
    - (1) The total activity released to the restricted area divided by the total air exhausted must be less than the applicable DAC for a restricted area. The total activity released to the restricted area is activity used each week multiplied by estimated fractional loss per study. The total air exhausted is the sum of all exhaust rates multiplied by the length of the workweek.
    - (2) If this is not the case, plan for fewer studies and do the calculations again. An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.

## M.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

- 1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable DAC value for an unrestricted area.
- 2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

## M.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

- 1. If the trap effluent is continuously monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions. Keep a record of the checks.
- 2. If you do not continuously monitor the trap effluent, check it on receipt and once each month. During one patient study, collect the effluent from the trap in a plastic bag and then monitor the activity in the bag by holding the bag against a camera. With the camera adjusted to detect the noble gas, compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm. *If there is a significant increase in the activity measured on the bag, the trap must be replaced.*

3. The charcoal Xenon trap should be replaced at time intervals recommended by the manufacturer.

### **PUBLIC DOSE FROM AIRBORNE EFFLUENT**

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value 4731.2750.

If you are not directly venting aerosols and gases to the atmosphere, you may respond by saying "We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit the calculations with your application, but you should keep them for MDH review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond by stating "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix M.3 to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If neither of the above applies, you may develop your own procedure for review. Say on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as Appendix M.3" and append your procedure for monitoring airborne effluent concentration.

### **SPIILLED GAS CLEARANCE TIME**

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, the calculations described in Appendix M.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

### **M.4 MODEL PROCEDURE FOR CALCULATING SPIILLED GAS CLEARANCE TIME**

1. Collect the following data:
  - a. A -- the highest activity of gas in a single container, in microcuries.
  - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser values), in milliliters per minute.
  - c. Q -- the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system
  - d. C -- the modified derived air concentrations (DAC) in restricted areas. These should be figured according to M.1, Numbers 1 and 2.
  - e. V -- the volume of the room in milliliters.
2. Make the following calculations for each room:

- a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
  - b. The evacuation time  $t = -V/Q \times \ln(C \times V/A)$ .
3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted
- 2.0 mrem in any one (1) hour from external sources, and
  - 100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.

Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

## APPENDIX N RADIATION SAFETY DURING RADIOPHARMACEUTICAL THERAPY

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix N to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure. State on your application, "We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as Appendix N" and include your procedure.

### MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care and still allows staff to control access. Access can be controlled by routine surveillance and by posting instructions for hospital staff and visitors at the entrance to the patient's room
2. Prepare the room for the procedure as follows:
  - a. Use the leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, doorknobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.
  - b. Prepare separate boxes for linen, disposable waste, and non-disposable contaminated items. Place a single large, re-closing plastic bag in each box, or supply several small plastic bags.
  - c. Prepare a station with disposable gloves and shoe covers (booties) outside the restricted area.
  - d. Prepare a station inside the restricted area, near the exit, for disposal of gloves and booties upon exiting the restricted area. All waste must be considered contaminated until surveyed and verified that it is not radioactive.
  - e. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.
    - (1) Containers should be unbreakable and re-closing.
    - (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.
    - (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.
    - (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately three (3) mm of lead.)
    - (5) Supply a wide-mouth anti-splash funnel.

- f. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.
3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
4. Supply the nurses with film badges, TLDs, OSDs, or pocket ionization chambers.
5. Brief the nurses on radiation safety precautions. Include instruction on entering and exiting the restricted area. The instruction should include wearing disposable gloves and booties upon entering the restricted area and the proper removal and disposal of those items upon exiting. A sample form is included in this regulatory guide. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.
6. Limit laboratory testing as much as possible. If laboratory testing, such as blood testing and urinalysis, is not avoidable, provide radiation safety instruction to the laboratory personnel.
7. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
8. Only those persons needed for medical, safety, or training purposes should be present during the administration.
9. Mark a visitor safe line on the floor with tape as far from the patient as possible.
10. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at one (1) meter from bedside, at the visitor safe line, and in the surrounding hallways and rooms. Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter sign-out form. Post the room with a "Radioactive Materials" sign.
11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
12. Do not release any patient until they have met the criteria of 4731.4427.
13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.
  - a. Remove all absorbent paper and place it in the appropriate container.
  - b. Transfer all containers to a decay-in-storage or decontamination area.
  - c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200-dpm/100 cm<sup>2</sup>.
  - d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

**Model Radiation Safety Checklist for  
Iodine Therapy**

Patient Name: \_\_\_\_\_ Room: \_\_\_\_\_ Date: \_\_\_\_\_

**PREPARATION:**

- Private room with private sanitary facilities.
- Large room surfaces and walk areas covered with absorbent paper.
- Devices that the patient will come in contact with are protected (e.g., telephone, doorknobs, toilet handles etc.)
- Station containing disposable gloves and booties placed outside room.
- Housekeeping notified not to clean the room until further notice.
- Plastic trash bags located inside the room for waste.
- Brief nursing staff on radiation safety precautions.
- Issue personnel dosimetry devices to nursing staff and instruction regarding proper wear.
- Insure that nursing staff caring for the patient is neither pregnant nor breast feeding.
- Order disposable table service.
- Prepare urine containers if urine is collected.
- If laboratory analysis is needed, instruct laboratory personnel in radiation safety precautions.

**ADMINISTRATION:**

- Clear the room of all unnecessary personnel.
- Brief patient on the clinical procedure and radiation safety precautions.
- Administer dose.
- Measure dose rates at bedside, one (1) meter from bedside, visitor safe line, and unrestricted areas around the patient's room.
- Calculate visiting and care time.
- Post room with "Caution- Radioactive Materials" sign.

**FOLLOW-UP:**

- Periodically survey dose rates at bedside, one (1) meter from patient, and door.
- Measure the thyroid burden of all personnel involved in the preparation and administration of the dose.
- Release patient when he/she meets the criteria in 4731.4427.
- Survey and decontaminate the patient room. Remove postings.
- Release room for general use.

List Individuals involved in the preparation and administration of the patient dose:

NAME	DEPARTMENT

**Model Nursing Instructions for Patients Receiving  
Radiopharmaceutical Therapy and Hospitalized**

Patient Name: \_\_\_\_\_

Patient ID Number: \_\_\_\_\_

Authorized User: \_\_\_\_\_

Contact Number: \_\_\_\_\_

Patient Room: \_\_\_\_\_

Dose: \_\_\_\_\_ mCi of \_\_\_\_\_ Time: \_\_\_\_\_ Date: \_\_\_\_\_

Authorized User Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Radiation Exposure Rates

Unrestricted Areas Surveyed and Dose Rates (mR/hr):

Initial Exposure Rate at one (1) meter from Patient (mR/hr):

Patient Position: \_\_\_\_\_

DATE	TIME	BEDSIDE	1 METER FROM PATIENT	DOOR

Instructions

Visitor Restrictions:

- No visitors.
- No visitors under 18 years of age, breast feeding, or pregnant.
- No visitors in the patient room more than \_\_\_\_\_ minutes per day.
- Visitor must stay behind line on floor at all times.

Nursing Restrictions:

- Patient is restricted to the room.
- No nurses who are pregnant or breast-feeding may render care.
- No nurse shall be in the patient's room for more than \_\_\_\_\_ minutes per day.

Patient Care:

- Wear disposable gloves and booties when entering the patient's room.
- Properly dispose of gloves and booties when exiting the patient's room.
- Properly dispose of linen, bedclothes, plates, utensils, dressings, etc.
- Discard urine and feces in toilet. Flush three times.
- Housekeeping personnel are not permitted to enter the room unless authorized by the RSO.
- Practice proper wearing of personnel dosimetry when caring for the patient.
- Do not share personnel dosimetry. Return dosimetry to designated area before end of shift.
- Emergency Procedures.

**Acknowledgment of Training:**

NAME	SIGNATURE

In the case of emergency, or if any questions arise call:

Radiation Safety Officer: \_\_\_\_\_

Work: \_\_\_\_\_

Home: \_\_\_\_\_

Pager: \_\_\_\_\_

## APPENDIX O RADIATION SAFETY DURING IMPLANT THERAPY

You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, indicate on your application, "We will establish and implement the model procedure for radiation safety implant therapy that was published in Appendix O to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own procedure for review. Indicate on your application, "We have developed a procedure for radiation safety and implant therapy for your review that is appended as Appendix O," and submit your procedure.

### ITEMS TO BE CONSIDERED

A model checklist is provided in this Appendix.

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in 4731.2090.
2. Supply the nurses with film badges, TLD's, OSDs, or pocket ionization chambers.
3. Brief the nurses on radiation safety precautions. Allow time for questions and answers during the briefing.
4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable, consistent with good medical care.
5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.
6. Mark a visitor safe line on the floor with tape as far from the patient as possible.
7. Following the implant, measure the exposure in mR/hr at bedside, at one (1) meter from bedside, at the visitor safe line, and in the surrounding hallways and rooms. Record all necessary information on the nursing instruction form or the nurses' dosimeter sign-out form. Post the room with a "Radioactive Materials" sign.
8. Do not release any patient who has received a temporary implant from the hospital until a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than one (1) millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.
9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than five (5) mR/hr at one (1) meter. Measure this exposure rate at a distance of one (1) meter from the umbilicus while the patient is standing.

**Model Radiation Safety Checklist for  
Temporary Implant Therapy**

Patient Name: \_\_\_\_\_ Room: \_\_\_\_\_ Date: \_\_\_\_\_

**PREPARATION:**

- Private room with private sanitary facilities preferably in a low traffic area.
- Housekeeping notified not to clean the room until further notice.
- Plastic trash bags located inside the room for waste.
- Brief nursing staff on radiation safety precautions.
- Issue personnel dosimetry devices to nursing staff and instruct on proper wear.
- Ensure that nursing staff caring for the patient is neither pregnant or breast feeding.

**ADMINISTRATION:**

- Clear the room of all unnecessary personnel.
- Brief patient on the clinical procedure and radiation safety precautions.
- Insert implant(s).
- Measure dose rates at bedside, one (1) meter from bedside, visitor safe line, and unrestricted Areas around the patient's room.
- Calculate visiting and care time.
- Post room with "Caution- Radioactive Materials" sign.

**FOLLOW-UP:**

- Perform a survey of the patient to ensure that all sources were removed.
- Survey linen, bedclothes and dressings to ensure no sources were dislodged.
- Count the number of sources removed to ensure that all sources were removed.
- Remove postings and release room for general use.

**Temporary Implant Therapy Removal Log**

NUMBER OF SOURCES REMOVED	SOURCE STRENGTH	DATE REMOVED

**Model Nursing Instructions for Patients Receiving  
Temporary Implant Therapy and Hospitalized**

Patient Name: \_\_\_\_\_ Patient ID#: \_\_\_\_\_

Authorized User: \_\_\_\_\_ Contact No.: \_\_\_\_\_ Patient Room: \_\_\_\_\_

Dose: \_\_\_\_\_ mCi of \_\_\_\_\_ Time: \_\_\_\_\_ Date: \_\_\_\_\_

The sources will be removed: Time: \_\_\_\_\_ Date: \_\_\_\_\_

Authorized User Signature: \_\_\_\_\_ Date: \_\_\_\_\_

NUMBER OF SOURCES INSERTED	SOURCE STRENGTH	DATE INSERTED

Radiation Exposure Rates

UNRESTRICTED AREAS SURVEYED AND DOSE RATES (MR/HR):	
Patient Position:	

Survey Results

DATE	TIME	BEDSIDE	1 METER FROM PATIENT	DOOR

Instructions:

Visitor Restrictions:

- No visitors.
- No visitors under 18 years of age or pregnant.
- No visitors in the patient room more than \_\_\_\_\_ minutes per day.
- Visitors must stay behind line on floor at all times.

Nursing Restrictions:

- Patient is restricted to the room.
- Patient is restricted to bed.
- Patient must not move.
- No nurses who are pregnant or breast-feeding may render care.
- No nurse shall be in the patient's room for more than \_\_\_\_\_ minutes per day.

Patient Care:

- If the source becomes dislodged, call the attending physician and RSO.
- Omit bed bath.
- No perineal care. Pad may be changed as necessary.
- Save linen, bedclothes, and dressings for survey .
- Housekeeping personnel are not permitted to enter the room unless authorized by the RSO.
- Proper wearing of personnel dosimetry when caring for the patient.
- Do not share personnel dosimetry. Return dosimetry to designated area before end of shift.
- Emergency Procedures.

**Acknowledgment of Training:**

NAME	SIGNATURE

In the case of emergency, or if any questions arise, call:

Radiation Safety Officer: \_\_\_\_\_

Work: \_\_\_\_\_

Home: \_\_\_\_\_

Pager: \_\_\_\_\_

## APPENDIX P WASTE DISPOSAL

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for waste disposal that is published in Appendix P to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance. State on your application, "We have developed a procedure for waste disposal for your review that is appended as Appendix P," and attach your procedure.

### OVERVIEW

There are four commonly used methods of waste disposal:

- Release to the environment through the sanitary sewer or by evaporative release
- Decay-in-storage (DIS)
- Transfer to a burial site or back to the manufacturer
- Release to in-house waste

With the exception of the patient excreta and generally licensed *in-vitro* kit exemptions, nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material.

### GENERAL GUIDANCE

1. All radioactivity labels must be defaced or removed from containers and packages before disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that non-radioactive waste, such as leftover reagents, boxes, and packing material, should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that no unnecessary radioactive waste is created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, and pathogenicity), and expense.

### MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

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

1. Regulations for disposal in the sanitary sewer appear in 4731.2420. There are specific limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy are exempt from all the above limitations.) Make a record of the date,

radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in 4731.2750. These limits normally apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity and concentration that was released (in millicuries or microcuries), and the vent site at which the material was released.
3. Liquid scintillation-counting media containing 0.05 microcuries per gram of H-3 or C-14 may be disposed of without regard to its radioactivity. Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

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

Short-lived material (physical half-life less than 120 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
3. Decay the material for at least 10 half-lives.
4. Before disposal as in-house waste, monitor each container as follows:
  - a. Check your radiation detection survey meter for proper operation.
  - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
  - c. Remove any shielding from around the container.
  - d. Monitor all surfaces of each individual container. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages).
  - e. Discard as in-house waste only those containers that cannot be distinguished from background. Check to be sure that no radiation labels are visible.
  - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99<sup>m</sup> generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, and then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

### **MODEL PROCEDURE FOR TRANSFER FOR BURIAL**

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

### **MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER**

Used Mo-99/Tc-99<sup>m</sup> generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container. See DOT regulations, 49 CFR 173.415(a).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Perform the dose rate and removable contamination surveys.
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

### **MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE**

Waste from *in-vitro* kits that are generally licensed is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

**APPENDIX Q**  
**MEDICAL USE OF STRONTIUM-90 EYE APPLICATORS**

New Sr-90 eye applicators typically contain a 54-millicurie (2 Gigabecquerel) source, exhibiting a surface dose rate of about 0.50 Gy (50 rad/sec). The half-life of the parent Sr-90 is 28.5 years. The maximum beta energy equal to 0.54 MeV, and the Yttrium-90 daughter half-life is 64.2 hours (beta-max, 2.27 MeV); therefore, both isotopes are in equilibrium on the eye applicator. Since Sr-90 and Y-90 are in equilibrium, emissions from both isotopes must be accounted for in dosimetry calculations.

The source output or activity that is used for ophthalmic treatments must be determined using a dosimetry system that has been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies, or calibrated by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The licensee is allowed to use measurements provided by the source manufacturer, or by a calibration laboratory accredited by the AAPM, that are made in accordance with the requirements of 10 CFR 35.432(a). Most licensees possessing Sr-90 eye applicators do not have their applicators calibrated to current standards. It should be noted that NIST-traceable calibrations of Sr-90 eye applicators preceding August of 1990 do not meet the revised criteria. In August of 1990, NIST implemented a new Sr-90 eye applicator calibration procedure that established the currently accepted national standards. Any NIST-traceable calibrations performed after this date should ensure compliance.

Licensees must develop written procedures for any brachytherapy dose, including assurance that the prescribed dose is the administered dose. A necessary part of this is to ensure that the dose rate emitted from an applicator is correct. If the manufacturer's certificate of calibration or original activity/dose rate nameplate is missing, the licensee should arrange with a qualified expert to determine the dose rate from the Sr-90 source. Only an authorized medical physicist can calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic treatments. Medical licensees who use Sr-90 eye applicators should check calibration records and take steps to assure that they will be in compliance.

**APPENDIX R  
MODEL ANNUAL AUDIT CHECKLIST**

**ORGANIZATIONAL STRUCTURE**

- a. Radiation Safety Committee (RSC)
  - (1) Meetings held quarterly.  N/A  Yes  No
  - (2) Quorums established.  N/A  Yes  No
  - (3) Committee reviews program annually.  N/A  Yes  No
  - (4) Record of Committee meetings.  N/A  Yes  No
- b. Radiation Safety Officer (RSO) same as listed on the license  N/A  Yes  No
- c. Visiting Authorized User(s)
  - (1) Has written permission.  N/A  Yes  No
  - (2) Visitor authorized user's license on file.  N/A  Yes  No
  - (3) Performs only those procedures authorized on visitor's license.  N/A  Yes  No
  - (4) Uses materials under licensee's license or 60 days per year or less.  N/A  Yes  No
  - (5) Records maintained three years after the visiting authorized user's last visit.  N/A  Yes  No
- d. Mobile Nuclear Medicine Service meets technical requirements.  N/A  Yes  No

**AUDIT HISTORY**

- a. Last audit conducted on: \_\_\_\_\_
- b. Deficiencies identified?  N/A  Yes  No
- c. Were they corrected?  N/A  Yes  No

**SCOPE OF PROGRAM**

- a. Are there multiple authorized locations of use?  
If multiple locations authorized, list locations audited.  N/A  Yes  No
- b. Have there been radiation safety program changes?  
If yes, list changes.  N/A  Yes  No

**TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS**

- a. Instructions to workers provided.  N/A  Yes  No
- b. Training program conducted according to license commitments.  N/A  Yes  No

**FACILITIES, MATERIALS, AND EQUIPMENT**

- a. Facilities are as described in the license application.  N/A  Yes  No
- b. Storage and use of radioactive material
  - (1) Adequate method to prevent unauthorized individuals from entering restricted area.  N/A  Yes  No
  - (2) Radioactive material secured to prevent unauthorized removal or access.  N/A  Yes  No
- c. Dose Calibrator
  - (1) Constancy checked.  N/A  Yes  No
  - (2) Linearity tested.  N/A  Yes  No
  - (3) Accuracy tested.  N/A  Yes  No
  - (4) Geometry dependence test.  N/A  Yes  No

- (5) Readings mathematically corrected if linearity error is greater than 10%.  N/A  Yes  No
- (6) Records maintained.  N/A  Yes  No
- (7) RSO signs linearity, accuracy, and geometry dependence tests.  N/A  Yes  No
- d. Survey instruments.
  - (1) Appropriate operable survey instruments.  N/A  Yes  No
  - (2) Calibration, as required.  N/A  Yes  No
  - (3) Records maintained.  N/A  Yes  No
- e. Syringes containing RAM properly labeled and shielded, unless contraindicated.  N/A  Yes  No
- f. Syringes properly labeled.  N/A  Yes  No
- g. Vials containing RAM properly shielded.  N/A  Yes  No
- h. Vials properly labeled.  N/A  Yes  No

**RADIOLOGICAL PROTECTION PROCEDURES**

- a. Individual has understanding of procedures.  N/A  Yes  No
  - (1) In general, rules for safe use.  N/A  Yes  No
  - (2) In emergency procedures  N/A  Yes  No

**MATERIALS**

- a. Molybdenum-99 breakthrough tests performed.  N/A  Yes  No
- b. Records Molybdenum-99 breakthrough tests maintained.  N/A  Yes  No
- c. Leak tests of sealed sources performed at appropriate intervals.  N/A  Yes  No
  - (1) Leak test records in units of microcuries.  N/A  Yes  No
  - (2) Leak test records signed by RSO.  N/A  Yes  No
  - (3) Records of leak tests kept for three years.  N/A  Yes  No
- d. Inventories  N/A  Yes  No
  - (1) Quarterly inventory of sealed sources.  N/A  Yes  No
  - (2) Inventory records signed by RSO.  N/A  Yes  No
  - (3) Records of leak tests and inventories kept for three years.  N/A  Yes  No

**RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL**

- a. Procedure for opening packages adequate.  N/A  Yes  No
- b. Incoming packages monitored for radioactive contamination.  N/A  Yes  No
- c. Incoming packages monitored for external radiation levels.  N/A  Yes  No
- d. Transfers performed, as required.  N/A  Yes  No
- e. Records of receipt surveys.  N/A  Yes  No
- f. Records of receipt, transfer, & disposal of radioactive material.  N/A  Yes  No

**AREA SURVEYS**

- a. Ambient dose rate surveys performed.  N/A  Yes  No
- b. Contamination surveys conducted.  N/A  Yes  No
- c. Trigger levels established.  N/A  Yes  No
- d. Dose rate survey records in mR/hr.  N/A  Yes  No
- e. Contamination survey records maintained in dpm/100 cm<sup>2</sup>.  N/A  Yes  No

**RADIOPHARMACEUTICAL THERAPY**

- a. Oral and written safety instructions provided to personnel caring for patients.  N/A  Yes  No
- b. Record of training maintained.  N/A  Yes  No
- c. Patient room surveys.  N/A  Yes  No

- d. Record of room survey.  N/A  Yes  No
- e. Performed according to license commitments.  N/A  Yes  No
- f. Release of patients containing radiopharmaceuticals meets 4731.4427 criteria.  N/A  Yes  No
- g. Thyroid burden measurements on all individuals involved in dose administration.  N/A  Yes  No
- h. Record of thyroid measurements.  N/A  Yes  No

**BRACHYTHERAPY**

- a. Oral and written safety instructions provided to personnel caring for patients.  N/A  Yes  No
- b. Record of training maintained.  N/A  Yes  No
- c. Patient area surveyed.  N/A  Yes  No
- d. Release of patients containing permanent implants according to license commitments.  N/A  Yes  No
- e. Surveys performed before releasing patients being treated with temporary implants.  N/A  Yes  No
- f. Record of patient survey.  N/A  Yes  No
- g. Brachytherapy sources inventoried each time sources are returned to storage after use.  N/A  Yes  No
- h. Record of brachytherapy source utilization.  N/A  Yes  No
- i. Brachytherapy sources inventoried each quarter.  N/A  Yes  No
- j. Record of inventory.  N/A  Yes  No
- k. Brachytherapy source storage area surveyed.  N/A  Yes  No
- l. Record of survey of storage area.  N/A  Yes  No

**PERSONNEL RADIATION MONITORING – EXTERNAL**

- a. Supplier NVLAP approved.  N/A  Yes  No
- b. Dose(s) exceeded regulatory limits.  N/A  Yes  No
- c. ALARA program implemented.
  - (1) Annual review by radiation safety committee completed.  N/A  Yes  No
  - (2) Written description of ALARA program available.  N/A  Yes  No

**PERSONNEL RADIATION MONITORING – INTERNAL**

- a. Bioassay program implemented and performed at proper intervals  N/A  Yes  No
- b. Radioactive gases
  - (1) Clearance time and safety procedures are posted.  N/A  Yes  No
  - (2) Reusable collection system checked monthly.  N/A  Yes  No
  - (3) Ventilation rates checked for negative pressure at six-month intervals.  N/A  Yes  No

**WASTE DISPOSAL**

- a. Radioactive material disposed of as authorized.  N/A  Yes  No
- b. Record of disposal by decay in storage maintained.  N/A  Yes  No
- c. Survey of waste before disposal.  N/A  Yes  No
- d. Records of waste surveys.  N/A  Yes  No

**NOTIFICATION AND REPORTS**

- a. Notifications and reports provided to individuals.  N/A  Yes  No
- b. Reporting theft or loss compliant with rules.  N/A  Yes  No
- c. Compliant regarding notification of incidents.  N/A  Yes  No

- d. Compliant regarding reporting of excessive levels and concentrations.  N/A  Yes  No
- e. Termination reports furnished, if requested by workers.  N/A  Yes  No

**MISADMINISTRATIONS**

- a. Misadministrations occurred  N/A  Yes  No
- b. Compliant with reporting requirements for misadministration.  N/A  Yes  No
- c. Appropriate action taken to prevent recurrence.  N/A  Yes  No
- d. Records maintained.  N/A  Yes  No

**POSTING AND LABELING**

- a. Radiation Areas posted.  N/A  Yes  No
- b. High Radiation Areas posted.  N/A  Yes  No
- c. Use or storage areas posted "Caution- Radioactive Material."  N/A  Yes  No
- d. Containers or devices labeled.  N/A  Yes  No
- e. Notice to Workers posted.  N/A  Yes  No
- f. Notice to Employees posted.  N/A  Yes  No

**TRANSPORTATION 49 CFR 171-178**

- a. Authorized packages used.  N/A  Yes  No
- b. DOT-7A performance test records on file. [173.415(a)]  N/A  Yes  No
- c. For special form sources, performance test records on file. [173.476(a)]  N/A  Yes  No
- d. Packages properly labeled. [172.403(b)]  N/A  Yes  No
- e. Packages properly marked. [172.301(a)]  N/A  Yes  No
- f. Proper shipping papers prepared. [172.200]  N/A  Yes  No
- g. Shipping paper contains emergency response telephone number. [172.201(d)]  N/A  Yes  No

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

#### Training records must include:

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including:

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### **Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

#### **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one or more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## En Route

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR DIAGNOSTIC MEDICAL PROCEDURES

The logo is circular with a stylized figure in the center. The text "Radioactive Materials Group" is written along the top arc, and "Minnesota Department of Health" is written along the bottom arc. The initials "RAM" are visible at the bottom of the figure.	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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## **REGULATORY GUIDE FOR DIAGNOSTIC MEDICAL PROCEDURES**

### **INTRODUCTION**

The Minnesota Department of Health (MDH) regulates the intentional internal or external administration of radioactive material or the radiation therefrom, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Minnesota Radioactive Materials Rules, Chapter 4731.4400.

You should carefully study this guide and all the regulations identified in Chapter 4741.4400 before completing 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

This guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for a medical use of radioactive materials in diagnostic procedures. The uses of radioactive material for a therapeutic administration or any administration of quantities greater than 30 microcuries of either sodium iodide (Iodine-125 or Iodine-131), which require a written directive, are not authorized in diagnostic procedures. A Radiation Safety Committee is not required for this type of license.

### **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.

### **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 propriety information to the public or substantial delays in processing your application.

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

Submit one copy of your application to:

Radioactive Materials Unit  
Minnesota Department of Health  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

Retain one copy for yourself because the license will be issued based on the statements and representations in your application and supplements to it as well as 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 Renewals to a License," section 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 or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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 Materials and Item 6: Purpose**

Radioactive material for medical use is divided into types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may state, "As needed" in the "Amount" column as shown. For implant material, express the total amount in millicuries (mCi). If you plan to have an eye applicator, list it as a separate item and note its total activity in mCi. For 4731.4432, 4433, and 4434 use, the applicant should define the purpose of use by stating the applicable section and the description of the applicable modality (e.g., any uptake dilution and excretion procedure for which a written directive is not required).

Table 1

RADIOACTIVE MATERIAL	AMOUNT	PURPOSE
5.a Material in 4731.4432	As needed	6.a Medical use
5.b Material in 4731.4433	As needed	6.b Medical use
5.c Material in 4731.4434	As needed	6.c Medical Use
5.d Material in 4731.4460	10 mCi	6.d Medical Use
5.e Cobalt-57	50 mCi	6.e Medical Use

If you need other items, make a separate line entry for each isotope. Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in millicuries, and the purpose for which the material will be used.

**For sealed sources used in devices:** An applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registration (SSDR) Certificate. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the licensed activity limit prior to installation in the device.

For use of sealed sources for diagnosis (4731.4460), the applicant should define the purpose of use by describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR.

**Calibration, Transmission, and Reference Sources:** For calibration, transmission, and reference sources covered in 4731.4423, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 4731.4400 for medical use of radioactive material.

**Item 7: Individual Users Responsible for the Radiation Safety Program**

Responsible individuals are the authorized users and the Radiation Safety Officer (RSO). 4731.4411 requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience. 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.

**Authorized Users For Medical Uses**

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiation dosage or dose and how it is to be administered.

3. Actual use or direction of technologists or other paramedical personnel in the use of radioactive material.
4. Interpretation of diagnostic procedures.

Applicants must meet recentness of training requirements described in 4731.4415. Authorized user applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Technologists, therapists, or other personnel may use radioactive material for medical use under an authorized user's supervision in accordance with 4731.4407, "Supervised Individuals."

There is no MDH requirement that an authorized user must render an interpretation of a diagnostic image. MDH recognizes that the authorized user may or may not be the physician who interprets such studies. Additionally, MDH rules do not restrict who can read and interpret diagnostic scans or the results of involving the administration of radioactive material to individuals.

#### ***Authorized Users For Non-Medical Use***

List the full name of each individual proposed as an authorized user for non-medical use. Submit a complete description of the person's training and experience in non-medical use areas.

For *in-vitro* and animal research (or other uses that do not involve the intentional exposure of humans), the list of proposed authorized users should include those individuals who will actually be responsible for the use of the requested radioactive material. Indicate which user will be involved with which use by reference to Items 5 and 6 of the application. Those authorized users may direct the use of the radioactive material by technologists or other individuals for the requested use.

#### ***Radiation Safety Officer (RSO)***

Radiation Safety Officers must have adequate training and experience. The training and experience requirements for the RSO are described in 4731.4411 and allow for the following four training pathways:

- Certification by one of the professional boards recognized by MDH, the NRC or another Agreement State.
- Didactic training, work experience, and preceptor statement as described in 4731.4411(B).
- Identification on the license as an Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO.

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 4731.4405, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities to ensure that radioactive materials are used in a safe manner. MDH requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. MDH has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to

conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 4731.4405.

### ***RSO Responsibilities***

Some of the typical duties and responsibilities of Radiation Safety Officers include ensuring the following:

- Unsafe activities involving licensed materials are stopped
- Radiation exposures are ALARA
- Material accountability and disposal
- Interaction with MDH
- Timely and accurate reporting and maintenance of appropriate records
- Annual program audits
- Proper use and routine maintenance
- Personnel training
- Investigation of medical events involving radioactive material

Appendix B contains a detailed list of typical duties and responsibilities of the RSO. Applicants are reminded of recentness of training requirements. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the following:

- Name of the proposed RSO.
  
- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

One of the following is also needed:

- Copy of the certification(s) for the board(s) recognized by NRC or Agreement State and as applicable to the types of use for which he or she has RSO responsibilities.
  
- Description of the training and experience specified in 4731.4411 subpart B.
  
- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities (refer to 4731.4433, 4434, 4444, and 4461).

In addition, provide both of the following:

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

### **Item 8: Training For Individuals Working In or Frequenting Restricted Areas**

Describe your training program for individuals who work with or near radioactive material. Include the training for individuals who handle non-medical radioactive materials.

## **Item 9: Facilities And Equipment**

Applications will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta emitters.

Applicants must describe the proposed facilities and equipment. The facility diagram should include the room or rooms and adjacent areas where radioactive material is prepared, used, administered, and stored that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

For use of unsealed radioactive material for uptake, dilution, or excretion, or for imaging and localization (4731.4432 or 4731.4433), applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described.

The applicant should demonstrate that the dose limits for individual members of the public (4731.2090) will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.
- Requesting prior MDH authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits. A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA must be developed.

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by MDH. If applicants elect to use portable shielding they should commit to having administrative procedures to control configuration management to maintain dose within regulatory limits.

### ***Annotated Drawings***

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used.
- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored.
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 4731.0100.
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

**Radiation Monitoring Instruments**

All licensees should possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

The radiation protection program that licensees are required to develop, document, and implement in accordance with 4731.2010 must include provisions for survey instrument calibration (4731.2200). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, since it is not expected that a survey be conducted each time such a procedure is performed. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

Qualified personnel must perform survey meter calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an MDH (or equivalent NRC or Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration.

Provide one or both of the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."
- A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 4731.2200 and that meet the requirements of 4731.4421." Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing."

Also provide a description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
Short Scientific, Inc.	LGD-310	1 - 100000 cpm

Provide a statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

**Dose Calibrator And Other Equipment Used To Measure Dosages Of Unsealed Radioactive Material**

As described in 4731.4422, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or a nuclear pharmacy and does not split, combine, or otherwise modify unit dosages, the licensee is not required to possess an

instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

#### **Item 10: Radiation Safety Program**

The elements of a radiation safety program are contained in Appendices A through L. 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."

Appendix A	Model Program for Maintaining Occupational Radiation Exposure ALARA
Appendix B	Duties and Responsibilities of the Radiation Safety Officer
Appendix C	Calibrating Dose Calibrators
Appendix D	Personnel Exposure Monitoring Program
Appendix E	Leak Testing Sealed Sources
Appendix F	Safe Use of Radiopharmaceuticals
Appendix G	Spill Procedures
Appendix H	Ordering and Receiving Radioactive Material
Appendix I	Safely Opening Packages Containing Radioactive Material
Appendix J	Records of Radioactive Material Use
Appendix K	Area Surveys
Appendix L	Monitoring, Calculating, and Controlling Air Concentrations

#### **Sealed Source Inventories**

State that you will conduct inventories at intervals not to exceed three months to account for all sealed sources received and possessed under your license. You should maintain records of the inventories for at least three years from the date of the inventory. The record should include:

- Model number of each source
- Serial number if one has been assigned
- Identity of each source radionuclide
- Estimated activity
- Location of each source

- Date of inventory
- Initials or name of individual performing the inventory
- Signature of the Radiation Safety Officer

**Annual Audit of the Radiation Safety Program**

4731.2010 requires that licensees review at least annually the radiation protection program content and implementation. Currently the MDH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that problems are promptly and comprehensibly corrected. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

The MDH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with MDH rules.

A model audit program is included in this Regulatory Guide.

**Item 11: Waste Management**

Submit your procedures for waste disposal, including a procedure for all material listed in Item 5. See Appendix R for more information on these procedures.

**Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

**AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

## **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of radioactive material are capable of complying with MDH rules. This guide provides one set of methods approved by 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  
MODEL PROGRAM FOR MAINTAINING  
OCCUPATIONAL RADIATION EXPOSURE ALARA**

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program that was published in Appendix A to the MDH Regulatory Guide for Medical Use Of Radioactive Material in Diagnostic Procedures." Submit the signed commitment in Section 6 of this appendix.

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in Section 6 of this appendix.

**ALARA PROGRAM**

**1. Management Commitment**

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

**2. Review of Proposed Users and Uses**

- a. The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- b. When considering the use of radioactive material, the RSC will review efforts of the applicant to maintain exposure ALARA.
- c. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- d. The RSC will delegate authority for enforcement of an ALARA program to the RSO.

- e. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- f. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- g. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

**Table A-1 – Investigational Levels**

	Investigational Levels (mrems per month)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

- h. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

**3. Radiation Safety Officer Commitment**

- a. Annual and Quarterly Review
  - The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
  - The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.
- b. Education Responsibilities for ALARA Program
  - The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.
- c. Cooperative Efforts for Development of ALARA Procedures
  - Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
  - The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
  - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- d. **Reviewing Instances of Deviation from Good ALARA Practices:**
- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
- e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

#### **4. Authorized Users Commitment**

- a. **New methods of Use Involving Potential Radiation Doses**
- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
  - The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
- b. **Authorized User's Responsibility to Supervised Individuals**
- The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
  - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

#### **5. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses<sup>1</sup>**

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table A-1. These levels apply to the exposure of individual workers.

The RSO will review and record on MDH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table A-1:

- a. **Personnel dose less than Investigational Level I**

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<sup>1</sup> MDH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table A-1 values for the investigational Level I.
- b. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II
- The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality. This review will be recorded in the Committee minutes.
- c. Personnel dose equal to or greater than Investigational Level II
- The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's "Occupational Exposure Record for Monitoring Period" and "Cumulative Occupational Exposure History," or its equivalent.
- d. Re-establishment of investigational levels to levels above those listed in Table I
- In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

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

**6. Signature of Certifying Official<sup>1</sup>** Sign and submit as part of Appendix A.

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

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (Print or type)

\_\_\_\_\_  
Title

<sup>1</sup> The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

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

You may use the following model guidelines to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for RSO published in Appendix B to the MDH Regulatory Guide for Diagnostic Medical Procedures."

You may develop your own guidelines for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. State on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

**MODEL PROCEDURE**

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
  - a. The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
  - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
  - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation exceeding ALARA levels or limits in 4731 are investigated and reported to MDH within the required time limits.

10. Ensure that fume hood flow rates are tested at appropriate intervals and that employees use hoods in accordance with the safe use of radiopharmaceuticals.
11. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
12. Ensure that licensed material is disposed of properly.
13. Ensure that the facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.
14. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

## APPENDIX C CALIBRATING DOSE CALIBRATORS

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you or the contractor follow the model procedure, you may state on your application, "We will establish and implement the model procedure for calibrating our dose calibrator published in Appendix C to the MDH Regulatory Guide for Diagnostic Medical Procedures."

If you develop your own dose calibrator calibration procedure for review, you should carefully review all the features in the model procedure. State on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as Appendix C," and submit your dose calibrator calibration procedure.

### MODEL PROCEDURE

Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of  $\pm 5$  are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

#### 1. Constancy

Constancy means reproducibility in measuring a source over a long period. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

- a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
- b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.
- c. Either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
- d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
- e. Establish an action level at which the individual performing the test will automatically notify the supervision of suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds  $\pm 10$  percent.

2. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

#### 3. Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99<sup>m</sup> whose activity is at least as large as the maximum activity normally assayed.

### **DECAY METHOD**

- a. Assay the Tc-99<sup>m</sup> syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time (to the nearest minute), and net activity. This first assay should be done in the morning at a regular time, for example, 8 a.m.
- b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity used. For dose calibrators with a range selection switch, select the range you would normally use for the measurement.
- c. Convert the recorded time and date to hours elapsed.
- d. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.
- e. Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  $(A_{\text{observed}} - A_{\text{line}})/A_{\text{line}} = \text{deviation}$ .

### **SHIELD METHOD**

If you decide to use a set of sleeves to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the sleeves must be performed each time the dose calibrator is returned from repair.

Follow the manufacturer's instructions when performing the linearity test.

#### **4. Geometry independence**

Geometry means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

- a. In a small beaker or vial, mix 2.0 cc of a solution of Tc-99<sup>m</sup> with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
- b. Draw 0.5 cc of the Tc-99<sup>m</sup> solution into the syringes and assay. Record the volume and millicuries.
- c. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- d. Repeat the process until you have assayed a 2.0 - cc volume.
- e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- f. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure

to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

- g. To test the geometry dependence of a 30-cc glass vial, draw 1.0 cc of the Tc-99<sup>m</sup> solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
- h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries indicated.
- i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
- j. Select as a standard the volume closest to that normally used for mixing radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- k. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure to label the table or graph, note the date of the test, and indicate the model number and serial number of the calibrator.

#### 5. Accuracy

Accuracy means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier. The supplier must compare that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. Consider using at least one reference source whose activity is within the range of activities normally assayed.

- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for three determinations.
- b. Average the three determinations. The average value should be within five (5) percent of the certified activity of the reference source, mathematically corrected for decay.
- c. Repeat the procedure for other calibrated reference sources.
- d. If the average value does not agree, within five (5) percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.
- e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values.

6. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

## APPENDIX D PERSONNEL EXPOSURE MONITORING PROGRAM

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may state on your application, "We will establish and implement the model personnel exposure monitoring program published in Appendix D.1 and/or D.2 to the MDH Regulatory Guide for Diagnostic Medical Procedures."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program. State on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.

### D.1. MODEL PROGRAM FOR EXTERNAL EXPOSURE

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor.
4. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

### D.2. MODEL PROGRAM FOR INTERNAL EXPOSURE

Medical personnel who administer substantial doses of radioiodine to patients may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Historically, bioassays for medical personnel have been required only in cases of administration to hospitalized patients because these are the patients receiving substantial doses of radiopharmaceuticals. This in turn meant that the medical personnel who prepared or administered the dosages to these patients handled substantial amounts of radioactive material, and therefore were at greatest risk for intakes. Patients who did not need to be confined after administration of radiopharmaceuticals were generally those patients who received relatively small dosages of these materials. The preparation or administration of these smaller dosages posed a relatively lower risk to the medical personnel involved.

The change in the criteria for release of patients who have been administered radiopharmaceuticals may involve the administration of relatively large dosages of radioactive materials without requiring patient

confinement. Bioassays are only applicable to the administration of radiopharmaceuticals at levels that require hospitalization. It may be possible for medical personnel to prepare or administer substantial doses of radiopharmaceuticals without meeting the requirement to perform a bioassay.

Although licensees may no longer be tied to a bioassay program because of the new patient release criteria, they remain subject to the requirements of 4731.2210 "Conditions requiring individual monitoring of external and internal occupational dose." This requires the licensee to monitor all occupationally exposed personnel who may receive, in one (1) year, an intake in excess of the applicable ALI in 4731.2750.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed ten percent of the limit in the year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For medical licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay. Baseline surveys should be completed for all individuals likely to require future monitoring.

## **APPENDIX E LEAK TESTING SEALED SOURCES**

As a licensee, you must perform leak testing of sealed sources. The MDH requires tests to determine whether or not there is any leakage from the radioactive source. The leak test should be performed at six-month intervals unless otherwise authorized by your license. You may use the following model procedure to leak test sealed sources. If you 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 (E.1 and/or E.2) to the MDH Regulatory Guide for Diagnostic Medical Procedures."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix E," and submit your leak test procedure.

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 send 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 kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix E.1 or submit your own procedures.

For Option 3, describe the procedure for taking the test sample. Identify 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 the minimum sensitivity for the instrument used for analysis and 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.

### **E.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES**

(Option 2)

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, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
- c. For the teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or crosshairs. Wipe the primary and secondary collimators and trimmers.
- d. If you are testing radium sources, you should also check 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.

## **E.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES**

(Option 3)

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries. 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 rate meter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that is the same isotope and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries 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 records for three years.

## **APPENDIX F SAFE USE OF RADIOPHARMACEUTICALS**

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 F to the MDH Regulatory Guide for Diagnostic Medical Procedures."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model. State on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Appendix F," and submit your model rules for the safe use of radiopharmaceuticals.

### **MODEL RULES**

1. Wear long-sleeved laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Before leaving the restricted area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins or infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve so syringe shields can still be used).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. 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.
8. Wear a finger exposure monitor while handling radioactive material including during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and while in contact with patients that have been administered radiopharmaceuticals.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe-test radioactive material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
12. With a radiation survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation.
14. A log should be used to record additional information such as:
  - The total prepared activity
  - Specific activity (in mCi/cc) at a specified time
  - Total volume prepared
  - The measured activity of each patient dosage
  - Any other appropriate information
15. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
16. Assay each patient dosage in the dose calibrator before administration. Only use a dosage that differs by more than ten percent of the prescribed dosage with approval of an authorized user (except for prescribed dosages of less than 10 microcuries). When measuring the dosage, the radioactivity that adheres to the syringe wall or remains in the needle does not need to be considered.
17. Check the patient's name, the prescribed radionuclide, and the dosage before administering.
18. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
19. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

## **APPENDIX G SPILL PROCEDURES**

You may use the following model procedures as they appear here, stating on your application, "We will establish and implement the model spill procedure published in Appendix G to the MDH Regulatory Guide for Diagnostic Medical Procedures."

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

### **MODEL PROCEDURES**

#### ***MINOR SPILLS OF LIQUIDS AND SOLIDS***

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector meter. Check the area around the spill. Also, check your hands, clothing, and shoes for contamination.
5. The RSO will review the radioactive spill contamination survey records for trends.

#### ***MAJOR SPILLS OF LIQUIDS AND SOLIDS***

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

#### ***DISCUSSION CONCERNING MAJOR SPILLS AND MINOR SPILLS***

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

**Table G-1 – Relative Hazards of Common Radionuclides**

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major. Spills of the amounts shown below are considered minor.	
<b>RADIONUCLIDE</b>	<b>MILLCURIES</b>
Co-60, Sr-89, I-125, I-131	1
F-18, P-32, Co-58, Fe-59, Se-75, Sr-85, Y-90, In-111, I-123, Sm-153, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99 <sup>m</sup> , Tl-201	100

## **APPENDIX H ORDERING AND RECEIVING RADIOACTIVE MATERIAL**

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may state on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix H to the MDH Regulatory Guide for Diagnostic Medical Procedures."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 4731.2350. State on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix K," and submit your procedure.

### **MODEL GUIDANCE**

1. The Radiation Safety Officer (RSO) or a designee must ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. For routinely used materials:
    - (1) Written records identifying the authorized user or department, isotope, chemical form, activity, and supplier.
    - (2) Verification that material received was ordered by an authorized user.
  - b. For occasionally used materials (e.g., therapeutic dosages):
    - (1) The authorized user who will perform the procedure will make a written request to confirm that the material received is what was ordered.
    - (2) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.
4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

**SAMPLE MEMORANDUM**

**MEMO TO:** Chief of Security

**FROM:** Radiation Safety Officer

**SUBJECT:** Receipt of Packages Containing Radioactive Material

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

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

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

\_\_\_\_\_, at \_\_\_\_\_.  
Name Home Telephone

Radiation Safety Officer: \_\_\_\_\_

Chief of Nuclear Medicine: \_\_\_\_\_

Chief of Nuclear Medicine Technologist: \_\_\_\_\_

Nuclear Medicine Technologist on call  
(Call page operator at extension \_\_\_\_\_)

Nuclear Medicine Physician on call  
(Call page operator at extension \_\_\_\_\_)

**APPENDIX I**  
**SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**  
In addition to 4731.2350

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

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion 4731.2350. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix I," and submit your procedure.

**MODEL PROCEDURE**

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination in accordance with 4731.2350.

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

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

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

- f. Open the package with the following precautionary steps:
  - (1) Remove packing slip.
  - (2) Open outer package following the supplier's instructions, if provided.
  - (3) Verify that the contents match the packing slip.
  - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

- (5) If anything is other than expected, stop and notify the RSO.
- g. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument [for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter] should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.
  - h. Check the user request to ensure that the material received is the material that was ordered.
  - i. Monitor the packing material and the empty packages for contamination with a survey meter before discarding.
    - (1) If contaminated, treat this material as radioactive waste.
    - (2) If not contaminated, remove or obliterate the radiation labels before discarding it.
  - j. Make a record of the receipt.
3. For packages received under the general license, the following procedure for opening each package will be followed:
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - b. Check to ensure that the material received is the material that was ordered.

**APPENDIX J  
RECORDS OF RADIOACTIVE MATERIAL USE**

**GENERAL**

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does *not* have to replicate entries. For example, if you prepare a multi-dose vial for use one day, you do not have to record the date each time you draw a dose from it.

**RECORDS OF UNIT DOSAGE USE**

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for a unit dosage record system published in Appendix J to MDH Regulatory Guide for Diagnostic Medical Procedures."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedures in the model procedure. Indicate on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as Appendix J" and submit your unit dosage record procedure.

**MODEL PROCEDURE**

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt
4. Supplier
5. Lot number or control number, if assigned, and expiration date
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time
7. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual)
  - b. Measured activity in millicuries or microcuries and date and time of assay and administration
  - c. Patient name and identification number if one has been assigned
8. If discarded, the date and method of disposal
9. Initials of the individual who performed the assay

Maintain these records for three (3) years.

## **RECORDS OF MULTI-DOSE VIAL USE**

You may use the following model procedure to keep a record of multi-dose vial use. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for a multi-dose vial record system published in Appendix J to MDH Regulatory Guide for Diagnostic Medical Procedures."

If you prefer, you may develop your own multi-dose vial record system for review. If you do so, you should consider for inclusion all the features in the model system. State on your application, "We have developed a procedure for a multi-dose vial record system for your review that is submitted as Appendix J" and submit your multi-dose vial record procedure.

## **MODEL PROCEDURE**

For each multi-dose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt or preparation
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml)
5. Supplier or kit manufacturer
6. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual)
  - b. Date and time dosage was drawn and measured
  - c. Calculated volume that is needed for the prescribed dosage
  - d. Measured activity in millicuries or microcuries
  - e. Patient name and identification number if one has been assigned
7. If discarded, the method of disposal and date
8. Initials of the individual who performed the assay

Maintain these records for three (3) years.

## **MEASURING AND RECORDING MOLYBDENUM CONCENTRATION**

Each licensee who uses a technetium generator to prepare radiopharmaceuticals must complete a test for molybdenum concentration. This measurement is usually made with a dose calibrator. Licensees may not distribute or administer radiopharmaceuticals that contain more than 0.15 microcuries of Mo-99 per millicurie of Tc-99<sup>m</sup> at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect.

The model procedure for measuring molybdenum concentration is based on the use of a molybdenum breakthrough pig. Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but

only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert the measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99<sup>m</sup> generator elution. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix J to MDH Regulatory Guide for Diagnostic Medical Procedures."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider the inclusion of all the features in the model procedure. Say on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as Appendix J" and submit your procedure for measuring and recording molybdenum concentration.

### ***MODEL PROCEDURE***

Each time a generator is eluted, record the following information:

1. Date the generator was received.
2. Product of the measured Mo-99 activity and the correction factor. This is noted by the manufacturer.

Maintain these records for three (3) years.

An action level of 0.07 allows for the decay of the Tc-99<sup>m</sup> throughout the day of use. It is assumed that the material will be used within six (6) hours, at which time the concentration of Mo-99 to Tc-99<sup>m</sup> would have doubled.

## APPENDIX K AREA SURVEYS

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys published in Appendix K to the MDH Regulatory Guide for Diagnostic Medical Procedures."

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

### MODEL PROCEDURE

#### AMBIENT DOSE RATE SURVEYS

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

Quarterly surveys should be accomplished in areas

  - Adjacent to restricted areas
  - Through which radioactive materials are transferred
  - Where radioactive material is temporarily stored before shipment

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

#### REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas:

In any area where the potential for spreading contamination is likely to occur (e.g., cafeterias, snack bars, furniture and equipment), survey at least *quarterly*. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.
2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200-dpm/100 cm<sup>2</sup> for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).

3. Immediately notify the RSO if you find levels that exceed the established action levels. Recommended removable surface contamination action levels are published in NRC Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions" or see Table N-1 below for guidance in establishing your action levels.

**RECORDS**

1. Records must contain the following:
  - The date of the survey
  - A sketch of each area surveyed
  - Action levels established for each area
  - The measured dose rate at several points in each area expressed in millirem (microSievert) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters
  - The serial number and the model number of the instrument used to make the survey or analyze the samples
  - The initials of the individual who performed the survey
2. In those cases in which radiation or contamination action levels were exceeded, a follow-up survey should be completed and recorded. The RSO should promptly review and sign survey records that document the results of any actions implemented to corrective the excessive radiation or contamination levels.

Maintain these records for three (3) years.

**Table K-1**

<b>RECOMMENDED ACTION LEVELS IN DPM/100 CM<sup>2</sup> FOR SURFACE CONTAMINATION</b>		
	<b>P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198</b>	<b>Cr-51, Co-57, Ga-67, Tc-99<sup>m</sup>, Hg-197, Tl-201</b>
<b>1. Unrestricted areas, personal clothing</b>	<b>200</b>	<b>2,000</b>
<b>2. Restricted areas, protective clothing used only in restricted areas, skin</b>	<b>2,000</b>	<b>20,000</b>

## **APPENDIX L MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS**

### **WORKER DOSE FROM NOBLE GASES**

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

You may respond by stating, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you are not monitoring trap effluent, you must estimate worker dose by calculation. If you exhaust spent gas to the atmosphere, you must also estimate worker dose by calculation. It is not necessary to submit the calculations, but you should keep them for MDH review during inspections. If you will follow the model procedure for calculating worker dose from noble gases, you may respond by stating, "We will follow the model procedure for calculating worker dose from noble gases published in Appendix L to the MDH Regulatory Guide for Diagnostic Medical Procedures."

If none of the above applies, you may develop your own procedure for review. State on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as Appendix L," and append your procedure for monitoring worker dose from noble gases.

### **WORKER DOSE FROM AEROSOLS**

You may respond by stating, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for MDH review during inspections.) If you follow the model procedure below for calculating worker dose from aerosols, you may respond by stating, "We will follow the model procedure for calculating worker dose from aerosol concentrations that is appended as Appendix L.2." Submit your procedure for monitoring worker dose from aerosols.

#### **L.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS**

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, OSD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the derived air concentration (DAC) for Xenon-133 (or other gas to be used) to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of five (5) rem (50 mSv) and divide this number by five (5) rem.

- a. This yields the fraction of the dose limit of five (5) rem that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in 4731.2750.
  - b. If the highest annual external dose is 2 rem, and the listed DAC value for Xenon-133 is  $1\text{E-}4$  mCi/ml, then the modified DAC value should be based on 3 rem that could still be incurred from internal exposure.
3. The following calculations must be made:
- a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
  - b. The estimated activity released to the restricted areas.
    - (1) The total activity released to the restricted area divided by the total air exhausted must be less than the applicable DAC for a restricted area. The total activity released to the restricted area is activity used each week multiplied by estimated fractional loss per study. The total air exhausted is the sum of all exhaust rates multiplied by the length of the workweek.
    - (2) If this is not the case, plan for fewer studies and do the calculations again. An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.

## L.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable DAC value for an unrestricted area.
2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

## L.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is continuously monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions. Keep a record of the checks.
2. If you do not continuously monitor the trap effluent, check it on receipt and once each month. During one patient study, collect the effluent from the trap in a plastic bag and then monitor the activity in the bag by holding the bag against a camera. With the camera adjusted to detect the noble gas, compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm. *If there is a significant increase in the activity measured on the bag, the trap must be replaced.*
3. The charcoal Xenon trap should be replaced at time intervals recommended by the manufacturer.

## **PUBLIC DOSE FROM AIRBORNE EFFLUENT**

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value 4731.2750.

If you are not directly venting aerosols and gases to the atmosphere, you may respond by stating, "We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit the calculations with your application, but you should keep them for MDH review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond by stating, "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix L.3 to MDH Medical Use Of Radioactive Material For Diagnostic Procedures."

If neither of the above applies, you may develop your own procedure for review. State on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as Appendix L.3" and append your procedure for monitoring airborne effluent concentration.

## **SPILLED GAS CLEARANCE TIME**

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, the calculations described in Appendix L.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

### **L.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME**

1. Collect the following data:
  - a. A -- the highest activity of gas in a single container, in microcuries.
  - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser values), in milliliters per minute.
  - c. Q -- the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system
  - d. C -- the modified derived air concentrations (DAC) in restricted areas. These should be figured according to L.1, Numbers 1 and 2.
  - e. V -- the volume of the room in milliliters.
2. Make the following calculations for each room:
  - a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
  - b. The evacuation time  $t = -V/Q \times \ln(C \times V/A)$ .

3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted
- 2.0 mrem in any one (1) hour from external sources, and
  - 100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.

Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

**ATTACHMENT II**  
**US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE**  
**ENHANCED SECURITY MEASURES**

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

### **Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

### **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one of more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR FIXED GAUGES

	<p><b>Radiation Control Unit</b> <b>Asbestos, Lead, Indoor Air &amp; Radiation Section</b> <b>Division of Environmental Health</b> <b>Minnesota Department of Health</b></p>
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January 2005

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## REGULATORY GUIDE FOR FIXED GAUGES

### 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 a license to use and possess sealed sources in non-portable gauging devices. An example of a non-portable gauging device is a gauge that contains a gamma-emitting sealed source, Cesium-137, to measure the density of coal in a hopper.

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

### 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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 of an existing license and provide the license number. See "Amendments and Renewals to a License," section 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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**

Applicants must provide the manufacturer's or distributor's name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State. NRC or an Agreement State performs a safety evaluation of fixed gauges before authorizing a manufacturer or distributor to distribute the gauges to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the SSD registration process was formalized, older gauges may not have been evaluated in a separate document; but were specifically approved on a license. Licensees can continue to use the gauges that are specifically listed on their licenses.

Consult with the proposed manufacturer or distributor to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with 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. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSD Registration Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by MDH, licensees are required to use gauges according to their respective SSD Registration Certificates. Accordingly, applicants may want to obtain a copy of the certificate and review it with the manufacturer or distributor or with NRC or the issuing Agreement State to ensure that it correctly reflects the radiation safety properties of the source or device.

Identify each radionuclide that will be used in each source in the gauging device(s).

Identify the manufacturer or distributor and model number of each type of 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 NRC or an Agreement State.

Confirm that the activity per source and maximum activity per device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State<sup>1</sup>.

**Financial Assurance and Recordkeeping for Decommissioning**

The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most fixed gauge applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the possession thresholds. The thresholds for typical radionuclides used for fixed gauge sealed sources are shown in Table 1.

**Table 1  
Examples of Minimum Inventory Quantities Requiring Financial Assurance**

Radionuclide (Sealed Sources)	Activity in Gigabecquerels	Activity in Curies
Co-60	$3.7 \times 10^5$	10,000
Kr-85	$3.7 \times 10^7$	1,000,000
Sr-90	$3.7 \times 10^4$	1,000
Cs-137	$3.7 \times 10^6$	100,000
Am-241	$3.7 \times 10^3$	100
Cf-252	$3.7 \times 10^3$	100

A licensee would need to possess hundreds of gauges before the financial assurance requirements would apply. Since the standard gauge license does not specify the maximum number of gauges that a licensee may possess (allowing flexibility in obtaining additional gauges specifically authorized by the license as needed without amending its license), it contains a condition requiring the licensee to limit its possession of fixed gauges to quantities not requiring financial assurance. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where gauges are used or stored and to leaking sources. Licensees must transfer these records important to decommissioning the new licensee before licensed activities are transferred or assigned or to MDH before the license is terminated. For

<sup>1</sup> For information on SSD registration certificates, contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.

fixed gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each gauge was used or stored.

#### **Item 6: Purpose(s) for Which Licensed Material Will Be Used**

Gauges should be used only for the purposes for which they were designed, according to the manufacturer's or distributor's recommendations and instructions, as specified in an approved SSD Registration Certificate, and as authorized on an NRC license. Uses other than those listed in the SSD Registration Certificate require review and approval by the NRC or an Agreement State. Requests to use fixed gauges for purposes not listed in the SSD Registration Certificate will be reviewed on a case-by-case basis. Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety-critical components of the device. MDH will evaluate the radiation safety program for each type and use of gauge requested.

If the fixed gauge(s) will be used for the purposes listed on the SSD Registration Certificate<sup>2</sup>, do one of the following:

- You should state, "The fixed gauge(s) will be used for the purposes described on the SSD Registration Certificate(s)"
- Provide a specific description of use for each type of gauge requested, e.g., "for use in measuring the thickness of paper, the bulk density and weight of coal on a belt scale, etc."

If the fixed gauge will be used for purposes other than those listed on the SSD Registration Certificate, specify these other purposes and submit safety analyses (and procedures, if needed) to support safe use.

#### **Item 7: Individual(s) Responsible for the Radiation Safety Program**

##### ***Radiation Safety Officer (RSO)***

The person responsible for the radiation protection program is called the Radiation Safety Officer (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. MDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO<sup>3</sup>.

Radiation Safety Officers (RSOs) must have adequate training and experience. Successful completion of training of one of the following is evidence of adequate training and experience:

- Fixed gauge manufacturer's or distributor's course for users or for RSOs
- An equivalent course that meets Appendix B criteria

Additional training is required for RSOs of programs that perform non-routine operations. This includes repairs involving or potentially affecting components related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding) and any other activities during which personnel could receive radiation doses exceeding MDH limits (e.g., installation,

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<sup>2</sup> Allowed uses of fixed gauges normally include process control methods such as measuring the thickness of paper, the density of coal, the level of material in vessels and tanks, etc. Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

<sup>3</sup> It is important to notify MDH, as soon as possible, of changes in the designation of the RSO.

initial radiation survey, gauge relocation, and removal of the gauge from service). See "Radiation Safety Program - Maintenance" in this report and Appendix C, "Non Routine Operations."

The licensee should provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.

As an alternative, the licensee should state that:

- a. Before obtaining licensed materials, the proposed RSO will have successfully completed the training described in Appendix B of this guide; or
- b. The new RSO will receive training described in Appendix B of this guide within a specified time after being appointed.

### **Authorized Users**

An authorized user (AU) is a person whose training and experience meet MDH criteria, who is named explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. Authorized users must ensure the proper use, security, and routine maintenance of fixed gauges containing licensed material. Therefore, they must attend the training and instruction given at the time of installation or receive equivalent training and instruction.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Authorized users (AUs) must have adequate training and experience. Successful completion of a fixed gauge manufacturer's or distributor's course for users will satisfy the training requirements.

Applicants requesting to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service, must provide additional training. See the section in this report entitled "Radiation Safety Program - Maintenance" and Appendix C.

### **Item 8: Training for Individuals Working In or Frequenting Restricted Areas**

Individuals who, in the course of employment, are likely to receive occupational doses of radiation in excess of 100 mrem (1 mSv) in a year must receive training. The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

Licensees need to perform a prospective evaluation to determine radiation doses likely to be received by different individuals or groups. Authorized users and individuals performing installations, relocations, non-routine maintenance, or repairs would be most likely to receive doses in excess of 100 mrem (1 mSv) in a year.

Licensee personnel who work in the vicinity of a fixed gauge but do not use gauges (ancillary staff) are not required to have radiation safety training as long as they are not likely to receive 100 mrem (1 mSv) in a year. However, to minimize potential radiation exposure when ancillary staff are working in the vicinity of a fixed gauge, it is prudent for them to work under the supervision and in the physical presence of an AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the gauge and the meaning of the radiation symbol, and should be instructed not to touch the gauge and to keep away from it as much as their work permits.

Some ancillary staff, although not likely to receive doses over 100 mrem, should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with

training commensurate with their assignments near the gauge to ensure the control and security of licensed material.

Submit the training program for individuals who, in the course of employment, are likely to receive occupational doses of radiation in excess of 100 mrem (1 Sv) in a year (occupationally exposed workers) and ancillary personnel.

#### **Item 9: Facilities and Equipment**

Fixed gauges incorporate many engineering features to protect the user from unnecessary radiation exposure in a wide variety of environments. Fixed gauges may be located in harsh environments involving variables such as pressure, vibration, mounting height/method, temperature, humidity, air quality, corrosive atmospheres, corrosive chemicals including process materials and cleaning agents, possible impact or puncture conditions, and fire, explosion, and flooding potentials. Applicants need to consult the sections on the SSD Registration Certificate entitled, "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" to determine the appropriate gauge for a location. In those instances when a proposed location is not consistent with the SSD Registration Certificate, the applicant may ask the source or device manufacturer or distributor to request an amendment to modify the SSD Registration Certificate to include the new conditions. If the manufacturer or distributor does not request an amendment, the applicant must provide MDH with specific information demonstrating that the proposed new conditions will not impact the safety or integrity of the source or device.

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

1. A sketch or description of the proposed location of each gauge within your facility.
2. The environmental conditions to which gauges will be exposed (e.g., elevated temperature, corrosive atmosphere, and vibration).
3. If the ambient temperature will exceed the maximum operating temperature specified by the manufacturer, thus creating a need to maintain a lower temperature by means of cooling jackets or similar measures, a description of the cooling system should be provided. In addition, provide a discussion of how the cooling system will be maintained and the consequences of a failure of the cooling system.
4. If a cooling system is used to maintain the temperature below the maximum operating temperature specified by the manufacturer, submit a description of the method and procedures for detecting a cooling system failure and your procedures for coping with a cooling system failure.
5. Confirm that the fixed gauge is secured to prevent unauthorized removal or access.

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

The elements of a radiation safety program are contained in Appendices A through E. Review each appendix carefully. (Some of these appendices have been addressed in the preceding 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."

Appendix A	Typical Duties and Responsibilities of the Radiation Safety Officer
Appendix B	Criteria for Acceptable Training for Radiation Safety Officers and Authorized Users
Appendix C	Information Needed to Support Applicant's Request to Perform Non-Routine Operations
Appendix D	Leak Testing Sealed Sources
Appendix E	Suggested Fixed Gauge Audit Checklist

### ***Leak testing of sealed sources***

As a licensee, you must perform leak tests to ensure that sources are not leaking. MDH requires tests to determine if there is any leakage from the sealed sources in the devices. Normally, leak tests should be performed at 6-month intervals. Some sealed source/device combinations have been authorized for a leak test interval of three years. Information about sealed source/device combinations that have three-year leak test intervals may be obtained from suppliers and manufacturers.

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. Use a commercial leak test kit. You take the smears and send them to the kit supplier, who will report the results to you.
3. Perform the entire leak test sequence yourself, including taking the smears and their measurements.

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

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

For Option 3, describe the procedure for taking the sample and the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used: hand-held survey meters will not normally be considered adequate for measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application. Commit to Appendix D or submit your own procedures.

### ***Lock-out procedures***

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

You must have "lockout" procedures so that personnel will not be subjected to unnecessary exposure. The procedures should specify the means for preventing employees from entering the radiation beam during maintenance, repairs, or other work in, on, or around the bin, tank, or hopper on which the device is mounted. You do not need to submit the procedures.

You should state in your application that you will prepare such procedures, that you will provide them to your personnel, and that the procedures will be posted so that personnel can see them. You should specify that the individual who will be responsible for ensuring that the lockout procedures are followed is the "responsible individual" named in Item 4.

### ***Maintenance***

Submit the information on the maintenance of gauges, including (but not limited to) frequency, checks for proper shutter operation, checks that labels are legible and visible, and checks that gauges are protected against corrosive materials or materials at high temperature.

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

### ***Radiation Detection Equipment***

If you plan to perform gauge servicing such as installation, initial radiation survey, maintenance, device relocation, removal, etc., you must have a survey meter that is calibrated annually and after servicing. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing." Provide the type and range of the meter and the name and address of the company who will calibrate the meter.

State that before using the survey meter, you will check the response of the instrument with a check source and that you will not use the meter until it is repaired and operable if the meter does not respond properly.

### ***Personnel Monitoring Equipment***

Personnel monitoring equipment must be used by individuals who receive or are likely to receive occupational exposure in one year from sources external to the body, in excess of 10% of the dose specified in paragraph 4731.2000. Individuals under 18 years or declared pregnant women are required to use personnel monitoring equipment if they receive or are likely to receive a dose in excess of 10% of the specified dose.

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

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

### ***Inventories***

State that you will conduct inventories at intervals not to exceed six (6) months to account for all sealed sources and gauges received and possessed under your license. You should maintain records of the inventories for at least five (5) years from the date of the inventory. The records should include the radionuclide and amount of material in each source, the manufacturer's name, model number and serial number of each gauge, the location of each, and the date of the inventory.

### ***Annual audits***

Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure compliance with MDH rules and the terms and conditions of the license. Records of audits and other reviews of program content are maintained for three years.

As part of the audit programs, you should consider performing unannounced audits of your authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

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

An audit program for a fixed gauge should include a review of:

- ✓ leak test records and procedures
- ✓ inventory records
- ✓ training
- ✓ the operating and emergency procedures
- ✓ survey instrument calibration records and procedures (if applicable)

See Appendix E for questions to consider in an annual audit. You, as the licensee, are responsible for the content and implementation of your radiation safety program and for all actions of your employees.

### ***Operating and emergency procedures***

State on your application that you will provide the operating and emergency procedures to each person responsible for the gauge. Submit the detailed operating and emergency procedures for review. The following topics should be covered:

1. Instructions for operating the gauge.
2. Instructions for performing routine cleaning and maintenance (e.g., calibration and lubrication) according to the manufacturer's or distributors recommendations and instructions.
3. Instructions for testing each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed six months or as specified in the SSD certificate.
4. Instructions for lock-out procedures, if applicable, that are adequate to assure that no individual or portion of an individual's body can enter the radiation beam.
5. Instructions to prevent unauthorized access, removal, or use of fixed gauges.
6. Steps to take to keep radiation exposures ALARA.
7. Steps to maintain accountability (i.e., inventory).
8. Instructions to ensure that non-routine operations such as installation, initial radiation survey, repair and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service are performed by the manufacturer, distributor or person specifically authorized by the NRC or an Agreement State.
9. Steps to ensure that radiation warning signs are visible and legible.
10. Develop, implement, and maintain emergency procedures for gauge malfunction or damage containing the following elements for each type of fixed gauge:

- a. Stop use of the gauge.
- b. Restrict access to the area.
- c. Contact responsible individuals. (Telephone numbers for the RSO, AUs, the gauge manufacturer or distributor, fire department or other emergency response organization, and the MDH should be posted or easily accessible.)
- d. Do not attempt repair or authorize others to attempt repair of the gauge except as specifically authorized in a license issued by the NRC or an Agreement State.
- e. Take additional steps, dependent on the specific situations.

11. Provide copies of operating and emergency procedures to all gauge users.

12. Post copies of operating and emergency procedures at each location of use or if posting procedures is not practicable, post a notice that briefly describes the procedures and states where they may be examined.

Operating and emergency procedures should be developed, maintained, and implemented to ensure that gauges are used only as they were designed to be used, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA.

Improper operation could lead to the damage or malfunction of a gauge and elevated exposure rates in the gauge's immediate vicinity. Emergency procedures should be developed to address a spectrum of incidents (e.g., fire, explosion, mechanical damage, flood, or earthquake).

***Transportation of devices***

The transport of licensed material must be carried out in accordance with the applicable requirements of the Department of Transportation (DOT).

**Item 11: Waste Management**

The only option for disposal of the licensed material contained in fixed gauges is to transfer the material to an authorized recipient. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it. Authorized recipients are the original suppliers of the device, a commercial firm licensed by an Agreement State or the NRC to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

**Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

### **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

### **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of byproduct material are capable of complying with MDH rules. This guide provides one set of methods approved by 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**  
**TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER**

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

- Activities involving licensed material that the RSO considers unsafe are stopped.
- Radiation exposures are ALARA.
- Development, maintenance, distribution, and implementation of up-to-date operating and emergency procedures.
- Individuals that use fixed gauges are properly trained.
- Possession, installation, relocation, use, storage, routine maintenance and non-routine operations of fixed gauges are consistent with the limitations in the license, the SSD Registration Certificate(s), manufacturer's or distributors recommendations and instructions.
- Safety consequences of non-routine operations are analyzed before conducting any such activities that have not been previously analyzed.
- Non-routine operations are performed by the manufacturer, distributor or person specifically authorized by the NRC or an Agreement State.
- Prospective evaluations are performed demonstrating that individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices.
- Personnel monitoring devices, if required, are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit as specified in 10 CFR 20.1301.
- Fixed gauges are properly secured.
- Notification of proper authorities of incidents such as damage to or malfunction of fixed gauges, fire, loss, or theft.
- Investigation of unusual occurrences involving the fixed gauge (e.g., malfunctions or damage), identification of cause(s), implement of appropriate and timely corrective action(s).
- Radiation safety program audits are performed at intervals not to exceed 12 months and development, implement, and documentation of timely corrective actions.
- When the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented.
- Licensed material is transported according to all applicable DOT requirements.
- Licensed material is disposed of properly.

- **Appropriate records are maintained.**
- **An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.**
- **Posting of documents or posting a notice indicating where these documents can be examined.**

**APPENDIX B  
CRITERIA FOR ACCEPTABLE TRAINING FOR RADIATION SAFETY OFFICERS AND AUTHORIZED  
USERS**

Classroom training may be in the form of lecture, videotape, or self-study emphasizing practical subjects important to safe use of the gauge. Training should include the following topics:

**Radiation Safety:**

- Radiation vs. contamination
- Internal vs. external exposure
- Biological effects of radiation
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure
- Location of sealed source within the gauge

**Regulatory Requirements:**

- Applicable regulations
- License conditions, amendments, renewals
- Locations of use and storage of radioactive materials
- Material control and accountability
- Annual audit of radiation safety program
- Transfer and disposal
- Recordkeeping
- Prior events involving fixed gauges
- Handling incidents
- Recognizing and ensuring that radiation warning signs are visible and legible
- Licensing and inspection by regulatory agency
- Need for complete and accurate information
- Employee protection
- Deliberate misconduct

- Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee:
- Operating and emergency procedures
- Routine vs. non-Routine maintenance
- Lock-out procedures

*On-the-job training must be done under the supervision of an AU or RSO.*

**Supervised Hands-on Experience Performing:**

- Operating procedures
- Test runs of emergency procedures
- Routine maintenance
- Lock-out procedures

**Training Assessment**

Management will ensure that proposed AUs are qualified to work independently with each type of gauge with which they may work. Management will ensure that proposed RSO's are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges to be possessed by the applicant. This may be demonstrated by written or oral examination or by observation.

**Course Instructor Qualifications**

Instructor should have:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of an 8 hour radiation safety course; and
- 8 hours hands-on experience with fixed gauges

**OR**

- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of 40-hour radiation safety course and 30 hours of hands-on experience with fixed gauges.

**OR**

- The applicant may submit a description of alternative training and experience for the course instructor.

Additional training is required for those applicants intending to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service. See Appendix C - "Non-Routine Operations."

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

Applicants should review the section in this document on "Maintenance," that discusses, in general, licensee responsibilities before any maintenance or repair is performed. Non-routine operations include installation of the gauge, initial radiation survey, repair or maintenance involving or potentially affecting components (including electronics) related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding). Non-routine operations also include gauge relocation, replacement, and disposal of sealed sources, alignment, removal of a gauge from service, and any other activities during which personnel could receive radiation doses exceeding MDH limits.

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

If non-routine operations are not performed properly with attention to good radiation safety principles, the gauge may not operate as designed and personnel performing these tasks could receive radiation doses exceeding MDH limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes, in less than one minute an unshielded Cesium-137 source with an activity of 100 millicuries can deliver 5 rems (0.05 Sv) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. However, gauges can contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 5 rems (0.05 Sv) per year.

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

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

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

A licensee may initially mount a gauge, without specific NRC or Agreement State authorization, if the gauge's SSD Certificate explicitly permits mounting of gauges by users and under the following conditions:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor;

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

Identify who will perform non-routine operations and their training and experience. Acceptable training would include manufacturer's or distributors courses for non-routine operations or equivalent.

Submit procedures for non-routine operations. These procedures should ensure the following:

- doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
- the source is secured against unauthorized removal or access or under constant surveillance;
- appropriate labels and signs are used;
- manufacturer's or distributors instructions and recommendations are followed;
- any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration; and
- before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.

Confirm that individuals performing non-routine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits.

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

- commit to performing surveys with a survey instrument (as described above);
- specify where and when surveys will be conducted during non-routine operations; and
- commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements).

## **APPENDIX D LEAK TESTING SEALED SOURCES**

You may use the following model procedure to leak test sealed sources. If you follow the model procedure you may indicate on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix (D.1 and/or D.2) to the MDH Regulatory Guide for Fixed Gauges."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Minnesota Rules. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix (D.1 and/or D.2)," and submit your leak test procedure.

### **D.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES**

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

### **D.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES**

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries. 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 either a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source. The source activity should be certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.

3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries 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 E  
SUGGESTED FIXED GAUGE AUDIT CHECKLIST**

All areas indicated in audit notes may not be applicable to every license 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, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Licensee's Name:	License Number:
Date of This Audit:	Date of Last Audit:
(Auditor Signature)	Date:
(Management Signature)	Date:

**Audit History**

- A. Last audit of this location was conducted on:
- B. Were previous audits conducted at intervals not to exceed 12 months?
- C. Were records of previous audits maintained?
- D. Were any deficiencies identified during the last two audits or two years, whichever is longer?
- E. Were corrective actions taken? (Look for repeated deficiencies).

**Organization and Scope of Program**

- A. If the mailing address or places of use have changed, was the license amended?
- B. If ownership changed or bankruptcy filed, was MDH prior consent obtained or was MDH notified?
- C. Relative to the Radiation Safety Officer:
  - 1. If the RSO was changed, was the license amended?
  - 2. Does the new RSO meet MDH training requirements?
  - 3. Is the RSO fulfilling his/her duties?
  - 4. To whom does the RSO report?

D. If the designated contact person for MDH changed, was MDH notified?

E. Relative to Sealed Sources and Devices:

1. Does the license authorize all of the MDH regulated radionuclides contained in gauges?
2. Are the gauges as described in the Sealed Source and Device (SSD) Registration Certificate?
3. Are there copies available of the manufacturers' or distributor's manuals for operation and maintenance?
4. Are the actual uses of gauges consistent with the authorized uses listed on the license?
5. Are the locations of the gauges compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD Registration Certificates?

#### **Training and Instructions to Workers**

A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed in accordance with 4731.1020?

1. Has refresher training been provided, as needed?
2. Are records maintained?

B. Did each AU receive training and instruction given at the time of gauge installation or equivalent training and instruction before using gauges?

C. Are training records maintained for each AU?

D. Did individuals who perform non-routine operations receive training before performing these operations?

E. Did interviews with AUs reveal that they know the emergency procedures?

F. Did this audit include observations of AUs using the gauge?

G. Did this audit include observations of workers performing routine cleaning and lubrication on the gauge?

H. Is HAZMAT training provided, if required? [49 CFR 172.700, 172.701, 172.702, 172.703, 172.704]

#### **Radiation Survey Instruments**

A. If the licensee is required to possess a survey meter, does it meet the MDH's criteria?

B. Are calibration records maintained?

### **Gauge Inventory**

- A. Are records kept showing the receipt of each gauge?
- B. Are all gauges physically inventoried every six months?
- C. Are records of inventory results with appropriate information maintained for three years?

### **Personnel Radiation Protection**

- A. Are ALARA considerations incorporated into the radiation protection program?
- B. Were prospective evaluations performed showing that unmonitored individuals receive 10% of the limit?
- C. Did unmonitored individuals' activities change during the year that could put them over 10% of the limit?
- D. If yes to C. above, was a new evaluation performed?
- E. Is external dosimetry required for individuals likely to receive greater than 10% of limit?
- F. Relative to dosimetry provided to these individuals:
  - 1. Is the dosimetry supplier NVLAP approved?
  - 2. Are the dosimeters exchanged monthly for film badges and quarterly for TLDs?
  - 3. Are dosimetry reports reviewed by the RSO when they are received?
  - 4. Are the records based on MDH Forms or equivalent?
    - a. Has MDH "Cumulative Occupational Exposure History" or equivalent been completed?
    - b. Has MDH "Occupational Exposure Record for a Monitoring Period" or equivalent been completed?
  - 5. For declared pregnant workers/embryo/fetus:
    - a. Was additional monitoring provided for a worker who declared her pregnancy?
    - b. Were records kept of the embryo/fetus dose?
- F. Are records of exposures, surveys, monitoring, and evaluations maintained?

### **Public Dose**

- A. Is public access to gauges controlled in a manner to keep doses below 1 mSv (100 mrem) in a year?
- B. Has a survey or evaluation been performed?

- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 2 mrem (0.02 mSv) in any one hour?
- E. Is gauge access controlled in a manner that would prevent unauthorized use or removal?
- F. Are records maintained?

#### **Operating and Emergency Procedures**

- A. Have operating and emergency procedures been developed?
- B. Do these procedures contain the required elements?
- C. Does each individual working with the gauges have a current copy of the operating and emergency procedures (including lock-out procedures and emergency telephone numbers)?
- D. Is a lockout warning sign posted at each entryway to an area where it is possible to be exposed to the beam?
- E. Have any emergencies occurred?
  - 1. If so, were they handled properly?
  - 2. Were appropriate corrective actions taken?
  - 3. Was MDH notification or reporting required?

#### **Leak Tests**

- A. Was each sealed source leak tested every 6 months or at other prescribed intervals?
- B. Was the leak test performed according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking?
- E. If yes to D. above, was MDH notified?

#### **Maintenance of Gauges**

- A. Are manufacturer's or distributor's procedures followed for routine cleaning and lubrication of the gauge?
- B. Was each on-off mechanism tested for proper operation every 6 months or at other prescribed intervals?

- C. Are repair and maintenance of components related to the radiological safety of the gauge performed by the manufacturer, distributor or person specifically authorized by the MDH or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument)?
- D. Are labels, signs, and postings identifying gauges containing radioactive material, radiation areas, and lockout procedures/warnings clean and legible?

#### **Transportation**

(This section will not apply if you have not transported gauges during the period covered by this audit.)

- A. Were DOT-7A or other authorized packages used? [49 CFR 173.415, 173.416(b)]
- B. Are package performance test records on file?
- C. Is special form sources documentation available? [49 CFR 173.476(a)]
- D. Did the package have two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [49 CFR 172.403, 173.441]
- E. Was the package properly marked? [49 CFR 172.301, 172.304, 172.310, 172.324]
- F. Was the package closed and sealed during transport? [49 CFR 173.475(f)]
- G. Were shipping papers prepared and used? [49 CFR 172.200(a)]
- H. Did shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} [49 CFR 172.200, 172.201, 172.202, 172.203, 172.204, 172.604]
- I. Were shipping papers within drivers reach and readily accessible during transport? [49 CFR 177.817(e)].
- J. Was the package secured against movement? [49 CFR 177.834]
- K. Were placards on vehicle, if needed? [49 CFR 172.504]
- L. Were there proper over packs, if used? [49 CFR 173.25]
- M. Were any incidents reported to DOT? [49 CFR 171.15, 171.16]

#### **Auditor's Independent Survey Measurements (If Made)**

- A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits?

### **Notification and Reports**

- A. Was any radioactive material lost or stolen?

Were reports made?

- B. Did any reportable incidents occur?

Were reports made?

- C. Did any overexposures and high radiation levels occur?

Were reports made?

- D. If any events (as described in items a through c above) did occur, what was root cause?

Were corrective actions appropriate?

- E. Is the management/RSO/shift foreman licensee aware of telephone number for MDH?

### **Posting and Labeling**

- A. Is MDH "Notice to Workers" posted?

- B. Are MDH regulations and license documents posted or is a notice posted?

- C. Is there other posting and labeling?

### **Record Keeping for Decommissioning**

- A. Are records kept of information important to decommissioning?

- B. Do the records include all information?

### **Bulletins and Information Notices**

- A. Were MDH Bulletins and MDH Information Notices received?

- B. Were appropriate training and action taken in response?

### **Special License Conditions or Issues**

- A. Did the auditor review special license conditions or other issues (e.g., non-routine operations)?

**Deficiencies Identified in Audit; Corrective Actions**

- A. Summarize problems/deficiencies identified during audit.
- B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? Include date(s) when corrective actions are implemented.
- C. Provide any other recommendations for improvement.

**Evaluation of Other Factors**

- A. Is senior licensee management appropriately involved with the radiation protection program and/or RSO oversight?
- B. Does the RSO have sufficient time to perform his/her radiation safety duties?
- C. Does the licensee have sufficient staff to support the radiation protection program?

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

#### Training records must include:

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including:

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### **Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

#### **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one of more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

#### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

#### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR GAMMA STEREOTACTIC RADIOSURGERY

	<p><b>Radiation Control Unit</b> <b>Asbestos, Lead, Indoor Air &amp; Radiation Section</b> <b>Division of Environmental Health</b> <b>Minnesota Department of Health</b></p>
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## **REGULATORY GUIDE FOR GAMMA STEREOTACTIC RADIOSURGERY**

### **INTRODUCTION**

The Minnesota Department of Health (MDH) regulates the intentional internal or external administration of radioactive material or the radiation from radioactive material to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Chapter 4731 of the Minnesota Department of Health Rules.

MDH usually issues a single radioactive material license to cover the radioisotope program. However, separate licenses must be obtained for the following applications:

- gamma stereotactic radiosurgery devices (gamma knives)
- high-, medium-, and low-dose rate afterloaders
- irradiators
- nuclear powered pacemakers
- teletherapy devices

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the rules identified in Chapter 4731 and 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.

The purpose of this guide is to assist applicants and licensees in preparing applications for new licenses, license amendments, and renewals that authorize the possession of radioactive material for medical use of gamma stereotactic radiosurgery devices (GSR). This regulatory guide provides specific information on the survey instruments, radiation monitors, performance of required surveys, and operating and emergency procedures associated with a GSR unit.

### **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.

### **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 this 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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. 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 or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and /or used at a field station, give the specific address of each field station.

If radiography 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**

Provide the following information for each radionuclide:

1. Radionuclide.
2. Manufacturer's name and model number.
3. Maximum activity per device. The activity may not exceed the activity specified by the manufacturer for the specific device and source combination.
4. Maximum number of sources to be possessed at any one time. You may wish to request authorization for sources used in the device and additional sources for replacement. The replacement sources will be stored in shipping containers until the manufacturer completes the change out. If more than one source model is referenced in item 2, you should indicate the maximum number of sources requested of each model number.
5. Maximum activity of the individual sources.
6. If applicable, you should request authorization for possession of depleted uranium in quantities sufficient to include shielding material in both the devices and source containers used for source exchange. Review and indicate the manufacturer's specifications for each device to determine the total quantity of depleted uranium present in the device in units of kilograms. Indicate whether depleted uranium is used for shielding the source(s) within the device.

Provide the following information for each device:

1. Specify the manufacturer's name, address, and telephone number for each device requested.
2. Indicate the model name and/or number and serial number for each device requested.

### **Item 6: Purpose(s) For Which Licensed Material Will Be Used**

You should specify the uses or types of treatment planned for the device. Any other intended uses (such as physics calibrations or medical research) should be described so that the intended uses are apparent to the MDH review staff.

### **Item 7: Individual(s) Responsible for the Radiation Safety Program**

Responsible individuals include the authorized users and the RSO. An applicant is required by 4731.4411 to be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and property. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience. 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.

#### ***Authorized Users For Medical Uses***

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiation dosage or dose and how it is to be administered.

3. Use of the radioactive material or supervising the use by technologists or other paramedical personnel in the use of radioactive material.
4. Interpretation of diagnostic procedures and the evaluation of therapy procedures.

Applicants must meet recentness of training requirements as described in 4731.4415. Authorized user applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Technologists, therapists, or other personnel may use radioactive material for medical use under an authorized user's supervision in accordance with 4731.4407, "Supervised Individuals."

There is no MDH requirement that an authorized user must render an interpretation of a diagnostic image or results of a therapeutic procedure. MDH recognizes that the authorized user may or may not be the physician who interprets such studies. Additionally, MDH rules do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of byproduct material to individuals.

All training for users of gamma stereotactic radiosurgery units must comply with the specifications in 4731.4479.

#### ***Radiation Safety Officer (RSO)***

Radiation Safety Officers must have adequate training and experience. The training and experience requirements for the RSO are described in 4731.4411 and 4731.4479 and allow for the following four training pathways:

- Certification by one of the professional boards recognized by MDH in 4731.4479.
- Didactic training and work experience as described in 4731.4479.
- Didactic training, work experience, and preceptor statement as described in 4731.4411(B).
- Identification on the license as an Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO.

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 4731.4405, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities to ensure that radioactive materials are used in a safe manner. MDH requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. MDH has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 4731.4405.

#### ***RSO Responsibilities***

Some of the typical duties and responsibilities of Radiation Safety Officers include ensuring the following:

- Unsafe activities involving licensed materials are stopped
- Radiation exposures are ALARA

- Material accountability and disposal
- Interaction with MDH
- Timely and accurate reporting and maintenance of appropriate records
- Annual program audits
- Proper use and routine maintenance
- Personnel training
- Investigation of incidents involving byproduct material (e.g., medical events)

Applicants are reminded of recentness of training requirements. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the following:

- Name of the proposed RSO.
- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

Submit one of the following:

- Copy of the certifications for the boards recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.
- Description of the training and experience specified in 10 CFR 35.900(b).
- Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.

In addition, provide both of the following:

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

### ***Authorized Medical Physicist (AMP)***

At many licensed medical facilities conducting radiation therapy treatments, an Authorized Medical Physicist is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in 4731.4415. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the name of the proposed AMP and one of the following:

- Previous license number or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named as an Authorized Medical Physicist for the units requested.
- Copy of the certification(s) for the board(s) recognized by NRC in 4731.4412 or 4731.4479.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4479 for the units requested.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4412 for the units requested.

In addition, provide both of the following:

- Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized Medical Physicist has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

**Item 8: Training For Individuals Working In or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)**

Describe your training program for individuals who work with or near radioactive material.

**Item 9: Facilities And Equipment**

***Facilities***

Submit annotated drawings of each dedicated treatment room indicating:

1. Scale, plan and elevation.
2. Identification of the rooms, including room numbers.
3. Type, density and thickness of all shielding materials, including walls, floor and ceiling.
4. The location of the gamma stereotactic unit within the room. Include distances from the isotope center of the device to the walls, doors, etc.
5. Location of doors, windows, and conduit.
6. Distance to and the nature of use for adjacent areas with indication of whether the areas are restricted or unrestricted, as defined in Chapter 4731.

**NOTE:** The information provided should be sufficient to enable MDH staff to conduct an independent review of the shielding design. To that end, distances from the source center should be referenced.

Treatments must be performed in rooms specially constructed or modified for radiosurgery. The use of gamma stereotactic devices must be restricted to the specific room described in your application. Relocation of a device to another area of use requires prior MDH approval.

## **Equipment**

A. If the gamma stereotactic radiosurgery device is not equipped with viewing and intercom systems, you should equip the treatment room to allow for patient observation during treatment. A description of the systems should be provided with the application and should include:

1. The primary intercom and viewing systems.
2. Backup systems to be used if the primary systems fail. Alternatively, you should commit to suspend treatments until the primary system is repaired.

You should describe the following:

- How the patient and device will be monitored during treatment.
- How to provide for prompt detection of any operational problems with the device during treatment.

B. Provide a description of the security to be provided for the room where a device is to be used or stored. Areas should be secured in accordance with 4731.2290. A description of the following is required:

1. The physical or administrative control of access.
2. The electrical interlock system installed at each entry, including the result of interrupting the interlock when the source is exposed.
3. The actions required following interruption of the interlock before resuming treatment, including confirmation that the interlock must be reset before the device can be activated.
4. The actions required in case of malfunction of the interlock system. You should confirm that if the system malfunctions, the shielding doors will be closed. Verify that the system will not be used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
5. The restricted area controls (e.g., signs, locks, visible and audible alarms, etc.), including descriptions of signs with their locations, sizes and wording. Each suite containing a gamma knife should be equipped with a radiation monitor. The monitor should be permanently mounted and equipped with an emergency power supply separate from the gamma knife unit itself. The monitor must be capable of providing a visible indication (e.g., flashing light, or "Beam On" light) of an exposed or partially exposed source. The indicator must be readily observable by any person entering the treatment room.
6. Provide the methods used to identify the high radiation areas inside the treatment room when the shield doors are open (e.g., colored floor tiles, warning tape, etc.).
7. The method to ensure that whenever the device is not in use or is unattended, the console key(s) will be inaccessible to unauthorized persons.
8. You should confirm that no other radiation-producing devices are located in the treatment room, or provide a description of the mechanisms installed to ensure that only one device can be placed in operation at a time.
9. Verify that the gamma knife, its control console, or any related components are not within close proximity of equipment that produces a high level of electromagnetic

disturbance (i.e., short wave equipment). Those fields have been demonstrated to interfere with the operation of the gamma knife control system.

C. To demonstrate compliance with 4731.2090, submit detailed calculations of maximum radiation levels (and dose rates) that will exist in each area (restricted and unrestricted). The calculations should include the following:

1. The expected radiation levels for each area adjacent to the room housing the device. The radiation levels should consider the most adverse source orientations and maximum source activity used in the device. This includes:
  - maximum source strength
  - combination of sources used for treatment
  - source orientation
  - room size
  - layout
  - treatment time

These calculations should be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s) meet the requirement of 4731.2090.

2. Specify all parameters used to perform the calculations described above. These parameters should include such factors as distance to each area of concern, the type and thickness of materials used in barriers and shields, and the transmission factor of the barriers or shields, and the maximum source strength.
3. The maximum anticipated workload data, such as maximum use time per hour and per week, that will be used in a dedicated room and occupancy factors used for all adjacent areas.
4. Calculations to determine the dose received by individuals present in unrestricted areas should consider continuous occupancy (occupancy factor of one) unless you can make a compelling argument for using a lower value. Calculations to determine the dose received by ancillary staff providing patient care during treatment should include full details of the occupancy factors used.
5. Results of the calculations are to be expressed in units of rem (or millisieverts) in any one hour or year, as appropriate.
6. You should demonstrate that the limits will not be exceeded. If your calculations demonstrate compliance with these limits, outline the steps taken to limit exposure to individual members of the public. Options that may be considered include:
  - a. Adding shielding to the barrier in question with a corresponding modification of the facility description (if necessary).
  - b. Request an exemption and demonstrate how the requirements of 4731.2090 will be met. You should demonstrate the need for and the expected duration of operations that will result in an individual dose exceeding the limits. A program to assess and control dose within the 0.5 rem (five mSv) annual limit and procedures followed maintaining the dose as low as is reasonable achievable should be developed and submitted for review.

D. Confirm the implementation of a survey program to demonstrate compliance with dose limits for members of the public. Submit a description of the program. The program should

include requirements for conducting surveys following source replacement. At a minimum, the survey program should be sufficient to confirm the following:

1. Radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of the occupational dose limits.
2. Radiation levels in unrestricted areas will not result in a dose to any member of the public in excess of the limits specified in 4731.2090.
3. Records of survey results will be maintained for inspection by the MDH for the duration of the license.

**Radiation Monitoring Instruments**

Describe any other equipment and facilities available for the use and/or storage that is listed in Item 6 of this application. Provide the manufacturer name, model number, and range of the survey instruments being used. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
LGD Scientific, Inc.	MSB-000	1 - 100000 cpm

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide for survey instrument calibration from the MDH.

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

**Item 10: Radiation Safety Program**

The RSO will promptly review all exposure records to look for workers or groups of workers whose exposures are unexpectedly high or low. This procedure does not apply to backup monitor records (for example, pocket ionization chambers) when the monitor of record is a thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

**Quality Management Program**

Each licensee reviews its operating procedures to ensure that they incorporate the following objectives:

- A. Before administration, a written directive is prepared for any gamma stereotactic radiosurgery radiation dose.
- B. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.
- C. Final plans of treatment and related calculations are in accordance with the respective written directives.
- D. Each administration is in accordance with the written directive.
- E. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

The licensee must retain each written directive and a record of each administered radiation dose for three years after the date of administration.

### ***Operating Procedures***

A. Submit a copy of your operating and emergency procedures. Minnesota Department of Health Radioactive Materials Rules, Chapter 4731.4466, provides the safety instructions that are required for operation of this type of device. However, in addition to the rules you may wish to incorporate the following into your operating procedures:

1. The device(s), console, and treatment or storage room will be secured when unattended.
2. During patient treatments, personnel must be immediately available to address radiological concerns and to serve as a resource in case of radiological problems. The appropriate personnel are:
  - The authorized user
  - The medical physicist
  - The Radiation Safety Officer

One or more of these individuals must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech. If the medical physicist is not physically present, that individual must be readily available during patient treatment.

Submit the protocol indicating who will be physically present during patient treatment and any actions that must be implemented to ensure that the medical physicist is readily available. Submit any alternative procedures for MDH review.

B. Chapter 4731.4474 provides the output spot checks and the required frequency. Confirm that as a minimum, the safety checks will be performed and that written, as well as verbal, instruction will be provided to individuals assigned to complete the checks.

A description of the method used to perform the checks and the frequency with which they will be made should be submitted for review. (At a minimum, the checks should be conducted monthly.) The operating procedures should specify when and how the checks are completed, and who completes them.

### ***Emergency Procedures***

A. Submit for review the emergency procedures approved by the authorized user(s) and Radiation Safety Officer or medical physicist. You should confirm that copies of the procedures will be provided to device operators, authorized users, and other personnel as necessary. In addition, a copy of the procedures should be posted at the device control console or in a conspicuous location at the treatment area.

B. At a minimum, the procedures should address the following:

1. The procedures to be implemented if the source cannot be fully shielded.
2. The means of controlling radiation exposures to personnel while manually closing the shield doors.
3. The means of physically removing the patient from the unit if the sliding cradle fails to retract as designed.
4. Systematic actions for single or multiple equipment failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios.

5. Requirements to restrict and post the treatment area with appropriate signs to minimize the risk of inadvertent exposure of personnel not directly involved in emergency recovery operations.
  6. The location of the equipment that may be necessary for the various equipment failures described in the procedure.
- C. During patient treatments, a device operator trained in the emergency procedures should be physically present at your facility. The medical physicist or Radiation Safety Officer and the authorized user should be available for prompt assistance in the event that the shielding doors become jammed. The authorized user, medical physicist or Radiation Safety Officer should be immediately notified of any problems encountered during a treatment. Device operators will follow the instructions of the authorized user, medical physicist, or the Radiation Safety Officer and implement emergency procedures as necessary.
- D. Commit to implement immediately applicable emergency procedures if the survey indicates that the source is not fully in a shielded position.

### **Maintenance**

- A. Confirm that only personnel who are licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such services will perform maintenance and repair on the device. Maintenance and repair includes installation, replacement, relocation or removal of the sealed source or the device that contains a sealed source. Maintenance and repair also means any adjustment involving any mechanism on the device, treatment console, or interlocks that could expose the source, reduce the shielding around the source, or affect the shield door drive controls.

Confirm that a record of any maintenance and repair performed on the device will be maintained for the duration that the device is in use. The record should include:

- the date of repair
  - a description of the nature of the maintenance or repair
  - the name of the individual who performed the repair
  - the Agreement State or NRC license number authorizing the individual who performed the repairs
- B. The requirements for full calibration of the device are included in 4731.4471.
- C. In addition to a full calibration, the licensee must ensure that each device will be fully inspected and serviced at a frequency not to exceed five years. The specific requirements associated with inspections are included in 4731.4477.
- D. You may request authorization for an employee trained by the manufacturer to perform maintenance and repair functions. Such authorization should list the employee by name. It should specify the maintenance and repair functions described in a certificate or letter from the manufacturer of the device documenting the training. A copy of the training certification and an outline of the training should be submitted with the request.

### **Leak Tests**

As a licensee, you must perform leak testing of sealed sources. The MDH requires tests to determine whether or not there is any leakage from the radioactive source(s). 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 send the sample to the kit supplier who will report the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurements.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to the following or submit your own procedures.

1. Identify the sources to be tested. This should include the isotope, the activity on a specified date, and the physical form.
2. Set out a survey meter, preferably with a speaker, so you can monitor your exposure rate. A survey should be done to be sure that sources are adequately shielded during the leak test period.
3. Prepare a cotton swab, injection prep pad, filter paper, or tissue paper. Number each wipe so you will know the location from which it was taken. Samples should be taken as follows:
  - a. Take the wipe with the sources in the shielded position.
  - b. Take the wipe on the shield doors and areas near the radiation port.

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 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.

#### ***Annual Audit of the Radiation Safety Program***

Annual audits are required by 4731.2010. Currently the MDH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that problems are promptly and comprehensibly corrected. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

The MDH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with MDH rules.

#### **Item 11: Waste Management**

Submit your procedures for waste disposal. Be sure to include a procedure for each material listed in Item 5.

## **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

## **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

## **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of byproduct material are capable of complying with MDH rules. This guide provides one set of methods approved by 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.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR GAS CHROMATOGRAPHS AND X-RAY FLUORESCENCE ANALYZERS

The logo is circular with the text "Radioactive Materials Group" at the top and "Minnesota Department of Health" at the bottom. In the center is a stylized figure of a person, and below it is the acronym "RAM".	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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# **REGULATORY GUIDE FOR GAS CHROMATOGRAPHS AND X-RAY FLUORESCENCE ANALYZERS**

## **INTRODUCTION**

This regulatory guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for license to use and possess gas chromatograph devices and x-ray fluorescence analyzers. An example of a gas chromatograph device is a device that contains a Hydrogen-3 or Nickel-63 foil source. Fluorescence analyzers normally contain Iron-55, Cadmium-109, Americium-241 or Curium-244.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in the 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.

## **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.

## **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 this 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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**

For each gas chromatograph device or fluorescence analyzer, provide the following:

1. Identify each radioisotope.
2. Identify the manufacturer and model number of each foil source, plated source or sealed source.
3. Specify the amount of radioactive material that will be in each foil source, plated source or sealed source.
4. Identify the manufacturer and model number of the device in which the sealed sources will be used.

You should consult with your proposed supplier for this information to be sure that your sources and devices conform to the sealed source and device designations registered with the US Nuclear Regulatory Commission (NRC) or an Agreement State. You do not have to list exempt calibration and reference sources.

**NOTE:** It is the practice of MDH to provide flexibility in the number of identical sealed source/device combinations you may want to possess at any one time. Therefore, it is not necessary for you to specify the number of identical source/device combinations. You will need to amend your license before you obtain a device other than those listed in Item 5.

**Item 6: Purpose(s) for Which Licensed Material Will Be Used**

Specify the purpose for which the gas chromatograph or fluorescence analyzer device you want to possess will be used. For example, a gas chromatograph is normally used for analyzing organic and non-organic compounds. In order for devices to be used safely, the device should be used only for the purposes for which it was designed and in accordance with the manufacturer's recommendations for use.

**Item 7: Individual(s) Responsible for Radiation Safety Program**

***Radiation Safety Officer (RSO)***

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience in radiation protection and the handling of the devices. Even if the licensee employs a consultant to assist the RSO, the licensee is still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations that are considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that the devices are used only by authorized individuals and in a safe manner. The RSO's duties and responsibilities should include those areas listed in Appendix A. You should commit to Appendix A or its equivalent.

***Authorized Users***

Unless you propose to perform maintenance or repairs, no specific training is necessary. However, individuals who will use devices or supervise their use should review the operating manual. No special training or experience is needed to perform leak tests using a leak test kit or to clean detector cells used in gas chromatograph devices provided the source or foil is not removed from the detector cell. Proposed users should not be named. *State that no maintenance or repair will be performed and that all users will follow the instructions in the operating manual.*

If you propose to perform any operations that involve removal of sources from the device or maintenance and repair of a device that involves the source, only a responsible individual may perform these operations. This responsible individual must have received instruction and training in the principles and practices of radiation safety, the use of radiation detection instruments, and the performance of these operations. Such training may normally be accomplished through a one- or two-day training from the manufacturer or equivalent. In your application, you should provide the following information:

1. The specific operations you wish to perform.
2. The name of each responsible individual who will perform the operations.
3. An outline of the instruction and training each responsible individual has received in the principles and practices of radiation safety, the use of radiation detection instruments, and the operations that will be performed, including actual practice in performing the operations. The amount of time spent on each topic in the training should be specified.
4. The name and affiliation of the person who provided the instruction and training and this person's qualifications to conduct the operations.

### **Item 8: Training for Individuals Working In or Frequenting Restricted Areas**

Describe your training program for individuals who work near the devices. This includes all employees (clerical, delivery, security, and housekeeping). Training should cover regulations, in-house work rules, and the location of posted notices and copies of regulations and the license.

### **Item 9: Facilities and Equipment**

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

1. A description of where the device will be stored when not in use or at field locations.
2. The security measures taken during storage and use when not at field locations. You should state that the room, laboratory, or area in which the device is located will be (a) accessible only to persons authorized to use the device and (b) locked when an authorized person is not physically present.
3. The security measures to be taken when stored in the field. State that
  - (a) the device will be locked in the trunk of a car, hidden from view while in a locked van. A restricted area does not include areas used as residential quarters, motel rooms, or occupied offices because they are accessible to unauthorized persons.
  - (b) the device will be physically watched by an authorized user at all times when the device is not in storage. It is not acceptable for a device to be left lying unattended at the place of use during lunch or breaks because the device would then be accessible to unauthorized persons.

Any change to permanent storage locations cannot be made unless approved by an amendment to the license.

### **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 A through K. 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."

Appendix A	Duties and Responsibilities of the Radiation Safety Officer
Appendix B	Leak Testing Sealed Sources

#### ***Leak Testing of Sealed Sources***

Each sealed source must be tested for leakage at intervals not to exceed 6 months. The leak test should be performed at 6-month intervals. The instrumentation should be sufficiently sensitive to detect 0.005 microcuries of radioactivity.

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. Use a commercial leak test kit. You take the smear and send the smear to the kit supplier, who will report the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurements.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier. In your application, you should state that the test samples will be taken by the individuals specified in Item 8 who are responsible for your radiation safety program. Commit to Appendix C.1.

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 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.

### ***Maintenance***

If you wish to request authorization to perform the maintenance and repair operations, you should state in your application what maintenance you wish to perform. Commit to following the written procedures provided by the device manufacturer for each such operation requested. If you will follow a procedure other than that provided by the device manufacturer, you should submit the procedure you propose to use for each operation requested.

You should state that any maintenance you will perform (such as cleaning) will always be done with the radioactive source in the safe shielded position. You may not do any maintenance unless the source is safely shielded.

To take the radioactive source out of the device, you must have special training and procedures, use a radiation survey meter, and take appropriate radiation safety precautions. If you plan to remove the source from the device for exchange or maintenance, your license must specifically authorize those procedures.

### ***Radiation Detection Equipment***

You do not need to have a radiation survey meter during routine use. If you plan to perform servicing that requires removal of the source from its shielded position, you must have a survey meter that is calibrated annually.

State that you do not intend to service the devices, or provide information concerning the survey meters available for use.

### ***Personnel Monitoring Equipment***

Personnel monitoring equipment is not normally required for gas chromatographs or x-ray fluorescent analyzer users. If you propose to service the gauges yourself, you should provide personnel monitoring devices for your personnel who will perform the operations. Film badges, thermoluminescent dosimeters (TLDs), or optically stimulated dosimeters (OSD) are acceptable.

### ***Inventories***

State that you will conduct inventories at intervals not to exceed six (6) months, to account for all sealed sources received and possessed under your license. You should maintain records of the inventories for at least three years from the date of the inventory. The records should include the radionuclide and amount of material in each source, the manufacturer's name, model number and serial number of each gauge, the location of each, and the date of the inventory.

### ***Annual Audits***

Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure compliance with MDH rules and the terms and conditions of the license. Records of audits and other reviews of program content are maintained for three years.

As part of your audit programs, you should consider performing unannounced audits of your authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

Once problems are identified, it is essential that they are corrected promptly and comprehensively. MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. MDH will normally exercise discretion and not cite violations previously identified and corrected by the licensee. The licensees are encouraged to regulate their own compliance.

An audit program for a portable gauge should include a review of:

- ✓ leak test records and procedures
- ✓ inventory records
- ✓ training
- ✓ the operating and emergency procedures
- ✓ survey instrument calibration records and procedures (if applicable)

You, as the licensee, are responsible for the content and implementation of your radiation safety program and for all actions of your employees.

### ***Operating and Emergency Procedures***

You should state on your application that you will provide the operating and emergency procedures to each person who uses the device. Submit the detailed operating and emergency procedures to the MDH for review. You should cover these topics in your procedures:

- Use of personnel monitoring - all personnel who use the device should wear their personal dosimeters if they are performing device maintenance or repair.
- Use of the device - systematic procedures for the use of the device.
- Storage of the device.
- Transportation - procedures for transporting devices to and from work sites.
- Emergency procedures - actions that workers should take in the event of an emergency. (Include individuals to be notified and their telephone numbers.)

### ***Transportation to Field Locations***

It is your obligation to obtain a copy of the DOT regulations on transportation of radioactive materials. The requirements for package labeling are in subpart E of 49 CFR Part 172 of the DOT regulations. General requirements for shipping and packaging radioactive material are in Subpart I of 49 CFR Part 173 of the DOT regulations. A copy of these regulations can be obtained by writing to the following address:

US Government Bookstore  
120 Bannister Road  
Kansas City, MO 64137  
(816) 765-2256

You should state in your application that packaging and transport of the device will be carried out in accordance with the applicable DOT regulations.

### **Item 11: Waste Management**

The only option for disposal of the licensed material contained in portable gauges is to transfer the material to an authorized recipient. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it. Authorized recipients are the original suppliers of the device, a commercial firm licensed by an Agreement State or the NRC to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

### **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

### **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

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An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

## **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of byproduct material are capable of complying with MDH rules. This guide provides one set of methods approved by 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  
DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)**

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for Radiation Safety Officer Duties published in Appendix A to the MDH Regulatory Guide for Gas Chromatographs and X-Ray Fluorescence Analyzers."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. Say on your application, "We have developed an RSO procedure for your review that is appended as Appendix A," and submit your procedure.

**MODEL PROCEDURE**

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include ensuring the following:

1. Licensed material is limited to the kinds, quantities and forms listed on the license.
2. Individuals using the material are properly trained, designated by the RSO, and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Material is properly secured against unauthorized removal at all times when material is not in use.
4. Proper authorities are notified in case of accident, damage, fire, or theft.
5. Audits are performed at least annually to ensure that:
  - a. The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained and approved users),
  - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA, and
  - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
6. Results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three (3) years. Ensure prompt action is taken to correct deficiencies.
7. Audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
8. Licensed material is transported in accordance with all applicable DOT requirements.
9. Licensed material is disposed of properly.
10. The facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.

11. The license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

## **APPENDIX B LEAK TESTING SEALED SOURCES**

You may use the following model procedure to leak test sealed sources. If you 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 (B.1 and/or B.2) to the MDH Regulatory Guide for Gas Chromatographs and X-Ray Fluorescence Analyzers."

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. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix B," and submit your leak test procedure..

### **B.1. MODEL PROCEDURE FOR TAKING SAMPLES**

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, you should also check for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

### **B.2. MODEL PROCEDURES FOR ANALYZING LEAK TEST SAMPLES**

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect the levels listed in 40.32. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with either a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a certified check source that has the same isotope as the sealed. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries 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 three years.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR HIGH DOSE RATE AFTERLOADERS

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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## REGULATORY GUIDE FOR HIGH DOSE RATE AFTERLOADERS

### INTRODUCTION

The Minnesota Department of Health (MDH) regulates the intentional internal or external administration of radioactive material or the radiation from radioactive material to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Chapter 4731 of the Minnesota Department of Health Rules.

MDH usually issues a single radioactive material license to cover the radioisotope program. However, separate licenses must be obtained for the following applications:

- gamma stereotactic radiosurgery devices (gamma knives)
- high-, medium-, and low-dose rate afterloaders
- irradiators
- nuclear powered pacemakers
- teletherapy devices

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the rules identified in Chapter 4731 and 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.

This guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for use of high dose-rate devices. It describes the regulations for their use as well as specific information on the survey instruments, radiation monitors, performance of required surveys, and operating and emergency procedures associated with a high dose rate afterloader. Guidance for medium, low and pulsed dose rate afterloaders may be similar to those for a high dose rate afterloader. However, some conditions may be relaxed based on the hazards of operation.

### DEFINITIONS

This guidance defines the following terms as:

- **High dose rate (HDR)** -- a dose rate of 20 or more centigray (rads) per minute.
- **Medium dose rate (MDR)** -- a dose rate between 200 centigray (rads) per hour and 20 centigray (rads) per minute.
- **Low dose rate (LDR)** -- a dose rate of 4 to 200 centigray (rads) per hour.
- **Pulsed dose rate afterloader (PDR)** -- a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose rate" range, but is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour. Based solely on their instantaneous exposure rate, these devices are treated the same as high dose-rate devices in this document.

### 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.

## **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 this 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and /or used at a field station, give the specific address of each field station.

If radiography 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**

Provide the following information for each radionuclide:

1. Radionuclide.
2. Manufacturer's name and model number.
3. Maximum activity per device. The activity may not exceed the activity specified by the manufacturer for the specific device and source combination.
4. Maximum number of sources to be possessed at any one time. You may wish to request authorization for sources used in the device and additional sources for replacement. The replacement sources will be stored in shipping containers until the manufacturer completes the change out. If more than one source model is referenced in item 2, you should indicate the maximum number of sources requested of each model number.
5. Maximum activity of the individual sources.
6. If applicable, you should request authorization for possession of depleted uranium in quantities sufficient to include shielding material in both the devices and source containers used for source exchange. Review and indicate the manufacturer's specifications for each device to determine the total quantity of depleted uranium present in the device in units of kilograms. Indicate whether depleted uranium is used for shielding the source(s) within the device.

Provide the following information for each device:

1. Specify the manufacturer's name, address, and telephone number for each device requested.
2. Indicate the model name and/or number and serial number for each device requested.

#### **Item 6: Purpose(s) for Which Licensed Material Will Be Used**

You should specify the uses or types of treatment planned for the device. Any other intended uses (such as physics calibrations or medical research) should be described so that the intended uses are apparent to the MDH review staff.

#### **Item 7: Individual Users Responsible for the Radiation Safety Program**

Responsible individuals include the authorized users and the RSO. An applicant is required by 4731.4411 to be qualified by training and experience to use the requested radioactive materials for the purposes

requested in such a manner as to minimize danger to public health and property. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience. 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.

#### ***Authorized Users For Medical Uses***

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiation dosage or dose and how it is to be administered.
3. Use of the radioactive material or supervising the use by technologists or other paramedical personnel in the use of radioactive material.
4. Interpretation of diagnostic procedures and the evaluation of therapy procedures.

Applicants must meet recentness of training requirements as described in 4731.4415. Authorized user applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Technologists, therapists, or other personnel may use radioactive material for medical use under an authorized user's supervision in accordance with 4731.4407, "Supervised Individuals."

There is no MDH requirement that an authorized user must render an interpretation of a diagnostic image or results of a therapeutic procedure. MDH recognizes that the authorized user may or may not be the physician who interprets such studies. Additionally, MDH rules do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

All training for users of high dose rate afterloader units must comply with the specifications in 4731.4479.

#### ***Radiation Safety Officer (RSO)***

Radiation Safety Officers must have adequate training and experience. The training and experience requirements for the RSO are described in 4731.4411 and 4731.4479 and allow for the following four training pathways:

- Certification by one of the professional boards recognized by MDH in 4731.4479.
- Didactic training and work experience as described in 4731.4479.
- Didactic training, work experience, and preceptor statement as described in 4731.4411(B).
- Identification on the license as an Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO.

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 4731.4405, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities to ensure that radioactive materials are used in a safe manner. MDH requires the name of the RSO on the license, and an agreement in writing from the RSO to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. MDH has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 4731.4405.

### ***RSO Responsibilities***

Some of the typical duties and responsibilities of Radiation Safety Officers include ensuring the following:

- Unsafe activities involving licensed materials are stopped
- Radiation exposures are ALARA
- Material accountability and disposal
- Interaction with MDH
- Timely and accurate reporting and maintenance of appropriate records
- Annual program audits
- Proper use and routine maintenance
- Personnel training
- Investigation of incidents involving radioactive material (e.g., medical events)

Applicants are reminded of recentness of training requirements. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the following:

- Name of the proposed RSO.
- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

One of the following is also needed:

- Copy of the certifications for the boards recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.
- Description of the training and experience specified in 10 CFR 35.900(b).
- Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.

In addition, provide both of the following:

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

### ***Authorized Medical Physicist (AMP)***

At many licensed medical facilities conducting radiation therapy treatments, an Authorized Medical Physicist is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in 4731.4415. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, medical physicist applicants

must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the name of the proposed AMP and one of the following:

- Previous license number or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named as an Authorized Medical Physicist for the units requested.
- Copy of the certification(s) for the board(s) recognized by NRC in 4731.4412 or 4731.4479.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4479 for the units requested.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4412 for the units requested.

Also provide the following:

- Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized Medical Physicist has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

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

Describe your training program for individuals who work with or near radioactive material.

**Item 9: Facilities And Equipment**

***Facilities***

Submit annotated drawings of each dedicated treatment room indicating:

1. Scale, plan and elevation.
2. Identification of the rooms, including room numbers.
3. Type, density and thickness of all shielding materials, including walls, floor and ceiling.
4. The location of the high dose rate afterloader within the room. Include distances from the isotope center of the device to walls, doors, etc.
5. Location of doors, windows, and conduit.
6. Distance to and the nature of use for adjacent areas with indication of whether the areas are restricted or unrestricted, as defined in Chapter 4731.

**NOTE:** The information provided should be sufficient to enable MDH staff to conduct an independent review of the shielding design. To that end, distances from the source center should be referenced.

Treatments must be performed in rooms specially constructed or modified for radiosurgery. The use of high dose rate afterloaders must be restricted to the specific room described in your application. Relocation of a device to another area of use requires prior MDH approval.

### **Equipment**

A. If the high dose rate afterloader is not equipped with viewing and intercom systems, you should equip the treatment room to allow for patient observation during treatment. A description of the systems should be provided with the application and should include:

1. The primary intercom and viewing systems.
2. Backup systems to be used if the primary systems fail. Alternatively, you should commit to suspend treatments until the primary system is repaired.

You should describe the following:

- How the patient and device will be monitored during treatment.
- How to provide for prompt detection of any operational problems with the device during treatment.

B. Provide a description of the security to be provided for the room where a device is to be used or stored. Areas should be secured in accordance with 4731.2290. A description of the following is required:

1. The physical or administrative control of access.
2. The electrical interlock system installed at each entry, including the result of interrupting the interlock when the source is exposed.
3. The actions required following interruption of the interlock before resuming treatment, including confirmation that the interlock must be reset before the device can be activated.
4. The actions required in case of malfunction of the interlock system. You should confirm that if the system malfunctions, the shielding doors will be closed. Verify that the system will not be used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
5. The restricted area controls (e.g., signs, locks, visible and audible alarms, etc.), including descriptions of signs with their locations, sizes and wording. Each suite containing a high dose rate afterloader should be equipped with a radiation monitor. The monitor should be permanently mounted and equipped with an emergency power supply separate from the high dose rate afterloader itself. The monitor must be capable of providing a visible indication (e.g., flashing light, or "Beam On" light) of an exposed or partially exposed source. The indicator must be readily observable by any person entering the treatment room.
6. Provide the methods used to identify the high radiation areas inside the treatment room when the shield doors are open (e.g., colored floor tiles, warning tape, etc.).
7. The method to ensure that whenever the device is not in use or is unattended, the console key(s) will be inaccessible to unauthorized persons.
8. You should confirm that no other radiation-producing devices are located in the treatment room, or provide a description of the mechanisms installed to ensure that only one device can be placed in operation at a time.

9. Verify that the high dose rate afterloader, its control console, or any related components are not within close proximity of equipment that produces a high level of electromagnetic disturbance (i.e., short wave equipment). Those fields have been demonstrated to interfere with the operation of the afterloader control system.
- C. To demonstrate compliance with 4731.2090, submit detailed calculations of maximum radiation levels (and dose rates) that will exist in each area (restricted and unrestricted). The calculations should include the following:

1. The expected radiation levels for each area adjacent to the room housing the device. The radiation levels should consider the most adverse source orientations and maximum source activity used in the device. This includes:
  - maximum source strength
  - combination of sources used for treatment
  - source orientation
  - room size
  - layout
  - treatment time

These calculations should be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s) meet the requirement of 4731.2090.

2. Specify all parameters used to perform the calculations described above. These parameters should include such factors as distance to each area of concern, the type and thickness of materials used in barriers and shields, and the transmission factor of the barriers or shields, and the maximum source strength.
3. The maximum anticipated workload data, such as maximum use time per hour and per week that will be used in a dedicated room and occupancy factors used for all adjacent areas.
4. Calculations to determine the dose received by individuals present in unrestricted areas should consider continuous occupancy (occupancy factor of one) unless you can make a compelling argument for using a lower value. Calculations to determine the dose received by ancillary staff providing patient care during treatment should include full details of the occupancy factors used.
5. Results of the calculations are to be expressed in units of rem (or millisieverts) in any one-hour or year, as appropriate.
6. You should demonstrate that the limits will not be exceeded. If your calculations demonstrate compliance with these limits, outline the steps taken to limit exposure to individual members of the public. Options that may be considered include:
  - a. Adding shielding to the barrier in question with a corresponding modification of the facility description (if necessary).
  - b. Request an exemption and demonstrate how the requirements of 4731.2090 will be met. You should demonstrate the need for and the expected duration of operations that will result in an individual dose exceeding the limits. A program to assess and control dose within the 0.5 rem (five mSv) annual limit and procedures followed maintaining the dose as low as is reasonable achievable should be developed and submitted for review.

- D. Confirm the implementation of a survey program to demonstrate compliance with dose limits for members of the public. Submit a description of the program. The program should include requirements for conducting surveys following source replacement. At a minimum, the survey program should be sufficient to confirm the following:
1. Radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of the occupational dose limits.
  2. Radiation levels in unrestricted areas will not result in a dose to any member of the public in excess of the limits specified in 4731.2090.
  3. Records of survey results will be maintained for inspection by the MDH for the duration of the license.

**Radiation Monitoring Instruments**

Describe any other equipment and facilities available for the use and/or storage that is listed in Item 6 of this application. Provide the manufacturer name, model number, and range of the survey instruments being used. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
LGD Scientific, Inc.	MSB-000	1 - 100000 cpm

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide for survey instrument calibration from the MDH.

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

**Item 10: Radiation Safety Program**

The RSO will promptly review all exposure records to look for workers or groups of workers whose exposures are unexpectedly high or low. This procedure does not apply to backup monitor records (for example, pocket ionization chambers) when the monitor of record is a thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

**Quality Management Program**

Each licensee reviews its operating procedures to ensure that they incorporate the following objectives:

- A. Before administration, a written directive is prepared for any high dose rate afterloader radiation dose.
- B. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.
- C. Final plans of treatment and related calculations are in accordance with the respective written directives.
- D. Each administration is in accordance with the written directive.

- E. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

The licensee must retain each written directive and a record of each administered radiation dose for three years after the date of administration.

### ***Operating Procedures***

- A. Submit a copy of your operating and emergency procedures. Minnesota Department of Health Radioactive Materials Rules, Chapter 4731.4466, provides the safety instructions that are required for operation of this type of device. However, in addition to the rules you may wish to incorporate the following into your operating procedures:

1. The device(s), console, and treatment or storage room will be secured when unattended.
2. During patient treatments, personnel must be immediately available to address radiological concerns and to serve as a resource in case of radiological problems. The appropriate personnel are:
  - The authorized user
  - The medical physicist
  - The Radiation Safety Officer

One or more of these individuals must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech. If the medical physicist is not physically present, that individual must be readily available during patient treatment.

Submit the protocol indicating who will be physically present during patient treatment and any actions that must be implemented to insure that the medical physicist is readily available. Submit any alternative procedures for MDH review.

- B. Chapter 4731.4473 provides the output spot checks and the required frequency. Confirm that as a minimum, the safety checks will be performed and that written, as well as verbal, instruction will be provided to individuals assigned to complete the checks.

A description of the method used to perform the checks and the frequency with which they will be made should be submitted for review. (At a minimum, the checks should be conducted monthly.) The operating procedures should specify when and how the checks are completed, and who completes them.

### ***Emergency Procedures***

- A. Submit for review the emergency procedures approved by the authorized user(s) and Radiation Safety Officer or medical physicist. You should confirm that copies of the procedures will be provided to device operators, authorized users, and other personnel as necessary. In addition, a copy of the procedures should be posted at the device control console or in a conspicuous location at the treatment area.

- B. At a minimum, the procedures should address the following:

1. The procedures to be implemented if the source cannot be fully shielded.
2. The means of controlling radiation exposures to personnel while manually closing the shield doors.
3. The means of physically removing the patient from the unit if the sliding cradle fails to retract as designed.

4. Systematic actions for single or multiple equipment failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios.
  5. Requirements to restrict and post the treatment area with appropriate signs to minimize the risk of inadvertent exposure of personnel not directly involved in emergency recovery operations.
  6. The location of the equipment that may be necessary for the various equipment failures described in the procedure.
- C. During patient treatments, a device operator trained in the emergency procedures should be physically present at your facility. The medical physicist or Radiation Safety Officer and the authorized user should be available for prompt assistance in the event that the shielding doors become jammed. The authorized user, medical physicist or Radiation Safety Officer should be immediately notified of any problems encountered during a treatment. Device operators will follow the instructions of the authorized user, medical physicist, or the Radiation Safety Officer and implement emergency procedures as necessary.
- D. Commit to implement immediately applicable emergency procedures if the survey indicates that the source is not fully in a shielded position.

#### ***Maintenance***

- A. Confirm that only personnel who are licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such services will perform maintenance and repair on the device. Maintenance and repair includes installation, replacement, relocation or removal of the sealed source or the device that contains a sealed source. Maintenance and repair also means any adjustment involving any mechanism on the device, treatment console, or interlocks that could expose the source, reduce the shielding around the source, or affect the shield door drive controls.

Confirm that a record of any maintenance and repair performed on the device will be maintained for the duration that the device is in use. The record should include:

- the date of repair
- a description of the nature of the maintenance or repair
- the name of the individual who performed the repair
- the Agreement State or NRC license number authorizing the individual who performed the repairs

- B. The requirements for full calibration of the device are included in 4731.4470.
- C. In addition to a full calibration, the licensee must ensure that each device will be fully inspected and serviced at a frequency not to exceed five years.
- D. You may request authorization for an employee trained by the manufacturer to perform maintenance and repair functions. Such authorization should list the employee by name. It should specify the maintenance and repair functions described in a certificate or letter from the manufacturer of the device documenting the training. A copy of the training certification and an outline of the training should be submitted with the request.

#### ***Leak Tests***

As a licensee, you must perform leak testing of sealed sources. The MDH requires tests to determine whether or not there is any leakage from the radioactive source(s). 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 send the sample to the kit supplier who will report the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurements.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to the following or submit your own procedures.

1. Identify the sources to be tested. This should include the isotope, the activity on a specified date, and the physical form.
2. Set out a survey meter, preferably with a speaker, so you can monitor your exposure rate. A survey should be done to be sure that sources are adequately shielded during the leak test period.
3. Prepare a cotton swab, injection prep pad, filter paper, or tissue paper. Number each wipe so you will know the location from which it was taken. Samples should be taken as follows:
  - a. Take the wipe with the sources in the shielded position.
  - b. Take the wipe on the shield doors and areas near the radiation port.

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 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.

#### ***Annual Audit of the Radiation Safety Program***

Annual audits are required by 4731.2010. Currently the MDH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that problems are promptly and comprehensibly corrected. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

The MDH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with MDH rules.

#### **Item 11: Waste Management**

Submit your procedures for waste disposal. Be sure to include a procedure for all material listed in Item 5.

## **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

## **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

## **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of byproduct material are capable of complying with MDH rules. This guide provides one set of methods approved by 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.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR INDUSTRIAL RADIOGRAPHY

	<p><b>Radiation Control Unit</b> <b>Asbestos, Lead, Indoor Air &amp; Radiation Section</b> <b>Division of Environmental Health</b> <b>Minnesota Department of Health</b></p>
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January 2005

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## **REGULATORY GUIDE FOR INDUSTRIAL RADIOGRAPHY**

### **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 the use of sealed sources used in industrial radiography. The term radiography as used in this guide means the examination of the structure of materials by nondestructive methods that use gamma-emitting radionuclides. The radionuclides most commonly used are Cobalt-60 and Iridium-192.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in this guide and then complete the application. MDH may request additional information when necessary to provide reasonable assurance that you have 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 by-product material program to ensure the continued safe use of by-product material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

### **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 proprietary 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 NRC, MDH, or other Agreement State 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 or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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**

#### ***Sealed Sources and Devices***

Applicants must provide the manufacturer's (or distributor's) name and model number for each requested source assembly (sealed source), exposure device, and source changer. Licensees will only be authorized for radiographic exposure devices, source assemblies or sealed sources containing radioactive material and associated equipment meeting MDH requirements and specifically approved or registered by the US Nuclear Regulatory Commission (NRC) or an Agreement State. Also, identify any depleted uranium that is used as shielding material. (Radiographic exposure devices, source changers and some collimators contain depleted uranium).

The NRC or an Agreement State performs a safety evaluation of radiography source assemblies (sealed sources) exposure devices and source changers before distribution of these sources/devices to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate issued to the manufacturer (or distributor). Therefore, if the source assemblies, exposure

devices, or source changers are approved for use by the NRC or an Agreement State, the applicant need only note the manufacturer's (or distributor's) name and model number of the sources or devices in its license application to demonstrate that the requirements are met.

Consult with the proposed supplier to ensure that sources and devices conform to the sealed source and device designations registered with the NRC or an Agreement State. To ensure that radiographic equipment is used in accordance with registration certificates, licensees may want to review the certificate, discuss with the manufacturer, or obtain a copy of the certificate. Licensees may not make modifications to exposure devices, source changers, source assemblies and associated equipment unless the design of any replacement component would not compromise the safety features of the system.

Consult with the manufacturer of the associated equipment (i.e., equipment that is used in conjunction with the exposure device that drives, guides, or comes in contact with the source) to be sure that the associated equipment is compatible with the sources and devices.

Identify each radionuclide that will be used. Identify the manufacturer (or distributor) and model number of each sealed source, source assembly, exposure device, and/or source changer to be possessed. Identify any depleted uranium that is used as shielding material.

Confirm that each sealed source, device, and source/device combination possessed is registered as an approved sealed source or device by MDH and will be possessed and used in accordance with the conditions specified in the registration certificate.

Confirm that associated equipment is compatible with the exposure devices, source changers, and sealed sources containing radioactive material.

Identify by radioisotope, manufacturer (or distributor), and model number any other sealed sources containing radioactive material (i.e., any source that will not be used for performing radiography).

Confirm that all radiographic exposure devices, source assemblies or sealed sources, and all associated equipment which meet the requirements specified in 4731.4030.<sup>1</sup>

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<sup>1</sup> For information on SSD registration certificates, contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.

**Table 1: Industrial Nuclear Model Ir-100 Exposure Device  
(Maximum Authorization -- 120 Ci)**

Element	Sealed Source	Curies	Source Changer Meeting 10 CFR 34 Requirements	Maximum Curies Authorized
Ir-192	• IN Model 32	120 Ci	• Amersham 550-SU • IN IR-50	120 Ci 120 Ci
Ir-192	• IN Model 33	120 Ci	• Amersham 550-SU • IN IR-50	120 Ci 120 Ci
Ir-192	• Amersham 87703	120 Ci	• Amersham 550-SU • Amersham 650L • Amersham 820 • Amersham 855 • IN IR-50	120 Ci 240 Ci 1,000 Ci 960 Ci 120 Ci
Ir-192	• Amersham 87704	120 Ci	• Amersham 550-SU • Amersham 650 • Amersham 820 • Amersham 855	120 Ci 240 Ci 1,000 Ci 960 Ci
Ir-192	• SPEC G-40F	120 Ci	• Amersham 550-SU • SPEC C-1 • IN IR-50	120 Ci 150 Ci 120 Ci
Ir-192	• SPEC G-40T	120 Ci	• Amersham 550-SU • SPEC C-1 • IN IR-50	120 Ci 150 Ci 120 Ci

**Table 2. Spec Model 150 Exposure Device  
(Maximum Authorization -- 150 Ci)**

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Ir-192	• SPEC G-60	240 Ci	• SPEC C-1	150 Ci

**Table 3: Amersham Model 680 System Exposure Device  
(Maximum Authorization -- 110 Ci)**

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Co-60	• Amersham A424-14	110 Ci	• Amersham 770 • Amersham 771	550 Ci 110 Ci
Co-60	• Amersham 943	110 Ci	• Amersham 770 • Amersham 771	550 Ci 110 Ci

**Table 4: Amersham Model 660 System Exposure Device  
(Maximum Authorization – 140 Ci)**

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Ir-192	IN Model 7	100 Ci	Amersham 550 -SU Amersham 650L Amersham 820 Amersham 855 IN IR-50 SPEC C-1	120 Ci 240 Ci 1,000 Ci 960 Ci 120 Ci 150 Ci
Ir-192	CIS-US702	120 Ci	Amersham 550 -SU IN IR-50 SPEC C-1	120 Ci 120 Ci 150 Ci
Ir-192	Amersham 91813	20 Ci	Amersham 650L	240 Ci
Ir-192	Amersham A424-22	240 Ci	Amersham 550 -SU Amersham 650L Amersham 820 Amersham 855	120 Ci 240 Ci 1,000 Ci 960 Ci
Ir-192	Amersham A424-9	240 Ci	Amersham 550 -SU Amersham 650L Amersham 820 Amersham 855 IN IR-50 SPEC C-1	120 Ci 240 Ci 1,000 Ci 960 Ci 120 Ci 150 Ci

***Financial Assurance and Recordkeeping for Decommissioning***

Licensees are required to maintain decommissioning records related to structures where devices are used or stored. Records relating to leaking sources must also be maintained. Licensees must transfer these records important to decommissioning either to any new licensee before licensed activities are transferred or assigned, or to MDH before the license is terminated.

The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most industrial radiography applicants and licensees do not need to comply with the financial assurance requirements because the thresholds for sealed sources containing radioactive material are  $3.7 \times 10^5$  Bq (10,000 curies) of Cobalt-60 and  $3.7 \times 10^6$  Bq (100,000 curies) of Cesium-137 or radioactive material with half-lives less than 120 days (e.g., Iridium-192). Thus, a licensee would need to possess hundreds of sources before the financial assurance requirements would apply. Since the standard industrial radiography license does not specify the maximum number of sources that the licensee may possess (allowing the licensee flexibility in obtaining sources/devices as needed without amending its license), it contains a condition requiring the licensee to limit its possession of sources to quantities not requiring financial assurance for decommissioning. Applicants and licensees desiring to possess sources exceeding the threshold amounts must submit evidence of financial assurance.

The same regulation also requires that licensees maintain records important to decommissioning in identified locations other than at any temporary jobsite. All industrial radiography licensees need to maintain records of structures and equipment where devices are used or stored. As-built drawings showing modifications to structures and equipment fulfill this requirement. If drawings are not available, licensees may substitute appropriate records (e.g., a sketch of the room and building, or a narrative description of the area) concerning the areas and locations. In addition, industrial radiography licensees who have experienced unusual occurrences (e.g., leaking sources or other incidents that involve spread of contamination, such as S-tube breakthrough) also need to maintain records about contamination that remains after cleanup or contamination that may have spread to inaccessible areas.

State the following in your application: "We shall maintain drawings records important to decommissioning. These records will be provided to a new licensee before licensed activities are transferred, or to MDH before the license is terminated."

If financial assurance is required, submit evidence.

#### **Item 6: Purpose(s) for Which Licensed Material Will Be Used**

Sources and devices will be used only for the purposes for which they were designed and in accordance with the manufacturer's recommendations for use as specified in an approved Sealed Source and Device (SSD) Registration Certificate.

The typical license authorizes persons to perform source exchanges and to conduct industrial radiography at temporary jobsites, field stations, and/or permanent radiographic installations. Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses. Applicants who plan to perform radiographic operations on lay-barges or underwater must specifically request these operations.

Specify the purposes for which the sources and device(s) will be used other than those included in the manufacturer's recommendations, as specified on the SSD Registration Certificate.

In addition, specify any plans to perform radiography underwater or on lay-barges.

#### **Item 7: Individual(s) Responsible for Radiation Safety Program**

##### ***Radiation Safety Officer (RSO)***

RSOs and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures must have adequate training and experience.

The person responsible for the radiation protection program is called the RSO. MDH believes the RSO is the key to overseeing and ensuring safe operation of the licensee's radiography program. 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.

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals (potential designees). For example, a large testing company with multiple field stations may appoint individuals designated as site RSOs who assist the RSO and are responsible for the day-to-day activities at the field stations. Licensees may also appoint other individuals who may step in as an emergency contact when the RSO is unavailable. The potential designees do not need to meet the required RSO qualifications; however, these individuals should be qualified, experienced radiographers who are adequately knowledgeable of the activities to which they are assigned. Applicants do not have to identify other responsible individuals if day-to-day tasks, etc. will not be delegated.

MDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO. Provide MDH with a copy of an organizational chart showing the RSO (and other designated responsible individuals) to demonstrate that he or she has sufficient independence and direct communication with responsible management officials. In addition, show in the organizational chart the position of the individual who signs the application.

To be considered eligible for the RSO position, an individual must be a qualified radiographer, have a minimum of 2,000 hours (one year full-time field experience) of hands-on experience as a qualified

radiographer, and have formal training in establishing and maintaining a radiation protection program<sup>2</sup>. This should be a course specifically designed to provide training in running a radiation safety program, a basic radiation safety course is not acceptable. While a course particular to industrial radiography would be highly encouraged, this is not required. Acceptable training programs would be a classroom course typical of those provided through universities or commercial training facilities. Hands-on experience means experience in all areas considered to be directly involved in the radiography process. This includes taking radiographs, surveying device and radiation areas, transporting the radiography equipment to temporary jobsites, posting, work sites, radiation area surveillance, completing and maintaining records, etc. Excessive time spent in only one or two of these operations (film development and/or area surveillance) should not be counted toward the 2,000 hours. Experience with radiography using x-rays can be included; however, the majority of experience should be in isotope radiography.

Provide the name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures<sup>3</sup>. Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position, demonstrating day-to-day oversight of the radiation safety activities.

Provide the following:

- The specific training and experience of the RSO and other potential designees.
- Include the specific dates of certification and/or training in radiation safety.
- Documentation to show that the RSO has a minimum of 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations.
- Documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

OR

- Alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g., Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least one year of experience in the conduct of a radiation safety program of comparable size and scope).
- Documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

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<sup>2</sup> MDH will consider individuals with alternative training and experience as RSOs. For example, a person certified in health physics or industrial hygiene with previous experience in managing a radiation safety program of comparable size and scope could be considered as an individual case. The qualifications, training, and experience required of the RSO may vary depending upon the complexity of the applicant's operations and number of radiography personnel.

<sup>3</sup> It is important to notify MDH and obtain a license amendment before making changes in the designation of the RSO responsible for the radiation safety program. If the RSO leaves the organization before an amendment is approved by the MDH, a potential designee, who meets the RSO qualification requirements, is responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the license and MDH regulations. Alternative responses will be reviewed against the criteria listed above.

**Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Radiographers and Radiographers' Assistants)**

Radiographers and radiographer's assistants must have adequate training and experience. A radiographer is a person who performs or personally supervises industrial radiography. This person is responsible for ensuring compliance with MDH regulations and the safe use of radioactive materials.

A radiographer is an individual who has been certified by a certifying entity to ensure he/she has met established radiation safety, testing, and experience criteria.

A radiographer's assistant is an individual who, under the direct supervision (in the physical presence) of the radiographer, uses radiographic equipment (sealed sources containing radioactive material or related handling tools, exposure devices, and radiation survey instruments) in performing industrial radiographic operations.

4731.4140 describes specific training requirements for radiographers and radiographer's assistants. It requires that all radiographers are certified. It also addresses annual refresher training and semiannual audits of radiographers and radiographer's assistants.

The applicant must submit a description of its training program for radiographers and radiographers assistants.

Because 4731.4140 contains different requirements for radiographers and radiographer's assistants, include training programs for each. When describing the training programs for these positions, include the sequence of events from the time of hiring through the designation of individuals as radiographers or radiographer's assistants. Experienced radiographers who have worked for another licensee should receive formal instruction similar to that given to prospective radiographer's assistants. This instruction must include training in your operating and emergency procedures, in the use of your exposure devices and associated equipment, and in the use of survey meters and other radiation monitoring devices.

Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those obtainable in a course similar to the one given to prospective radiographers. Individuals who provide instruction in the hands-on use of radiography equipment should be qualified radiographers with at least one year of experience in performing radiography, or should possess a thorough understanding of the operation of radiographic equipment (e.g., a manufacturer's service representative).

An internal inspection program (audit program) of the job performance of each radiographer and radiographer's assistant ensures that MDH rules, license requirements, and the licensee's operating and emergency procedures are followed. The audit must include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation at intervals not to exceed 6 months. If a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months, the individual must demonstrate knowledge of the training requirements by practical examination before participating in a radiographic operation. The person conducting internal inspections should have a minimum of one year of actual experience as a radiographer.

Submit an outline of the training to be given to prospective radiographers and radiographer's assistants. Submit your procedures for experienced radiographers who have worked for another licensee.

Provide a copy of a typical examination and the correct answers to the examination questions. Indicate the passing grade.

Specify the qualifications of your instructors in radiation safety principles and describe their experience with radiography. If training will be conducted by someone outside the applicant's organization, identify the course by title and provide the name and address of the company providing the training.

Describe the field (practical) examination that will be given to prospective radiographers and radiographer's assistants. The MDH suggests using the checklist in Appendix B as a source of potential areas to review during the field examination.

Describe the annual refresher training program, including topics to be covered and how the training will be conducted.

Submit your procedures for verifying and documenting the certification status of radiographers and for verifying that their certification remains valid. As a minimum your procedures for newly hired, previously certified individuals should require documentation that you contacted the certifying entity and confirmed the certification. Your procedures should also ensure you are aware of certification expiration dates, and that individuals with expired certifications do not act as radiographers.

Submit a description of your program for inspecting the job performance of each radiographer and radiographers' assistant at intervals not to exceed six months.

### **Item 9: Facilities and Equipment**

#### ***Annotated Drawing for Storage of Devices***

Submit an annotated drawing of the room or rooms and adjacent areas where the radiographic exposure device will be stored. Include the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The type, thickness, and density of shielding materials on all sides of the storage area, including the floor and roof.
3. Types of posting and their locations.
4. The locations of entrances and other points of access into the installation.
5. Security controls to prevent unauthorized access.
6. A description of the nature of the areas adjacent to the installation, and the distance to these areas.
7. The results of dose calculations or actual radiation measurements adjacent to, above, and below the installation.

#### ***Annotated drawing for permanent installation***

Submit an annotated drawing of the room or rooms and adjacent areas where the radiographic exposure device will be stored. Include the following:

1. Identify its location and describe the visible and audible signal system.
2. Submit the results of radiation level calculation or actual radiation measurements adjacent to, above, and below the installation. For determination of installation adequacy, provide information showing that the radiation level in all directions around the installation, including the roof, will not exceed 2.0 mrem (0.02 mSv) in any one hour. Identify the type of source, including isotope, amount, and the location of the source within the facility for the calculations or measurements. Take into account the highest quantity of radioactive material that will be used in the facility and any limitations on source positioning.

Variances will be considered if construction requirements preclude shielding the roof to meet the 2.0 millirem (0.02 mSv) in any one hour. Provide the following information to obtain approval for a variance:

- a. Means of access to the roof.
- b. Procedures for ensuring that no individual is on the roof or could gain access to the roof during performance of radiography.
- c. A commitment that the roof will be posted with "Caution (or Danger) Radiation Area" signs.
- d. Steps taken to minimize radiation on the roof.

A radiation level on the roof that exceeds 100 millirem (1.0 mSv) per hour at 30 cm from the surface will not be considered acceptable. This level constitutes a high radiation area and requires special precautions, such as a visible and/or audible signal system.

- 3. Identify limitations on positioning of sources or type and amount of radioactive material that may be used in the installation to ensure that areas adjacent to, above, and below the installation will be unrestricted areas during performance of radiography.

**Survey Equipment**

Describe your survey instruments. Instrumentation must include the range from 2.0 milliroentgens (0.02 mSv) per hour to 1.0 roentgen (10 mSv) per hour and must be calibrated every six months. Electronic calibrations alone are not acceptable. Records of equipment problems and maintenance performed must be retained for three years. Battery changes are not considered "maintenance."

In order to assure that the radiation surveys are accomplished, you must maintain an adequate number of appropriate radiation survey instruments that are both calibrated and operable at each location where radioactive material is present.

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

**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. In addition to the information in this regulatory guide, the following appendices may be useful in developing your program:

Appendix A	Training
Appendix B	Model Six-Month Radiographer/Radiographer Trainee Inspection Checklist
Appendix C	Model Annual Audit Checklist
Appendix D	Model Procedure for Leak Testing Sealed Sources
Appendix E	Daily Maintenance Check of Radiographic Equipment
Appendix F	Transportation
Appendix G	Operating and Emergency Procedures

### ***Leak Testing of Sealed Sources***

Each sealed source must be tested for leakage at intervals not to exceed six months. The leak test should be performed at six-month intervals. The instrumentation should be sufficiently sensitive to detect 0.005 microcuries of radioactivity.

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. Use a commercial leak test kit. You take the smear and send the smear to the kit supplier, who reports the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurement.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier. In your application, you should state that the test samples will be taken by the individuals specified in Item 8 who are responsible for your radiation safety program. Commit to Appendix D.1.

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 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 Appendices D.1 and D.2.

### ***Maintenance***

Each licensee must inspect radiographic exposure devices, storage containers, and source changers before each day or shift of use. The licensee must also conduct a program of inspection and maintenance of radiographic exposure devices, storage containers, and source changers to ensure proper functioning of components important to safety. Inspections and maintenance should be accomplished at intervals not to exceed three months. If instruments are stored for longer than three months, maintenance should be performed before use. You must commit to a program of inspection and maintenance and submit the procedures.

### ***Transportation of Devices***

The transport of licensed material must be carried out in accordance with the applicable requirements of the Department of Transportation (DOT).

It is your obligation to obtain a copy of the DOT regulations on transportation of radioactive materials. The requirements for package labeling are in 49 CFR Part 172, subpart E of the DOT regulations. General requirements for shipping and packaging radioactive material are in 49 CFR Part 173, subpart I. Write to the following address for a copy of these regulations:

US Government Bookstore  
120 Bannister Road  
Kansas City, MO 64137  
(816) 765-2256

You should state that packaging and transport of the device will be carried out in accordance with the applicable DOT regulations.

The following items should be covered in the instructions to personnel:

- Labeling containers appropriately (i.e., when to use labels Radioactive White I, Radioactive Yellow II, or Radioactive Yellow III.)
- Securing the exposure device or storage container within the transport vehicle.
- Preparation of shipping papers. The instructions should specify that the papers must be completed before transporting licensed material and must be accessible in the driver's compartment at all times.
- Placarding both sides, the front, and the back of the vehicle with "RADIOACTIVE" placards if the package being transported requires a Radioactive Yellow III label.
- If an exposure device is transported in an overpack, the procedures should include instructions that the overpack must be properly marked with the shipping name and identification number, and labeled (Radioactive White I or Radioactive Yellow II).

### ***Inventories***

State that you will conduct inventories at intervals not to exceed three months to account for all sealed sources and devices containing depleted uranium received and possessed under your license. You should maintain records of the inventories for at least two years from the date of the inventory. The records should include the radionuclide and amount of material in each source; the manufacturer's name, model number, and serial number of each device containing depleted uranium or radioactive material; and the location of each device and date of inventory.

### ***Operating and Emergency Procedures***

You should state on your application that you will provide the operating and emergency procedures to each person who uses the device. Submit the detailed operating and emergency procedures to MDH for review. See Appendix G for sample operating and emergency procedures.

### **Item 11: Waste Management**

The only option for disposal of the licensed material contained in industrial radiography devices is to transfer the material to an authorized recipient. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it. Authorized recipients include the original suppliers of the device, a commercial firm licensed by an Agreement State or the NRC to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

### **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

### **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

### **RENEWAL OF A LICENSE**

An application for the renewal of a license should be filed at least 30 days before the license expiration date. This will ensure that the license does not expire before MDH has taken the final action on the application. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of byproduct material are capable of complying with MDH rules. This guide provides one set of methods approved by 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 TRAINING**

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, the application should state, "We will establish and implement the model training program published in Appendix A to MDH Regulatory Guide for Industrial Radiography."

If you prefer, you may develop your own training program. If you do so, carefully review the requirements of 4731.4000. State in your application, "We have established a training program for your review that is appended as Appendix A." Provide a detailed outline of each topic covered in the course.

The safety course for prospective radiographers requires at least 40 hours of classroom instruction. Regardless of whether you choose to implement the model program or one of your own, you should do the following:

- Identify the course segments by title and instructor.
- Submit a description of each demonstration provided in the course.
- If any equipment or visual aids are used, provide a description. These may include filmstrips, videotapes, movies, dummy sources, survey instruments, and handling equipment.
- Provide a copy of books, training manuals, workbooks, and handouts used in the course. If these resources are available commercially, you may instead provide the title, author(s), and publishing companies.
- Submit a copy of a typical examination together with the correct answers to the examination questions. Indicate the passing grade and describe the re-instruction to be given in areas in which individuals are found deficient. Indicate the frequency at which the test will be periodically changed. Provide the security measures taken to protect the examination and the answers.

Records of training will include the date of training. These records will be retained for three years.

### **INSTRUCTOR QUALIFICATIONS**

Identify the instructor who will instruct in the classroom, and the topics in which they will provide instruction.

Submit specific information about the qualifications of the instructors. Include the location and date of their training in the principles of radiation and radiation safety, and identify their industrial radiography experience. The person who instructs individuals in the classroom on the principles of radiation and radiation safety should have a knowledge and understanding beyond that obtainable in a course similar to the one provided to the radiographers. Alternatively, that person should possess a thorough understanding of the operation of radiographic equipment (e.g., a manufacturer's service representative).

## **MODEL PROCEDURE**

Personnel will be instructed

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

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employee will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the RSO.
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure.
9. Locations of notices, copies of pertinent regulations, and copies of the current license (including applications and applicable correspondence).
10. Review of operating procedures.
11. Question and answer period.

**APPENDIX B**  
**MODEL SIX-MONTH RADIOGRAPHER/RADIOGRAPHER TRAINEE INSPECTION CHECKLIST**

Date:	Time:
Radiographic Location:	
Radiographer/Radiographer's Assistant:	
Device Model Number:	Serial Number:

Survey Meter Functionality  Yes  No

Calibrated (date):  Yes  No

Daily source check  Yes  No

Dosimetry  Yes  No

- OSD
- TLD
- Film Badge
- Pocket Dosimeter

Calibrated (date):  Yes  No

Alarming Dosimeter:  Yes  No

Calibrated (date):  Yes  No

- Were other individuals working within the restricted area wearing film badges/TLDs/OSDs dosimeters and alarm dosimeters?
- Was the restricted area posted with the appropriate "CAUTION (or DANGER): RADIATION AREA" sign(s)?
- Was the restricted area properly controlled to prevent unauthorized entry?
- Was the high-radiation area posted with the appropriate "CAUTION (or DANGER): HIGH RADIATION AREA" sign(s)?
- Was the utilization log properly filled out?
- Did the radiographer/radiographer's assistant have sufficient knowledge of safety rules? (Ascertained by oral questions.)
- Was the radiographer working with proper inspected and operable equipment?
- Did the radiographer/radiographer's assistant properly survey the source projector?
- Did the radiographer properly supervise the radiographer assistant?

- Was the source projector properly locked and secured to prevent unauthorized removal?
- Was the restricted area properly controlled?
- Was the high radiation area under continuous direct observation except where entry had been prevented?
- Were radioactive isotopes stored properly and kept locked to prevent removal?
- Was the storage area posted with the appropriate "CAUTION (or DANGER): RADIOACTIVE MATERIAL" sign(s)?
- Did the radiographer/radiographer assistant possess and use a copy of the operating and emergency procedures and MDH rules and regulations for protection against radiation?
- Were there any other safety items found to be lacking? If yes, explain in Remarks.

Remarks:

**APPENDIX C  
MODEL ANNUAL AUDIT CHECKLIST**

**ORGANIZATIONAL STRUCTURE**

- a. Matches license conditions  N/A  Yes  No
- b. Temporary sites authorized  N/A  Yes  No

**RADIATION SAFETY OFFICER**

- a. Named on license  N/A  Yes  No
- b. Fulfills duties as RSO  N/A  Yes  No
- c. Meets requirements  N/A  Yes  No

**RADIOGRAPHER TRAINERS**

- a. Trainers listed in license  N/A  Yes  No
- b. Have appropriate ID card  N/A  Yes  No
- c. Radiographers have ID card  N/A  Yes  No
- d. Radiographer Trainees have trainee status card  N/A  Yes  No

**AUDIT HISTORY**

- a. Last audit conducted on:
- b. Deficiencies identified?  N/A  Yes  No
- c. Were they corrected?  N/A  Yes  No

**SCOPE OF PROGRAM**

- a. Are there multiple authorized locations of use?  
If multiple locations authorized, list locations audited.  N/A  Yes  No
- b. Have there been radiation safety program changes?  
If yes, list changes.  N/A  Yes  No

**TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS**

- a. Instructions to workers provided.  N/A  Yes  No
- b. Training program conducted according to license commitments.  N/A  Yes  No
- c. Radiographers are familiar with:
  - 1. The rules contained in 4731.2000 and 4731.4000  N/A  Yes  No
  - 2. The appropriate conditions of the license or registration  N/A  Yes  No
  - 3. The operating and emergency procedures  N/A  Yes  No
- d. Copies are furnished to radiographer trainees and radiographers  N/A  Yes  No
- e. Specific training
  - 1. Written tests completed by all radiographers and radiographer trainees  N/A  Yes  No
  - 2. Oral tests  N/A  Yes  No
  - 3. All radiographers completed on-the-job training  N/A  Yes  No
  - 4. Periodic training program implemented  N/A  Yes  No
  - 5. Records maintained  N/A  Yes  No

## OPERATING AND EMERGENCY PROCEDURES

- a. Procedures are current  N/A  Yes  No  
b. Procedures contain all required information  N/A  Yes  No

## INTERNAL AUDITS

- a. Audits/inspections of each radiographer and radiographer trainees conducted at six-month intervals or after as appropriate  N/A  Yes  No  
b. Equipment check before use each day  N/A  Yes  No  
c. Equipment inspection and maintenance performed at three-month intervals  N/A  Yes  No  
d. Records maintained  N/A  Yes  No

## FACILITIES

- a. Facilities are as described in the license application.  N/A  Yes  No  
b. Permanent radiographic installations meet MDH requirements  N/A  Yes  No  
1. Visible and audible radiation signals  N/A  Yes  No  
2. Visible signal actuates if entry is attempted when source is exposed  N/A  Yes  No  
3. Audible signal actuates if entry is attempted when source is exposed  N/A  Yes  No  
4. System tested daily with radiation source  N/A  Yes  No  
5. Records maintained for two years  N/A  Yes  No  
c. Entrance controls are as described 4731 part 2000  N/A  Yes  No  
d. High radiation areas posted  N/A  Yes  No  
e. Storage and use of radioactive material  N/A  Yes  No  
(1) Adequate method to prevent unauthorized individuals from entering restricted area.  N/A  Yes  No  
(2) Radioactive material secured to prevent unauthorized removal or access.  N/A  Yes  No  
f. Sources locked in devices  N/A  Yes  No  
g. Devices secured to prevent tampering or unauthorized removal  N/A  Yes  No

## EQUIPMENT

- a. Radiography devices, source assemblies and source changers in use meet requirements  N/A  Yes  No  
b. Associated equipment in use complies with  N/A  Yes  No  
c. Source changers and storage containers have radiation level less than 200 hr/hr (2 mSv) on surface and 10 mrem/hr (0.1 mSv) at one meter  N/A  Yes  No  
d. Equipment exempted by specific license condition is used in accordance with license commitments and authorization  N/A  Yes  No

## MATERIAL

- a. Isotope, chemical/physical form, quantity and use as authorized  N/A  Yes  No  
b. All sealed sources not fastened to or contained in an exposure device are tagged  N/A  Yes  No  
c. During radiographic operations, sources are secured in shielded position each time source is returned to that position  N/A  Yes  No  
d. Leakage and contamination tests  N/A  Yes  No  
e. Sealed sources  N/A  Yes  No  
1. Leak test method approved  N/A  Yes  No  
2. Leak tests performed at 6-month interval  N/A  Yes  No  
3. Leakage is less than 0.005 microcuries (185 Becquerels (Bq))  N/A  Yes  No  
f. Depleted uranium (DU) shielding with S-tubes  N/A  Yes  No

- |  |                              |                              |                             |
|--|------------------------------|------------------------------|-----------------------------|
| 1. Test every 12 months [34.27]                                | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. DU is less than 0.005 microcuries (185 Bq)                  | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Records maintained for 3 years                              | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Inventories   |                              |                              |                             |
| 1. Conducted quarterly (not to exceed 3 months)                | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Contain all required information                            | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Most recent inventory conducted on:                         |                              |                              |                             |
| i. Utilization Logs  |                              |                              |                             |
| 1. Utilization logs maintained                                 | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Contain all required information                            | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| j. Survey instruments  |                              |                              |                             |
| (1) Appropriate operable survey instruments available and used | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Calibration every six (6) months                           | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (3) Records maintained for three years                         | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

### RADIOLOGICAL PROTECTION PROCEDURES

- |   |                              |                              |                             |
|---|------------------------------|------------------------------|-----------------------------|
| a. Individual has understanding of procedures | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (1) In general, rules for safe use            | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Emergency procedures                      | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

### RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- |   |                              |                              |                             |
|---|------------------------------|------------------------------|-----------------------------|
| a. Procedure for opening packages adequate                          | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Incoming packages monitored for external radiation levels        | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Transfers performed, as required                                 | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Records of receipt surveys                                       | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Records of receipt, transfer, & disposal of radioactive material | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

### AREA SURVEYS

- |   |                              |                              |                             |
|---|------------------------------|------------------------------|-----------------------------|
| a. Area or facility surveys conducted   | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Records maintained   | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Survey after each exposure, including device, guide tube, ensuring source has returned to the shielded position  | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Survey of device when place in storage to ensure source is in shielded position  | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Protection of members of the public  | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Adequate surveys made to demonstrate   |                              |                              |                             |
| 1. The TEDE to the individual likely to receive the highest dose does not exceed 100 mrem (0.1 mSv) in a year, or   | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. That if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem (0.02 mSv) in any hour and 100 mrem (1.0 mSv) in a year | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Unrestricted area radiation levels do not exceed 2 mrem (0.02 mSv) in any one hour   | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Records maintained   | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

### PERSONNEL RADIATION MONITORING

- |   |                              |                              |                             |
|---|------------------------------|------------------------------|-----------------------------|
| a. Film badges, TLDs, OSDs                    |                              |                              |                             |
| 1. Supplier NVLAP approved                    | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Dosimeters exchanged at required frequency | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Dosimetry records maintained               | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- b. Dosimeters
  - 1. Read and recorded at start of each shift  N/A  Yes  No
  - 2. Daily readings recorded  N/A  Yes  No
  - 3. Dosimeters checked for response ( $\pm 20\%$ ) at intervals not to exceed 12 months  N/A  Yes  No
  - 4. Off-scale dosimeter procedure and records  N/A  Yes  No
- c. Alarm Ratemeters
  - 1. Checked that alarm functions properly at start of each shift  N/A  Yes  No
  - 2. Preset at 500 mrem (5 mSv) per hour  N/A  Yes  No
  - 3. Calibrated to  $\pm 20\%$  at intervals not to exceed 12 months  N/A  Yes  No
  - 4. Records maintained  N/A  Yes  No
- d. Dose(s) exceeded regulatory limits.  N/A  Yes  No
- e. ALARA program implemented.  N/A  Yes  No
- f. Written description of ALARA program available.  N/A  Yes  No
- g. Workers monitored as required

**WASTE DISPOSAL**

- a. Radioactive material disposed of as authorized.  N/A  Yes  No

**NOTIFICATION AND REPORTS**

- a. Notifications and reports provided to individuals. [  N/A  Yes  No
- b. Reporting theft or loss compliant with rules. [  N/A  Yes  No
- c. Compliant regarding overexposures and notification of incidents.  N/A  Yes  No
- d. Compliant regarding reporting of excessive levels and concentrations.  N/A  Yes  No
- e. Termination reports furnished, if requested by workers.  N/A  Yes  No

**POSTING AND LABELING**

- a. Radiation Areas posted  N/A  Yes  No
- b. High Radiation Areas posted  N/A  Yes  No
- c. Use or storage areas posted "Caution: Radioactive Material"  N/A  Yes  No
- d. Containers or devices labeled  N/A  Yes  No
- e. Notice to Workers posted  N/A  Yes  No
- f. Notice to Employees posted  N/A  Yes  No

**TRANSPORTATION (10 CFR 49)**

- a. Authorized packages used.  N/A  Yes  No
- b. DOT-7A performance test records on file. [173.415(a)]  N/A  Yes  No
- c. For special form sources, performance test records on file. [173.476(a)]  N/A  Yes  No
- d. Packages properly labeled. [172.403(b)]  N/A  Yes  No
- e. Packages properly marked. [172.301(a)]  N/A  Yes  No
- f. Proper shipping papers prepared. [172.200]  N/A  Yes  No
- g. Shipping paper contains emergency response telephone number. [172.201(d)]  N/A  Yes  No

## APPENDIX D MODEL PROCEDURE FOR LEAK TESTING SEALED SOURCES

You may use the following model procedure to leak test sealed sources. If you follow the model procedure for taking leak test samples for analysis by a contractor, you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix (D.1 and/or D.2) to the MDH Regulatory Guide for Industrial Radiography."

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. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix D," and submit your leak test procedure.

### D.1 MODEL PROCEDURE FOR TAKING LEAK 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 greater 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.
  - b. For larger sealed sources and devices, 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.

### D.2 MODEL PROCEDURE FOR ANALYZING LEAK TEST SAMPLES

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect the 0.005 microcuries. 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 either a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries 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 records for three years.

## **APPENDIX E DAILY MAINTENANCE CHECK OF RADIOGRAPHIC EQUIPMENT**

The radiographer or radiographer's assistant shall perform a daily maintenance check of the exposure device and related radiographic equipment. This inspection will be performed before using the equipment on each day the equipment is to be used. Report defective equipment to the RSO immediately. Do **not** attempt to use defective equipment. After the inspection, document the results of the inspection.

1. Inspect the survey meter. If batteries are low, replace, then check for operability. If you are not able to correct a problem with the survey meter, obtain another meter and start over.
2. Check the survey meter with a check source (or check with camera) as indicated on the survey meter<sup>4</sup>. If the reading is not acceptable, obtain another meter and start again.
3. Inspect the remote-control radiographic equipment as follows:

Inspect the cables for cuts, breaks, and broken fittings.

Carefully inspect approximately one foot of the drive cable immediately next to the male connector. Take care not to introduce any dirt or dust on the drive cable during this inspection. In addition to the previously mentioned items, the examination of the cable should look for any of the following:

- excessive or uneven wearing
- fraying
- unraveling
- nicks
- kinks or bends
- loss of flexibility (abnormal stiffness)
- excessive grit or dirt
- stretching

Inspect the crank unit for damage and loose hardware.

Check operation of the control for freedom of drive cable movement.

Inspect the guide tube for cuts, crimps, and broken fittings.

Survey for radiation levels and record readings. The radiation levels should be about the same as those in the previous day's inspection, unless there has been a source change.

Check that all safety plugs are in place.

Inspect the exposure device for damage to fittings, lock, fasteners, and labels.

Check for any impairment of the locking mechanism.

4. Record the results of the daily inspection.

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<sup>4</sup> The RSO or calibration vendor should determine the acceptable meter reading for each survey meter and post the expected reading on each instrument. This reading shall be obtained and noted at the time of calibration

## **APPENDIX F TRANSPORTATION**

The following are the major areas in DOT regulations most relevant for transporting radiographic exposure devices and source exchangers that are shipped as Type B quantities:

- A. Table of Hazardous Materials and Special Provisions - 49 CFR 172.101**
  - 1. 49 CFR 172.101 - Hazardous Materials Table [proper shipping name, hazard class, identification number]
  - 2. Table 2, Appendix A, 49 CFR 172.101 - List of Hazardous Substances and Reportable Quantities [for radionuclides]
  
- B. Shipping Papers - 49 CFR 172.200**
  - 1. 49 CFR 172.201 - General entries [on shipping papers]
  - 2. 49 CFR 172.202 - Description of hazardous material on shipping papers
  - 3. 49 CFR 172.203 - Additional description requirements
  - 4. 49 CFR 172.204 - Shipper's certification [if applicable]
  
- C. Package Markings - 49 CFR 172.300**
  - 1. 49 CFR 172.301 - General marking requirements for non-bulk packaging
  - 2. 49 CFR 172.304 - Marking requirements
  - 3. 49 CFR 172.310 - Radioactive material [Type B]
  - 4. 49 CFR 172.324 - Hazardous substances in non-bulk packaging [designation of "reportable quantities" with the letters "RQ"]
  
- D. Package Labeling - 49 CFR 172.400**
  - 1. 49 CFR 172.400(a) - General labeling requirements
  - 2. 49 CFR 172.403 - Radioactive materials [types and contents of labels]
  - 3. 49 CFR 172.406 - Placement of labels
  
- E. Placarding of Vehicles - 49 CFR 172.500**
  - 1. 49 CFR 172.504 - General placarding requirements
  - 2. 49 CFR 172.516 - Visibility and display of placards
  - 3. 49 CFR 172.556 - RADIOACTIVE placard
  
- F. Emergency Response Information - Subpart G**
  - 1. 49 CFR 172.600 - Applicability and general requirements
  - 2. 49 CFR 172.602 - Emergency response information

3. 49 CFR 172.604 - Emergency response telephone number

**G. Training - Subpart H**

1. 49 CFR 172.702 - Applicability and responsibility for training and testing [for HAZMAT employees]
2. 49 CFR 172.702 - Training requirements (includes types of training, when it must be conducted, need for refresher training every 3 years, record keeping)

**H. Shippers - General Requirements for Shipments and Packaging - 49 CFR 173**

1. 49 CFR 173.25 - Requirements for use and labeling of overpacks
2. 49 CFR 173.403 - Definitions
3. 49 CFR 173.411 - General design requirements
4. 49 CFR 173.413 - Additional design requirements for Type B packages
5. 49 CFR 173.416 - Authorized Type B packages [includes packaging certification requirements]
6. 49 CFR 173.441 - Radiation levels
7. 49 CFR 173.471 - Additional requirements for Type B packages approved by NRC
8. 49 CFR 173.476 - Approval of special form radioactive materials [includes requirement for documentation of special form status]

**I. Carriage by Public Highway - 49 CFR 177**

1. 49 CFR 177.817 - Shipping paper [location of shipping papers during transport]
2. 49 CFR 177.842 - Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

## APPENDIX G OPERATING AND EMERGENCY PROCEDURES

You may use the following model procedure to leak test sealed sources. If you follow the model procedure for Operating and Emergency Procedures, you may state on your application, "We will establish and implement the model procedure for Operating and Emergency Procedures published in Appendix G to the MDH Regulatory Guide for Industrial Radiography."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. State on your application, "We have developed operating and emergency procedures for your review that is appended as Appendix G," and submit your operating and emergency procedures.

### MODEL OPERATING AND EMERGENCY PROCEDURES

#### A. Handling and Use of Sources of Radiation

Procedures should include systematic procedures for the handling and use of devices containing sources of radiation so that an individual will not receive an exposure in excess of the limits specified in 4731.2000.

#### B. Methods and Occasions for Conducting Radiation Surveys

The procedures should identify

- when surveys will be made.
- what should be surveyed.
- acceptable radiation levels.

Necessary surveys include the following:

1. Surveys that verify that the source has been returned to the shielded position. These surveys are conducted after each exposure. This survey should include both the source tube, if one is used, and the device.
2. Surveys of the restricted area perimeter. NOTE: It is not necessary to perform a survey of the perimeter of the high radiation area. Exposure levels may be determined by calculation, in keeping with the ALARA concept.
3. Determination of radiation levels at the external surfaces of temporary storage facilities.
4. Determination of radiation levels in the cab of transportation vehicles and around vehicles used for transporting sources and devices.
5. Determination that sources are in safe storage positions before securing radiographic exposure devices or storage containers.
6. Determinations that the containers prepared for shipment comply with the regulations of the Department of Transportation.

**C. Methods of Controlling Access to Radiographic Areas**

1. Procedures should ensure that a second radiographer observes the operations and is capable of providing immediate assistance to prevent unauthorized entry.
2. Include procedures to control access to areas in which radiographic operations are being performed such as posting, constant surveillance of perimeter of the restricted area, and steps to follow when unauthorized personnel enter the restricted area.

**D. Methods and Occasions for Locking and Securing Radiographic Exposure Devices, Storage Containers and Sealed Sources**

1. The procedures should contain instructions for securing the source at the time of the survey to determine that the source has been returned to the shielded position after each exposure. This is usually accomplished by locking the device. However, other methods may be preferred.
2. You should state that the radiographic exposure device will be stored in a locked enclosure (transport vehicle, store room, closet, shed, etc.) in a way that will prevent access by unauthorized persons. You should keep in mind that the radiographic exposure device needs to be in storage or physically watched by an authorized user at all times. It is not acceptable for a radiographic exposure device to be chained to a post or left lying unattended at the place of use during lunch or breaks, because the radiographic exposure device would then be accessible to unauthorized persons.
3. Provide instructions and procedures for storage of sources and devices at both permanent and temporary job sites including posting of storage areas, and surveys around the storage area. Any area outside the storage area should be considered an unrestricted area.

**E. Personnel Monitoring**

1. Procedures should state that personnel are required to wear direct-reading pocket dosimeters, alarm rate-meters, and personnel monitoring devices (film badges, TLDs, or OSDs) when they are engaged in radiographic operations. Personnel should be instructed to charge pocket dosimeters at the start of each workday so the dosimeters are capable of reading full scale. Readings should be recorded at the beginning and end of each workday. Alarm rate-meters should be tested at the start of each shift to ensure that the alarm functions properly (audibly). Include instructions regarding how and where dosimetry devices are to be stored when not in use.
2. Include instructions for action taken in the case of a lost, damaged, or off-scale pocket dosimeter.

**F. Transportation to Field Locations, Including Packaging of Sources of Radiation in the Vehicles, Posting of Vehicles, and Control of Sources of Radiation During Transportation**

1. The transportation of radioactive material over public highways in exposure devices or storage containers is subject to US Department of Transportation regulations (DOT).
2. The procedures should contain instructions on how exposure devices and storage containers should be secured within a transporting vehicle to prevent movement and possible damage to, or loss of, the exposure device or storage container.

3. Instructions for surveys should be available in and around the vehicle. For the passenger compartment, it is recommended that the radiation level not exceed 2 milliroentgens (mR) per hour. Although it is not specifically required for transport, there are occasions when the vehicle may be used for storage. In that case, the area outside the vehicle should be considered an unrestricted area so that a specification of the radiation level of 2 mR per hour at any external surface of the vehicle should be provided. When a vehicle is used for storage, it must be posted with a "Caution, Radioactive Material" sign.

**G. Minimizing Exposure of Individuals in the Event of an Accident**

These procedures must contain clear and specific instructions concerning emergencies. In general, the steps to be taken by radiography personnel should be limited to:

1. Surveying the area;
2. Establishing the restricted area;
3. Notifying appropriate persons; and
4. Maintaining direct surveillance and control over the area until the situation is corrected.

**H. The Procedure for Notifying Proper Personnel in the Event of an Accident or Unusual Occurrence**

Procedures should be provided with the name of appropriate personnel to contact in case of an accident or unusual occurrence. MDH telephone numbers should be included.

**I. Maintenance of Records**

Procedures should contain instructions to radiography personnel, outlining the records that must be maintained during the course of their work. This would include, but not necessarily be limited to, the following:

1. Dosimeter records;
2. Utilization records;
3. Survey records; and
4. Records of the daily inspection and maintenance of radiographic equipment.

**J. The Daily Inspection and Maintenance of Radiographic Exposure Devices, Storage Containers, Survey Meters and Personnel Monitoring Devices**

These procedures should contain specific instructions for the radiographer to perform daily inspections of radiographic equipment. These checks may not be as detailed as the quarterly inspection and preventive maintenance, but should follow the guidelines recommended by the manufacturer of the equipment. A checklist should be provided for the radiographer, listing the items to be covered in the daily inspection. If the equipment manufacturer's procedures are to be followed, this should be included as a part of the operating procedures, not merely referenced.

**K. Identifying and Reporting Defects and Noncompliance**

If radiography personnel discover any malfunction or defect in radiography equipment, instructions should require management notification so it can take appropriate reporting action.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including:

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### **Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

#### **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one or more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

#### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

#### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

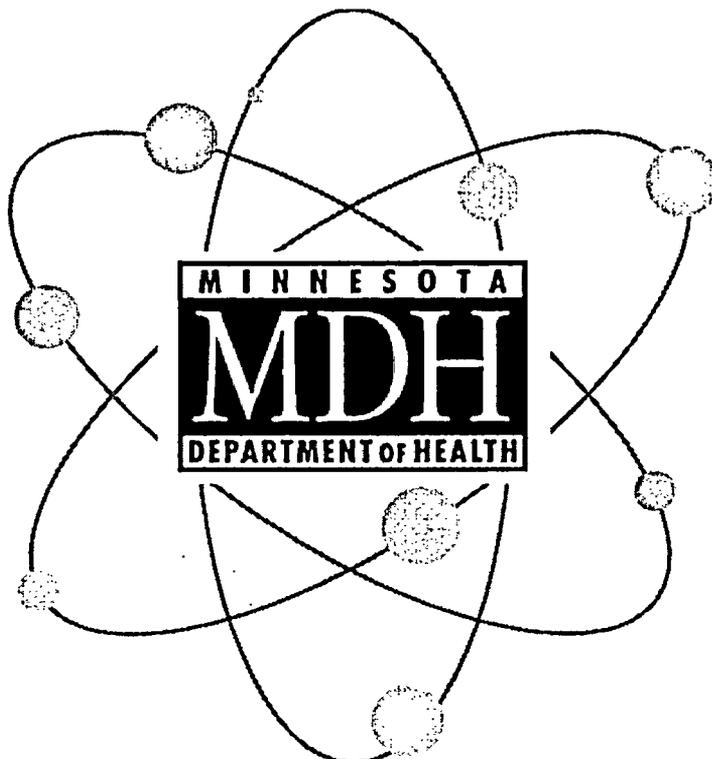
- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR MOBILE NUCLEAR MEDICAL SERVICE

The logo is circular with the text "Radioactive Materials Group" at the top, "Minnesota Department of Health" at the bottom, and "RAM" in the center. In the middle of the circle is a stylized animal head, possibly a moose or bear.	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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## **REGULATORY GUIDE FOR MOBILE NUCLEAR MEDICAL SERVICE**

### **INTRODUCTION**

The Minnesota Department of Health (MDH) regulates the administration of radioactive material to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Minnesota Radioactive Materials Rules, Chapter 4731.4400.

You should carefully study this guide and all the regulations identified in Chapter 4731.4400 before completing 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.

This guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for a mobile nuclear medicine service license. It also summarizes the radioactive material regulations for medical use in a mobile environment.

This regulatory guide is intended for use by mobile nuclear medicine services regardless of the type of service provided. As such, not all sections are applicable. The licensee should review the information and respond as appropriate.

Historically, mobile nuclear medicine services provided a variety of diagnostic nuclear medicine procedures. However, MDH licenses mobile nuclear services that only provide imaging systems, which does not include the preparation or administration of radiopharmaceuticals. Licensees should use the relevant portions of this guidance for administration of the radioactive materials programs.

### **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.

### **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 propriety information to the public or substantial delays in processing your application.

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

Submit one copy of your application to:

Radioactive Materials Unit  
Minnesota Department of Health  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will not be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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 Materials and Item 6: Purpose**

Radioactive material for medical use is divided into types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may state, "As needed" in the "Amount" column as shown. For implant material, express the total amount in millicuries (mCi). If you plan to have an eye applicator, list it as a separate item and note its total activity in mCi.

For 4731.4432, 4433, and 4434 use, the applicant should define the purpose of use by stating the applicable section and the description of the applicable modality (e.g., any uptake dilution and excretion procedure for which a written directive is not required).

**Table 1**

<b>RADIOACTIVE MATERIAL</b>	<b>AMOUNT</b>	<b>PURPOSE</b>
5.a Material in 4731.4432	As needed	6.a Medical use
5.b Material in 4731.4433	As needed	6.b Medical use
5.c Material in 4731.4434	As needed	6.c Medical Use
5.d Material in 4731.4460	10 mCi	6.d Medical Use
5.e Cobalt-57	50 mCi	6.e Medical Use

If you need other items, make a separate line entry for each isotope. Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in millicuries, and the purpose for which the material will be used.

**For sealed sources used in devices:** An applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registration (SSDR) Certificate. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the licensed activity limit prior to installation in the device.

For use of sealed sources for diagnosis (4731.4460), the applicant should define the purpose of use by describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR.

**Calibration, Transmission, and Reference Sources:** For calibration, transmission, and reference sources covered in 4731.4423, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 4731.4400 for medical use of radioactive material.

**Item 7: Individual Users Responsible for the Radiation Safety Program**

Responsible individuals are the authorized users and the RSO. 4731.4411 requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience. 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.

**Authorized Users For Medical Uses**

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.

2. Prescription of the radiation dosage or dose and how it is to be administered.
3. Actual use or direction of technologists or other paramedical personnel in the use of radioactive material.
4. Interpretation of diagnostic procedures.

Applicants must meet recentness of training requirements described in 4731.4415. Authorized user applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Technologists, therapists, or other personnel may use radioactive material for medical use under an authorized user's supervision in accordance with 4731.4407, "Supervised Individuals."

There is no MDH requirement that an authorized user must render an interpretation of a diagnostic image. MDH recognizes that the authorized user may or may not be the physician who interprets such studies. Additionally, MDH rules do not restrict who can read and interpret diagnostic scans or the results of involving the administration of radioactive material to individuals.

#### ***Radiation Safety Officer (RSO)***

Radiation Safety Officers must have adequate training and experience. The training and experience requirements for the RSO are described in 4731.4411 and allow for the following four training pathways:

- Certification by one of the professional boards recognized by MDH, the NRC or another Agreement State.
- Didactic training, work experience, and preceptor statement as described in 4731.4411(B).
- Identification on the license as an Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO.

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 4731.4405, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities to ensure that radioactive materials are used in a safe manner. MDH requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. MDH has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 4731.4405.

#### ***RSO Responsibilities***

Some of the typical duties and responsibilities of Radiation Safety Officers include ensuring the following:

- Unsafe activities involving licensed materials are stopped
- Radiation exposures are ALARA
- Material accountability and disposal
- Interaction with MDH

- Timely and accurate reporting and maintenance of appropriate records
- Annual program audits
- Proper use and routine maintenance
- Personnel training
- Investigation of medical events involving radioactive material

Appendix B contains a detailed list of typical duties and responsibilities of the RSO. Applicants are reminded of recentness of training requirements. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the following:

- Name of the proposed RSO.
- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

One of the following is also needed:

- Copy of the certification(s) for the board(s) recognized by NRC or Agreement State and as applicable to the types of use for which he or she has RSO responsibilities.
- Description of the training and experience specified in 4731.4411 subpart B.
- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities (refer to 4731.4433, 4434, 4444, and 4461).

In addition, provide both of the following:

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

#### **Item 8: Training for Individuals Working In or Frequenting Restricted Areas**

Describe your training program for individuals who work with or near radioactive material. Include the training for individuals who handle non-medical radioactive materials.

#### **Item 9: Facilities and Equipment**

Applications will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.).

Applicants must describe the proposed facilities and equipment. The facility diagram should include information sufficient to demonstrate that the facilities and equipment are adequate to protect health and

minimize danger to life or property. The applicant should demonstrate that the dose limits for individual members of the public (4731.2090) will not be exceeded.

### **Annotated Drawings**

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used.
- Principal use of each area where radioactive material is prepared, used or stored.
- Principal use of each adjacent areas; indicate whether the area is a restricted or unrestricted area as defined in 4731.0100.
- Provide information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used.

The locations of use for mobile nuclear medicine service licensees, which provide diagnostic imaging and bone mineral analysis services, are of two basic types. One type of location is the base hot lab where licensed material shall be received, stored and used. The other type of location is the temporary job site at medical care (client) facilities.

#### **A. Base Hot Lab**

Depending upon the scope of services, the licensee may request multiple base hot lab locations. The base hot lab may be located in a medical institution or a non-medical facility. The application should specify whether the proposed facility is a medical institution. The following information should be requested from the applicant:

##### **1. Medical Institutions**

If the applicant is part of a medical institution, there must be a clear link to the medical facility and its management. The mobile nuclear medicine license must be issued to one management entity, which presides over all base hot lab locations and has full responsibility for assuring compliance with all applicable regulatory requirements.

If the base hot lab is in a medical institution *that is not a licensee*, the mobile nuclear medicine licensee must assume full responsibility for the used space(s). The license must provide MDH with a statement verifying that arrangement.

##### **2. Non-Medical Facilities**

Base hot labs are typically authorized at commercial facilities. However, applicants have also requested base hot labs at residential locations.

a. Requests for base hot labs that appear to be located at a residence require the following additional information:

- (1) Justification for a private residence location rather than a commercial location. This justification should be based on patient need, public health and safety, and adequate radiological protection.
- (2) Documentation of a clear contractual agreement concerning access to the residence for purposes of decontamination or removal of licensed material from the residence in case of disharmony between these two entities. Signed

documentation from both parties must be provided to illustrate the agreement between the residence owner and the licensee.

- (3) Confirmation in the form of letters from local agencies that operation of the base hot lab does not conflict with local codes and zoning laws.
- (4) Confirmation in the form of signed statements by the licensee that police and fire departments with jurisdiction in the area shall be notified of radioactive material content initially and at six-month intervals.
- (5) Detailed descriptions and diagrams of the facility should include information regarding construction of the building and adjacent areas.
- (6) A description of the scope of activities conducted at each location. Locations may range from being a hot lab up to a full-service imaging center from which the mobile nuclear medicine service is based.
- (7) Demonstration that restricted areas shall not include areas adjacent to restricted areas, including above and below. The applicant should discuss how radiation levels in unrestricted adjacent areas will remain in compliance with 641-40.26.
- (8) A description of the security provisions used to restrict facility access from unauthorized persons. The facility should be of adequate construction and design to ensure security of licensed material and prevent unauthorized access. Security should consider residents and the general public.

- b. Documentation must be submitted for all commercial facilities to indicate the management body that presides over all proposed locations. This documentation should show clear delineation of authority and responsibility. The mobile nuclear medicine service license should be issued to one management entity that presides over all base hot lab locations. If business arrangements exist which would negate the issuance to one entity, documentation describing the business arrangement and the base hot lab management must be included in the application.

#### B. Temporary Job Site

The temporary job site at medical care facilities (client's address) is where a mobile nuclear medicine service uses radioactive material. The mobile nuclear medicine service may transport licensed material and equipment from the van into a client's building, or bring patients into the van located on the client's property. The application should clearly describe whether scan-in-van services will be provided. If an applicant requests scan-in-van service, the following information should be submitted:

1. Procedures for positioning the mobile van at temporary job sites. Mobile vans should be sited on the client's property, preferably adjacent to the building.
2. A detailed diagram of the mobile van.
3. How the scan-in-van operation shall remain in compliance with requirements for unrestricted areas (e.g., outside of van).
4. Procedures that describe how the client will assure that services are conducted in accordance with the regulations while the mobile nuclear medicine service is under the client's direction.
5. Survey procedures to check for contamination before leaving each location of use to ensure compliance with 4731.2200 to 4731.2950.

#### ***Radiation Monitoring Instruments***

All licensees should possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

The radiation protection program that licensees are required to develop, document, and implement in accordance with 4731.2010 must include provisions for survey instrument calibration (4731.2200). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used.

Qualified personnel must perform survey meter calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an MDH (or equivalent NRC or Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration.

Provide one or both of the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."
- A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 4731.2200 and that meet the requirements of 4731.4421." Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing."

Also provide both of the following:

- A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
Short Scientific, Inc.	LGD-310	1 - 100000 cpm

- A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

***Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material***

As described in 4731.4422 and 4428, dosage measurement is required for licensees who prepare patient dosages. Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The activity must be determined by direct measurement. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is

involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

#### **Item 10: Radiation Safety Program**

The elements of a radiation safety program are contained in Appendices A through L. 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."

Appendix A	Model Program for Maintaining Occupational Radiation Exposure ALARA
Appendix B	Duties and Responsibilities of the Radiation Safety Officer
Appendix C	Calibrating Dose Calibrators
Appendix D	Personnel Exposure Monitoring Program
Appendix E	Leak Testing Sealed Sources
Appendix F	Safe Use of Radiopharmaceuticals
Appendix G	Spill Procedures and Action Limits
Appendix H	Ordering and Receiving radioactive material
Appendix I	Safely Opening Packages Containing Radioactive Material
Appendix J	Records of Radioactive Material Use
Appendix K	Area Surveys
Appendix L	Monitoring, Calculating, and Controlling Air Concentrations

#### ***Sealed Source Inventories***

State that you will conduct inventories at intervals not to exceed three months to account for all sealed sources received and possessed under your license. You should maintain records of the inventories for at least three years from the date of the inventory. The record should include:

- Model number of each source
- Serial number if one has been assigned
- Identity of each source radionuclide
- Estimated activity
- Location of each source
- Date of inventory
- Initials or name of individual performing the inventory
- Signature of the Radiation Safety Officer

#### ***Transportation***

All licensees are required to comply with 4731.0400 regarding transportation of licensed material. The mobile nuclear medicine service acts as a shipper and carrier of radioactive material. Review of mobile van licensee inspection reports indicates a relatively high incidence of violations pertaining to transportation; therefore, the applicant should provide a description of the mechanisms or procedures used to assure the following:

- A. Transportation of radioactive material is in accordance with 4731.0400. Procedures should include:
  1. Approved packages
  2. Appropriate labeling
  3. Proper surveys
  4. Complete and accurate shipping papers
  5. Bracing of packages
  6. Security provisions

## 7. Emergency procedures

- B. Training for drivers and technologists, which includes transportation regulations and emergency procedures. Documentation of this training should minimally include dates, topics discussed, attendees and instructor's name.
- C. Emergency procedures that van drivers shall follow in case of an accident involving licensed material in transport should be maintained in the vehicle during transport. Emergency procedures should minimally include posting the area, maintaining surveillance, and notifying the RSO. A copy of these procedures must be included in the application.
- D. Procedures for handling radioactive waste during transport. Describe the method of storage and final disposal.

### ***Annual Audit of the Radiation Safety Program***

4731.2010 requires that licensees review at least annually the radiation protection program content and implementation. Currently the MDH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that problems are promptly and comprehensibly corrected. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

The MDH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with MDH rules.

A model audit program is included in this regulatory guide.

### **Item 11: Waste Management**

Submit your procedures for waste disposal, including a procedure for all materials listed in Item 5. See Appendix R for more information on these procedures.

### **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application

acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

## **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

## **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of radioactive material are capable of complying with MDH rules. This guide provides one set of methods approved by 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**  
**MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AS LOW AS**  
**REASONABLY ACHIEVABLE (ALARA)**

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix A to the MDH Regulatory Guide for Mobile Nuclear Medicine Service." Submit the signed commitment in Section 6 of this appendix.

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in Section 6 of this appendix.

**ALARA PROGRAM**

**1. Management Commitment**

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

**2. Review of Proposed Users and Uses**

- a. The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- b. When considering the use of radioactive material, the RSC will review efforts of the applicant to maintain exposure ALARA.
- c. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- d. The RSC will delegate authority for enforcement of an ALARA program to the RSO.

- e. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- f. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- g. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

**Table A-1 – Investigational Levels**

	Investigational Levels (mrems per month)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

- h. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

**3. Radiation Safety Officer Commitment**

- a. Annual and Quarterly Review
  - The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
  - The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.
- b. Education Responsibilities for ALARA Program
  - The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.
- c. Cooperative Efforts for Development of ALARA Procedures
  - Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
  - The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
  - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- d. **Reviewing Instances of Deviation from Good ALARA Practices:**
- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
- e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

**4. Authorized Users Commitment**

- a. **New methods of Use Involving Potential Radiation Doses**
- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
  - The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
- b. **Authorized User's Responsibility to Supervised Individuals**
- The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
  - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

**5. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses<sup>1</sup>**

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table A-1. These levels apply to the exposure of individual workers.

The RSO will review and record on MDH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table A-1:

- a. **Personnel dose less than Investigational Level I**

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<sup>1</sup> MDH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table A-1 values for the investigational Level I.
- b. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II
- The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality. This review will be recorded in the Committee minutes.
- c. Personnel dose equal to or greater than Investigational Level II
- The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's "Occupational Exposure Record for Monitoring Period" and "Cumulative Occupational Exposure History," or its equivalent.
- d. Re-establishment of investigational levels to levels above those listed in Table I
- In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

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

**6. Signature of Certifying Official<sup>1</sup> Sign and submit as part of Appendix A.**

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

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (Print or type)

\_\_\_\_\_  
Title

<sup>1</sup> The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

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

You may use the following model guidelines to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for Radiation Safety Officer duties published in Appendix B to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

You may develop your own guidelines for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. State on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

### **MODEL PROCEDURE**

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include the following:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
  - a. The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
  - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
  - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation exceeding ALARA levels or limits in 4731 are investigated and reported to MDH within the required time limits.

10. Ensure that fume hood flow rates are tested at appropriate intervals and that employees use hoods in accordance with the safe use of radiopharmaceuticals.
11. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
12. Ensure that licensed material is disposed of properly.
13. Ensure that the facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.
14. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

## APPENDIX C CALIBRATING DOSE CALIBRATORS

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may state on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If you develop your own dose calibrator calibration procedure for review, you should carefully review all the features in the model procedure. State on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as Appendix C," and submit your dose calibrator calibration procedure.

### MODEL PROCEDURE

Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of  $\pm 5$  are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

#### 1. Constancy

Constancy means reproducibility in measuring a source over a long period. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

- a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
- b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.
- c. Either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
- d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
- e. Establish an action level at which the individual performing the test will automatically notify the supervision of suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds  $\pm 10$  percent.

2. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

#### 3. Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99<sup>m</sup> whose activity is at least as large as the maximum activity normally assayed.

##### **DECAY METHOD**

- a. Assay the Tc-99<sup>m</sup> syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time (to the nearest minute), and net activity. This first assay should be done in the morning at a regular time, for example, 8 a.m.

- b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity used. For dose calibrators with a range selection switch, select the range you would normally use for the measurement.
- c. Convert the recorded time and date to hours elapsed.
- d. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.
- e. Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  $(A\text{-observed} - A\text{-line})/(A\text{-line}) = \text{deviation}$ .

#### **SHIELD METHOD**

If you decide to use a set of sleeves to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the sleeves must be performed each time the dose calibrator is returned from repair.

Follow the manufacturer's instructions when performing the linearity test.

#### **4. Geometry independence**

Geometry means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

- a. In a small beaker or vial, mix 2.0 cc of a solution of Tc-99<sup>m</sup> with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
- b. Draw 0.5 cc of the Tc-99<sup>m</sup> solution into the syringes and assay. Record the volume and millicuries.
- c. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- d. Repeat the process until you have assayed a 2.0 - cc volume.
- e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- f. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
- g. To test the geometry dependence of a 30-cc glass vial, draw 1.0 cc of the Tc-99<sup>m</sup> solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

- h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries indicated.
- i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
- j. Select as a standard the volume closest to that normally used for mixing radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- k. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure to label the table or graph, note the date of the test, and indicate the model number and serial number of the calibrator.

## 5. Accuracy

Accuracy means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier. The supplier must compare that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. Consider using at least one reference source whose activity is within the range of activities normally assayed.

- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for three determinations.
- b. Average the three determinations. The average value should be within five (5) percent of the certified activity of the reference source, mathematically corrected for decay.
- c. Repeat the procedure for other calibrated reference sources.
- d. If the average value does not agree, within five (5) percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds ten percent.
- e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values.

- 6. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

## **APPENDIX D PERSONNEL EXPOSURE MONITORING PROGRAM**

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may state on your application, "We will establish and implement the model personnel exposure monitoring program published in Appendix D.1 and/or D.2 to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program. State on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.

### **D.1. MODEL PROGRAM FOR EXTERNAL EXPOSURE**

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor.
4. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

### **D.2. MODEL PROGRAM FOR INTERNAL EXPOSURE**

Medical personnel who administer substantial doses of radioiodine to patients may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Historically, bioassays for medical personnel have been required only in cases of administration to hospitalized patients because these are the patients receiving substantial doses of radiopharmaceuticals. This in turn meant that the medical personnel who prepared or administered the dosages to these patients handled substantial amounts of radioactive material, and therefore were at greatest risk for intakes. Patients who did not need to be confined after administration of radiopharmaceuticals were generally those patients who received relatively small dosages of these materials. The preparation or administration of these smaller dosages posed a relatively lower risk to the medical personnel involved.

The change in the criteria for release of patients who have been administered radiopharmaceuticals may involve the administration of relatively large dosages of radioactive materials without requiring patient confinement. Bioassays are only applicable to the administration of radiopharmaceuticals at levels that

require hospitalization. It may be possible for medical personnel to prepare or administer substantial doses of radiopharmaceuticals without meeting the requirement to perform a bioassay.

Although licensees may no longer be tied to a bioassay program because of the new patient release criteria, they remain subject to the requirements of 4731.2210 "Conditions requiring individual monitoring of external and internal occupational dose." This requires the licensee to monitor all occupationally exposed personnel who may receive, in one (1) year, an intake in excess of the applicable ALI in 4731.2750.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed ten percent of the limit in the year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For medical licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay. Baseline surveys should be completed for all individuals likely to require future monitoring.

## **APPENDIX E LEAK TESTING SEALED SOURCES**

As a licensee, you must perform leak testing of sealed sources. The MDH requires tests to determine whether or not there is any leakage from the radioactive source. 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 send 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 kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix E.1 or submit your own procedures.

For Option 3, describe the procedure for taking the test sample. Identify 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 the minimum sensitivity for the instrument used for analysis and 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.

You may use the following model procedure to leak-test sealed sources. If you 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 (E.1 and/or E.2) to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix E," and submit your leak test procedure.

### **E.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES (Option 2)**

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, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
- c. For the teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or crosshairs. Wipe the primary and secondary collimators and trimmers.
- d. If you are testing radium sources, you should also check 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.

## **E.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES**

(Option 3)

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries. 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 rate meter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that is the same isotope and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries 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 records for three years.

## **APPENDIX F SAFE USE OF RADIOPHARMACEUTICALS**

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 F to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model. State on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Appendix F," and submit your model rules for the safe use of radiopharmaceuticals.

### **MODEL RULES**

1. Wear long-sleeved laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Before leaving the restricted area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins or infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve so syringe shields can still be used).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. 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.
8. Wear a finger exposure monitor while handling radioactive material including during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and while in contact with patients that have been administered radiopharmaceuticals.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe-test radioactive material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
12. With a radiation survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation.
14. A log should be used to record additional information such as:
  - The total prepared activity
  - Specific activity (in mCi/cc) at a specified time
  - Total volume prepared
  - The measured activity of each patient dosage
  - Any other appropriate information
15. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
16. Assay each patient dosage in the dose calibrator before administration. Only use a dosage that differs by more than ten percent of the prescribed dosage with approval of an authorized user (except for prescribed dosages of less than 10 microcuries). When measuring the dosage, the radioactivity that adheres to the syringe wall or remains in the needle does not need to be considered.
17. Check the patient's name, the prescribed radionuclide, and the dosage before administering.
18. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
19. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

## **APPENDIX G MODEL SPILL PROCEDURES**

You may use the following model procedures as they appear here, stating on your application, "We will establish and implement the model spill procedure published in Appendix G to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

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

### **MODEL PROCEDURES**

#### ***MINOR SPILLS OF LIQUIDS AND SOLIDS***

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

#### ***MAJOR SPILLS OF LIQUIDS AND SOLIDS***

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

#### ***DISCUSSION CONCERNING MAJOR SPILLS AND MINOR SPILLS***

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

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

**Table G-1 Relative Hazards of Common Radionuclides**

Estimate the amount of radioactivity spilled. If the amount spilled is greater than the amount indicated below for that isotope, the spill is considered major. Below these limits, the spill is considered minor.	
RADIONUCLIDE	MILLICURIES
Co-60, Sr-89, I-125, I-131	1
F-18, P-32, Co-58, Fe-59, Se-75, Sr-85, Y-90, In-111, I-123, Sm-153, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99 <sup>m</sup> , Tl-201	100

## **APPENDIX H ORDERING AND RECEIVING RADIOACTIVE MATERIAL**

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may state on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix H to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 4731.2350. State on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix H," and submit your procedure.

### **MODEL GUIDANCE**

1. The Radiation Safety Officer (RSO) or a designee must ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. For routinely used materials:
    - (1) Written records identifying the authorized user or department, isotope, chemical form, activity, and supplier
    - (2) Verification that material received was ordered by an authorized user.
  - b. For occasionally used materials (e.g., therapeutic dosages):
    - (1) The authorized user who will perform the procedure will make a written request to confirm that the material received is what was ordered.
    - (2) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.
4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

**SAMPLE MEMORANDUM**

**MEMO TO:** Chief of Security

**FROM:** Radiation Safety Officer

**SUBJECT:** Receipt of Packages Containing Radioactive Material

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

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

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

\_\_\_\_\_, at \_\_\_\_\_.  
Name Home Telephone

Radiation Safety Officer: \_\_\_\_\_

Chief of Nuclear Medicine: \_\_\_\_\_

Chief of Nuclear Medicine Technologist: \_\_\_\_\_

Nuclear Medicine Technologist on call  
(Call page operator at extension \_\_\_\_\_)

Nuclear Medicine Physician on call  
(Call page operator at extension \_\_\_\_\_)

**APPENDIX I**  
**SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**  
In addition to 4731.2350

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix I to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion 4731.2350. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix I," and submit your procedure.

**MODEL PROCEDURE**

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination in accordance with 4731.2350.
2. The following procedures for opening each package will be followed:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
  - c. Measure the exposure rate from the package at one (1) meter and at the package surface. If it is more than 10 millirem per hour at three (3) feet (1 meter), stop and notify the RSO. (The transport index noted on packages with Yellow II or Yellow III labels is the approximate dose rate, in millirem per hour, at one (1) meter from the package surface).
  - d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with White I labels should be less than 0.5 millirem per hour on the external surface of the package.
  - e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

Beta-gamma-emitting radionuclides; all radionuclides with half-lives less than ten days.....	22 dpm/cm <sup>2</sup>
All other alpha-emitting radionuclides.....	2.2 dpm/cm <sup>2</sup>
  - f. Open the package with the following precautionary steps:
    - (1) Remove packing slip.
    - (2) Open outer package following the supplier's instructions, if provided.
    - (3) Verify that the contents match the packing slip.
    - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

- (5) If anything is other than expected, stop and notify the RSO.
- g. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument [for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter] should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.
  - h. Check the user request to ensure that the material received is the material that was ordered.
  - i. Monitor the packing material and the empty packages for contamination with a survey meter before discarding.
    - (1) If contaminated, treat this material as radioactive waste.
    - (2) If not contaminated, remove or obliterate the radiation labels before discarding it.
  - j. Make a record of the receipt.
3. For packages received under the general license, the following procedure for opening each package will be followed.
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - b. Check to ensure that the material received is the material that was ordered.

## APPENDIX J RECORDS OF RADIOACTIVE MATERIAL USE

### GENERAL

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does *not* have to replicate entries. For example, if you prepare a multi-dose vial for use one day, you do not have to record the date each time you draw a dose from it.

### RECORDS OF UNIT DOSAGE USE

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix J to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedures in the model procedure. Indicate on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as Appendix J" and submit your unit dosage record procedure.

### MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt
4. Supplier
5. Lot number or control number, if assigned, and expiration date
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time
7. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual)
  - b. Measured activity in millicuries or microcuries and date and time of assay and administration
  - c. Patient name and identification number if one has been assigned
8. If discarded, the date and method of disposal
9. Initials of the individual who performed the assay

Maintain these records for three (3) years.

## **RECORDS OF MULTI-DOSE VIAL USE**

You may use the following model procedure to keep a record of multi-dose vial use. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for a multi-dose vial record system that was published in Appendix J to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If you prefer, you may develop your own multi-dose vial record system for review. If you do so, you should consider for inclusion all the features in the model system. State on your application, "We have developed a procedure for a multi-dose vial record system for your review that is submitted as Appendix J" and submit your multi-dose vial record procedure.

## **MODEL PROCEDURE**

For each multi-dose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt or preparation
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml)
5. Supplier or kit manufacturer
6. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual)
  - b. Date and time dosage was drawn and measured
  - c. Calculated volume that is needed for the prescribed dosage
  - d. Measured activity in millicuries or microcuries
  - e. Patient name and identification number if one has been assigned
7. If discarded, the method of disposal and date
8. Initials of the individual who performed the assay

Maintain these records for three (3) years.

## **MEASURING AND RECORDING MOLYBDENUM CONCENTRATION**

Each licensee who uses a technetium generator to prepare radiopharmaceuticals must complete a test for molybdenum concentration. This measurement is usually made with a dose calibrator. Licensees may not distribute or administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect.

The model procedure for measuring molybdenum concentration is based on the use of a molybdenum breakthrough pig. Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert the measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99<sup>m</sup> generator elution. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix J to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider the inclusion of all the features in the model procedure. State on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as Appendix J," and submit your procedure for measuring and recording molybdenum concentration.

**MODEL PROCEDURE**

Each time a generator is eluted, record the following information:

1. Date the generator was received.
2. Product of the measured Mo-99 activity and the correction factor. This is noted by the manufacturer.

Maintain these records for three (3) years.

An action level of 0.07 allows for the decay of the Tc-99<sup>m</sup> throughout the day of use. It is assumed that the material will be used within six (6) hours, at which time the concentration of Mo-99 to Tc-99<sup>m</sup> would have doubled.

## APPENDIX K MODEL PROCEDURE FOR AREA SURVEYS

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix K to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

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

### MODEL PROCEDURE

#### **AMBIENT DOSE RATE SURVEYS**

##### 1. Surveys -- Restricted Areas:

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

##### 2. Surveys -- Unrestricted Areas:

Quarterly surveys should be accomplished in areas

- Adjacent to restricted areas
- Through which radioactive materials are transferred
- Where radioactive material is temporarily stored before shipment

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

#### **REMOVABLE CONTAMINATION SURVEYS**

##### 1. Survey Areas:

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

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200-dpm/100 cm<sup>2</sup> for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).
3. Immediately notify the RSO if you find levels that exceed the established action levels. Recommended removable surface contamination action levels are published in NRC Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions" or see Table N-1 below for guidance in establishing your action levels.

**RECORDS**

1. Records must contain the following:

- The date of the survey
- A sketch of each area surveyed
- Action levels established for each area
- The measured dose rate at several points in each area expressed in millirem (microSievert) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters
- The serial number and the model number of the instrument used to make the survey or analyze the samples
- The initials of the individual who performed the survey

2. In those cases in which radiation or contamination action levels were exceeded, a follow-up survey should be completed and recorded. The RSO should promptly review and sign survey records that document the results of any actions implemented to correct the excessive radiation or contamination levels.

Maintain these records for three (3) years.

**Table K-1**

<b>RECOMMENDED ACTION LEVELS IN DPM/100 CM<sup>2</sup> FOR SURFACE CONTAMINATION</b>		
	<b>P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198</b>	<b>Cr-51, Co-57, Ga-67, Tc-99<sup>m</sup>, Hg-197, Tl-201</b>
<b>1. Unrestricted areas, personal clothing</b>	<b>200</b>	<b>2,000</b>
<b>2. Restricted areas, protective clothing used only in restricted areas, skin</b>	<b>2,000</b>	<b>20,000</b>

**APPENDIX L  
MONITORING, CALCULATING,  
AND CONTROLLING AIR CONCENTRATIONS**

**WORKER DOSE FROM NOBLE GASES**

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

You may respond by stating, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you are not monitoring trap effluent, you must estimate worker dose by calculation. If you exhaust spent gas to the atmosphere, you must also estimate worker dose by calculation. It is not necessary to submit the calculations, but you should keep them for MDH review during inspections. If you will follow the model procedure for calculating worker dose from noble gases, you may respond by stating, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix L to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If none of the above applies, you may develop your own procedure for review. State on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as Appendix L," and append your procedure for monitoring worker dose from noble gases.

**WORKER DOSE FROM AEROSOLS**

You may respond by stating, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for MDH review during inspections.) If you follow the model procedure below for calculating worker dose from aerosols, you may respond by stating, "We will follow the model procedure for calculating worker dose from aerosol concentrations that is appended as Appendix L.2." Submit your procedure for monitoring worker dose from aerosols.

**L.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS**

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, OSD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the derived air concentration (DAC) for Xenon-133 (or other gas to be used) to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of five (5) rem (50 mSv) and divide this number by five (5) rem.

- a. This yields the fraction of the dose limit of five (5) rem that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in 4731.2750.
  - b. If the highest annual external dose is 2 rem, and the listed DAC value for Xenon-133 is  $1E-4$  mCi/ml, then the modified DAC value should be based on 3 rem that could still be incurred from internal exposure.
3. The following calculations must be made:
- a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
  - b. The estimated activity released to the restricted areas.
    - (1) The total activity released to the restricted area divided by the total air exhausted must be less than the applicable DAC for a restricted area. The total activity released to the restricted area is activity used each week multiplied by estimated fractional loss per study. The total air exhausted is the sum of all exhaust rates multiplied by the length of the workweek.
    - (2) If this is not the case, plan for fewer studies and do the calculations again. An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.

## L.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable DAC value for an unrestricted area.
2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

## L.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is continuously monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions. Keep a record of the checks.
2. If you do not continuously monitor the trap effluent, check it on receipt and once each month. During one patient study, collect the effluent from the trap in a plastic bag and then monitor the activity in the bag by holding the bag against a camera. With the camera adjusted to detect the noble gas, compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm. *If there is a significant increase in the activity measured on the bag, the trap must be replaced.*

3. The charcoal Xenon trap should be replaced at time intervals recommended by the manufacturer.

### **PUBLIC DOSE FROM AIRBORNE EFFLUENT**

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value 4731.2750.

If you are not directly venting aerosols and gases to the atmosphere, you may respond by stating, "We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit the calculations with your application, but you should keep them for MDH review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond by stating, "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix L.3 to the MDH Regulatory Guide for Mobile Nuclear Medicine Service."

If neither of the above applies, you may develop your own procedure for review. State on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as Appendix L.3," and append your procedure for monitoring airborne effluent concentration.

### **SPILLED GAS CLEARANCE TIME**

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, the calculations described in Appendix L.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

#### **L.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME**

1. Collect the following data:
  - a. A -- the highest activity of gas in a single container, in microcuries.
  - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser values), in milliliters per minute.
  - c. Q -- the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system
  - d. C -- the modified derived air concentrations (DAC) in restricted areas. These should be figured according to L.1, Numbers 1 and 2.
  - e. V -- the volume of the room in milliliters.

2. Make the following calculations for each room:
  - a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
  - b. The evacuation time  $t = -V/Q \times \ln (C \times V/A)$ .
3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted
  - 2.0 mrem in any one (1) hour from external sources, and
  - 100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.

Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### Security Plan

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

#### Personnel Security

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one of more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

#### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

#### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR NUCLEAR PHARMACIES

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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## REGULATORY GUIDE FOR NUCLEAR PHARMACIES

### INTRODUCTION

This report provides guidance to an applicant applying for a commercial radiopharmacy license, as well as providing MDH with the appropriate criteria for evaluating such applications. Within this document, the phrases or terms, "commercial radiopharmacy," "radiopharmacy," "nuclear pharmacy," and "pharmacy" are used interchangeably.

Commercial radiopharmacy licenses are those licenses issued by MDH for the possession and use of radioactive materials for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 4731.5000. Within this document, preparation includes the making of radiopharmaceuticals from reagent kits (i.e., technetium-99<sup>m</sup> MAA [macro-aggregated albumin]), and from raw materials (i.e., the compounding of radioiodine capsules for diagnostic and therapeutic medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits, radiopharmaceuticals to licensees authorized to possess them for other than human medical use (i.e., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them. In addition, 4731.2000 authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a licensed manufacturer.

Specific guidance for applicants requesting to manufacture and initially distribute Molybdenum-99/Techneium-99<sup>m</sup> generators, *in vitro* kits, radiochemicals, and sealed sources is not within the scope of this guidance for commercial radiopharmacies. These activities require specific NRC or Agreement State authorization and must be included on a specific license.

Furthermore, specific guidance for applicants requesting authorization to manufacture, distribute, and redistribute radioactive drugs to persons exempt from licensing (i.e., Carbon-14 tagged urea) is not within the scope of this guidance. These activities require specific NRC authorization and require the issuance of a separate license for exempt distribution.

This guide identifies the information needed to complete MDH "Application for Radioactive Material License," for the use of radioactive materials in commercial radiopharmacies.

### 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.

#### ***Management Responsibilities***

The MDH recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. MDH also believes that consistent compliance with its regulations provides

reasonable assurance that licensed activities will be conducted safely. MDH also believes that effective management will result in increased safety and compliance.

"Management" refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

To ensure adequate management involvement, a duly authorized management representative *must* sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations.
- Completeness and accuracy of the radiation safety records and all information provided to MDH.
- Knowledge about the contents of the license and application.
- Compliance with current MDH and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures.
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that public and workers are protected from radiation hazards and compliance with regulations is maintained.
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for their licensed activities.
- Prohibition against discrimination of employees engaged in protected activities.
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct.
- Obtaining MDH's prior written consent before transferring control of the license.
- Notifying appropriate MDH in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

## **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 this 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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.

All items in the application should be completed in enough detail for the MDH to determine that the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect health and minimize danger to life and property. Consideration shall be given, when developing your application, to the concepts of ALARA and the minimization of contamination.

All information submitted to MDH during the licensing process will be incorporated as part of the license and will be subject to review during inspection.

The following comments apply to the indicated items on MDH "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 Renewals to a License," section 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 NRC, MDH, or other Agreement State 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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 an MDH license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit). The applicant should list each requested radioisotope by its element name and its mass number (e.g., Technetium-99<sup>m</sup>) 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 generally required.

For unsealed radioactive material, it is also necessary to specify whether requested radioisotopes will be handled in volatile or non-volatile form, since additional safety precautions are required when handling and using material in a volatile form. For example, when requesting authorization to possess and distribute Iodine-131, the applicant must specify whether the material will be manipulated at the radiopharmacy in a volatile form (e.g., compounding of Iodine-131 capsules) or received in the form in which it will be distributed (e.g., redistribution of sealed, unopened vials of Iodine-131). Applicants requesting authorization to manipulate volatile radioactive material must describe appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

The anticipated possession limit in curies (Ci) or becquerels (Bq) for each radioisotope should also be specified. Possession limits must include the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and abilities 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 Recordkeeping for Decommissioning.

Applicants will be authorized to possess and use only those sealed sources, such as calibration and reference sources that are specifically approved or registered by the NRC or an Agreement State. 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<sup>1</sup>. 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 designations registered with 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.

The applicant must also request authorization to possess depleted uranium if it will be used for shielding of Molybdenum-99/Technetium-99<sup>m</sup> generators. Depleted uranium is frequently used as shielding for generators when the Molybdenum-99 activity is greater than 4 curies (148 gigabecquerels). Depleted uranium is exempt from the requirements for a license to the extent that the material is used as a shipping container, such as when Molybdenum-99/Technetium-99<sup>m</sup> generators are in transit from their manufacturer to the pharmacy. However, a specific license or authorization from the MDH is needed to possess and use the depleted uranium as a shield during the time that the pharmacy uses or stores the generator at its facility. The applicant must specify the total amount of depleted uranium, in kilograms, that will be needed.

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<sup>1</sup> Information on SSD registration certificates is available on the NRC's web site at <http://www.hsrdo.nrc.gov/nrc/sources/index.cfm> and may also be obtained by contacting the Registration Assistant by calling MDH's toll free number, (800) 368-5642, Extension 415-7231.

If an applicant requests quantities of licensed material in excess of the limits in 4731.3150, "Radioactive Material; Emergency Plan Quantities," the applicant must:

- Submit an emergency plan for responding to a release of radioactive materials; or
- Perform an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 millisieverts) effective dose equivalent or 5 rems (50 mSv) to the thyroid<sup>2</sup>.

Licensees must submit a license amendment and receive MDH authorization before they may make changes in the types, forms, and quantities of materials possessed.

For unsealed materials:

Identify each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit.

For potentially volatile materials (e.g., Iodine-131):

Specify whether open containers of the materials will be manipulated at the radiopharmacy.

For sealed materials:

Identify each radionuclide (element name and mass number) that will be used in each source;

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; and

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.

For depleted uranium, specify the total amount (in kilograms).

#### ***Financial Assurance and Recordkeeping for Decommissioning***

The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most commercial radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements, because the vast majority of radioactive materials they possess and redistribute do not have half-lives greater than 120 days and the total inventory of licensed materials with half-lives greater than 120 days do not exceed the thresholds for financial assurance.

Applicants requesting more than one radionuclide may determine whether financial assurance for decommissioning is required by calculating, for each radionuclide with a half-life greater than 120 days, the ratio between the activity possessed, in curies, and the radionuclide's threshold activity requiring financial assurance, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds "1" (i.e., "unity"), then applicants must submit evidence of financial assurance for decommissioning.

Licensees are also required to maintain records important to decommissioning in an identified location<sup>3</sup>. All commercial nuclear pharmacy licensees need to maintain records of structures and equipment where radioactive material was used or stored. As-built drawings with modifications of structures and equipment

<sup>2</sup> For radiopharmacies, Iodine-131 is the radionuclide most likely to trigger the need for an emergency plan due to the 10 curie threshold.

<sup>3</sup> For radiopharmacy licensees whose contamination incidents did not involve radioactive materials with half-lives exceeding 120 days and whose sealed sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where radioactive material was used or stored.

shown fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations.

If radiopharmacy licensees have experienced unusual occurrences (e.g., incidents that involve spread of contamination or leaking sources), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

#### **Item 6: Purpose(s) for Which Licensed Material Will Be Used**

##### ***Distribution and Redistribution of Sealed and Unsealed Materials***

Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a supplier not licensed under 4731.3395 (chemical grade materials). Radioactive drugs are those materials suitable for human use and include radiobiologics (e.g., monoclonal antibodies and Technetium-99<sup>m</sup>-tagged red blood cells) and radiopharmaceuticals. However, the terms, "radiopharmaceutical" and "radioactive drug" will be used interchangeably in this guidance document, and reference to one is not meant to exclude the other.

Distribution activities are normally classified as either "distribution" or "redistribution." "Distribution" applies to those radioactive drugs and radiochemicals initially prepared by the pharmacy. "Redistribution" refers to those materials received from another person, authorized pursuant to 4731.3390, 3395, or 3400, depending on the product distributed. The distribution of radioactive materials to other persons requires specific approval from the MDH, either by MDH rules or by a license authorizing the activity. A person licensed pursuant to 4731.3395 must prepare the initial distribution of radioactive drugs for medical use. The redistribution of *in vitro* kits and sealed sources containing radioactive material for medical use is authorized pursuant to 4731.3390 and 4731.3400, respectively, if the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to 4731.3390 or 4731.3400, respectively. The transfer of radioactive materials for non-medical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to 4731.3105.

All radioactive material listed above shall be distributed only to persons authorized by an NRC or Agreement State license to receive such materials, or by a general license or equivalent Agreement State regulation) to receive *in vitro* test materials.

Initial distribution of unsealed radioactive material in the form of radiopharmaceuticals intended for human diagnostic and therapeutic use by medical licensees comprises the bulk of virtually all radiopharmacy activities. Before the transfer, distribution, or redistribution of any licensed material, the radiopharmacy must verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. The pharmacy should verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer's license. The most common form of verification is for the radiopharmacy to possess a valid copy of the customer's NRC or Agreement State license or other applicable document.

For radiopharmaceuticals, provide the following as applicable:

- Confirm that radiopharmaceuticals will be prepared under the supervision of an Authorized Nuclear Pharmacist (ANP) or will be obtained from a supplier authorized pursuant to 4731.3395, or under equivalent NRC or other Agreement State requirements.
- Describe all licensed material to be distributed or redistributed.

For generators, provide the following as applicable:

- Confirm that the generators will be obtained from a manufacturer licensed pursuant to 4731.3395, or under equivalent Agreement State requirements.

- Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

For redistribution of used generators<sup>4</sup>, provide the following as applicable:

- Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.
- Confirm that the manufacturer's packaging and labeling will not be altered.
- Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.
- Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.
- Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

For redistribution of sealed sources -- for brachytherapy or diagnosis, provide the following as applicable:

- Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 4731.3400, or under equivalent Agreement State requirements; and
- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of calibration and reference sealed sources, provide the following as applicable:

- Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 4731.3400 or under equivalent Agreement State requirements, to initially distribute such sources; and
- Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of prepackaged units for *in vitro* tests, confirm that the prepackaged units for *in vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 4731.3390, or under an equivalent license of an Agreement State.

For redistribution to general licensees:

- Confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way; and
- Confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

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<sup>4</sup> Although redistribution of used generators may be authorized by the MDH, approval does not relieve the licensee from complying with applicable FDA or other Federal and State requirements.

For redistribution to specific licensees:

- Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 4731.3245).
- Confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 4731.2300 and 2330.

#### ***Preparation of Radiopharmaceuticals***

The bulk of radiopharmacy activities involve the preparation of radiopharmaceuticals for commercial distribution to medical users. The applicant should indicate the types of radiopharmaceutical preparation activities it intends to perform (e.g., compounding of Iodine-131 capsules, radioiodination, and Technetium-99<sup>m</sup> kit preparation).

#### ***Sealed Sources for Calibration and Checks***

The applicant should describe the intended use of sealed sources. This will normally be for calibration and checks performed only on the applicant's instruments and equipment. Any sources intended for use in a specific instrument calibration device should be identified, along with the manufacturer and model number of the device. The use of depleted uranium for shielding (e.g., incorporated into Molybdenum-99/Technetium-99<sup>m</sup> generators) should also be specified, if appropriate.

Supply specific information concerning the use of sealed sources for reference and calibration.

#### ***Service Activities***

If the applicant intends to provide radiation protection services to customers, the services must be described. Typically, these services include instrument calibration and sealed source leak testing.

Specify the customer radiation protection services involving licensed material that will be provided. The applicant must submit specific procedures for all service activities that it intends to provide.

### **Item 7: Individual(s) Responsible for Radiation Safety Program**

Individuals responsible for the radiation protection program include the licensee senior management, the Radiation Safety Officer (RSO), ANPs, and authorized users (AUs). MDH requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Specific criteria for acceptable training and experience for ANPs is included in 4731.5000.

The minimum training and experience criteria for RSOs and AUs, though not specifically described in for radiopharmacy licensees, should include a bachelor's degree in a physical science, or equivalent, and previous experience handling and supervising similar activities. Applicants should note that a resume or curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience.

MDH holds the licensee responsible for the radiation protection program. Therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO, in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding MDH rules. The RSO should also be given license provisions and authority to terminate unsafe activities involving radioactive material. The licensee maintains the ultimate responsibility, nevertheless, for the conduct of licensed activities.

### ***Radiation Safety Officer (RSO)***

MDH requires the name, training, and experience of the proposed RSO to ensure that the applicant has identified a responsible, qualified person to oversee the radiation safety program. When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position, and select an individual who is qualified and has the time and resources to fulfill those duties and responsibilities. Typical duties and responsibilities of a radiopharmacy RSO are included in Appendix A.

The RSO needs a level of basic technical knowledge sufficient to understand the work to be performed with radioactive materials at the radiopharmacy and to be qualified by training and experience to perform the duties required for that position. Any individual who has sufficient training and experience to be named as an authorized nuclear pharmacist (ANP) is also considered qualified to serve as the facility RSO. The same is true for an authorized user (AU) who has had adequate training and experience in the radiation safety aspects associated with the use of similar types of radioactive material.

The training and experience requirements for the RSO may be met by any of the following:

- Qualification as an ANP;
- Identification as an AU on the license and experience in the use of the types and quantities of licensed material for which the individual has RSO responsibilities; or
- Didactic and work experience.

In order 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, or 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 and measurement instrumentation
- Biological hazards of exposure to radiation (appropriate to types and forms of byproduct material to be used)
- MDH regulatory requirements and standards
- Hands-on use of radioactive materials commensurate with the uses proposed by the applicant

The length of training and experience will depend upon the type, form, quantity, and proposed use of the licensed material requested. The proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. The requisite training may be obtained from formal courses consisting of lectures and laboratories designed for RSOs presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not be counted toward the hours documenting length of training unless it was obtained as part of a formal training course. A formal training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to MDH upon request.

- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to MDH upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
- A permanent record that the student successfully completed the course is kept at the institution.

Provide the name of the proposed RSO and a copy of the license (NRC or Agreement State) that authorizes the uses requested and on which the individual is specifically named as the RSO, an ANP, or an AU. Alternatively, submit a description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies.

***Authorized Nuclear Pharmacist (ANP)***

Each commercial nuclear pharmacy must have an authorized nuclear pharmacist to prepare or supervise the preparation of radioactive drugs for medical use. Any individual who is not qualified to be an authorized nuclear pharmacist may work under the supervision of an authorized nuclear pharmacist.

On-the-job training may not be counted toward the hours listed above unless it was obtained as part of a formal training course. A formal training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to MDH upon request.
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to MDH upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
- A permanent record that the student successfully completed the course is kept at the institution.

For each proposed ANP, provide the name of the pharmacist, a copy of the State pharmacy licensure or registration for the pharmacist, a copy of the license (NRC or Agreement State) on which the individual was specifically named as an ANP, and a description of the recentness of training.

In place of a copy of a license (NRC or Agreement State) on which the individual was specifically named as an ANP, the applicant may submit the following:

- A copy of the permit maintained by a licensee of broad scope that identifies the individual as ANP;
- A copy of previous NRC or Agreement State license issued to a commercial radiopharmacy on which the pharmacist was specifically named as an authorized user;
- Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience; and written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy

***Authorized Users (AU)***

If the applicant intends to perform functions other than the preparation and distribution of radioactive drugs, the applicant may request that an individual other than an ANP perform and/or supervise those functions. This individual, if approved, would be designated on the license as an AU. These other functions may include leak testing of sealed sources or instrument calibration services for the pharmacy and its customers.

In order to demonstrate adequate training and experience, the proposed AU should have (1) as a minimum, a bachelor's degree or equivalent training and experience in physical, chemical, or 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 and measurement instrumentation
- Biological hazards of exposure to radiation (appropriate to types and forms of byproduct material to be used)
- MDH regulatory requirements and standards
- Hands-on use of radioactive materials commensurate with uses proposed by the applicant

The length of training and experience listed above will depend upon the type, form, quantity, and proposed use of the licensed material requested. The proposed AU's training and experience should be sufficient to identify and control the anticipated radiation hazards. The above training may be obtained from formal radiation safety courses consisting of lectures and laboratories presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A formal training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to MDH upon request.
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to MDH upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
- A permanent record that the student successfully completed the course is kept at the institution.

The AU must demonstrate training and experience with the type and quantity of material that is to be used at the pharmacy. For example, someone with training and experience only with microcurie quantities of unsealed radioactive material may not be qualified to use or supervise the use of higher activity sealed radioactive sources for instrument calibration. 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.

For each proposed Authorized User (AU), submit the user's name; identify types, quantities, and proposed uses of licensed material; and include a copy of the license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials.

**Item 8: Training for Individuals Working In or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)**

***Occupationally Exposed Workers and Ancillary Personnel***

Individuals working with licensed material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. In addition, those individuals who,

in the course of employment, are likely to receive in a year a dose in excess of 100 mrem (1 mSv) must receive instructions as specified in 4731.1000.

Each licensee must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with 4731.2000. Each individual working with radioactive material must be trained in the radiation safety procedures applicable to their job before beginning work with licensed materials. Licensees should not assume that safety instruction has been adequately covered by prior employment or training. Practical, site-specific training should be provided for all individuals before beginning work with, or in the vicinity of, licensed material. Training should also be performed whenever there is a significant change in duties, procedures, regulations, or terms of the license. Each individual should also receive periodic refresher training at a frequency sufficient to ensure that all staff remain adequately trained.

Additional training is required if an individual is likely to receive a dose in excess of 1 mSv (100 mrem) in a year. ANPs and others involved in the preparation of radiopharmaceuticals are most likely to receive doses in excess of 1 mSv (100 mrem) in a year; however, potential radiation doses received by all employees must also be evaluated. The evaluation must include consideration of assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during licensed activities.

If individuals making deliveries of radioactive material at the licensee's facility are likely to receive a dose in excess of 1 mSv (100 mrem) in a year from the licensee's activities, the licensee is responsible for ensuring that the person has received the training, regardless of whether that person is an employee of the licensee. If the training has been provided by someone else (such as the shipper or another licensee), the licensee does not have to provide training except for instruction in site-specific radiation hazards.

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. A method should be provided for individuals receiving instructions and training to ask questions. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual (e.g., the RSO, an ANP, AU, or radiation safety professional familiar with the licensee's program).

Licensee personnel who work in the vicinity of, but do not handle, radioactive materials (ancillary staff) are not required to have radiation safety training as long as they are not likely to receive 100 mrem (1 mSv) in a year. However, to minimize potential radiation exposure when ancillary staff are working in the vicinity of radioactive material, it is prudent for them to work under the supervision and in the physical presence of an ANP/AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the radioactive material and the meaning of the radiation symbol. They should also be instructed not to handle radioactive materials and to keep away from them as much as their work permits.

Some ancillary staff, although not likely to receive doses over 100 mrem (1 mSv), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments in the vicinity of the radioactive material to ensure the control and security of the material.

The applicant should state, "We have developed and will implement and maintain written procedures for a training program for each group of workers, including topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training."

### ***Personnel Involved in Hazardous Materials Package Preparation and Transport***

Applicants must train personnel involved in the preparation and transport of hazardous material packages in the applicable DOT regulations<sup>5</sup>. Licensees who prepare packages of radioactive materials or transport their own packages must provide training to their employees who perform those functions. The training must include:

- General awareness and familiarization training designed to provide familiarity with DOT requirements, and the ability of the employee to recognize and identify hazardous materials.
- Function-specific training concerning the DOT requirements that are specifically applicable to the functions the employee performs, (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in DOT's regulations governing package labeling).
- Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed to in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

The training must be provided initially, and every three years thereafter. Records of training must be maintained.

Submit the following statement: "We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable."

### ***Instruction for Supervised Individuals Preparing Radiopharmaceuticals***

Individuals who prepare radioactive material for medical use under the supervision of an authorized nuclear pharmacist must be instructed in the preparation of radioactive material for medical use, the principles of radiation safety, and the licensee's procedures for the use of radioactive material. They must also follow the instructions given, and have records kept reflecting their work periodically reviewed by the supervising ANP.

### **Item 9: Facilities and Equipment**

Applicants must provide MDH with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of their employees and the public. The facilities and equipment must also keep exposures to radiation and radioactive materials ALARA and minimize the risks from the uses of the types and quantities of radioactive materials. The applicant should provide clear delineations between its restricted and unrestricted areas through the use of barriers, postings, and worker instructions.

Applicants may delay completing facilities 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 cannot 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 are required to be maintained in an identifiable location. For further information, see the section entitled, "Financial Assurance and Record Keeping for Decommissioning."

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<sup>5</sup> The licensee is not responsible for providing DOT-required hazardous materials training to common carriers to whom the pharmacy offers radioactive materials packages for transport.

Applicants must provide a description of the facilities and equipment to be made available at each location where radioactive material will be used. A diagram should be submitted showing the applicant's entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions should be indicated.

Submit an annotated drawing of the room or rooms and adjacent areas. Include the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. Descriptions of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials and the location(s) for radioactive waste storage.
3. The type, thickness, and density of shielding materials within the facility area (including the floor and roof). Sufficient detail in the diagram to indicate the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.
5. A description of the nature of the areas adjacent to the installation, and the distance to these areas.
6. Types of posting and their locations.
7. The locations of entranceways and other points of access into the installation.
8. Security controls to prevent unauthorized access.
9. The results of radiation-level calculations or actual radiation measurements adjacent to, above, and below the installation.
10. A general description of the ventilation system, including representative equipment such as glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials with the probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions.

#### ***Radiation Monitoring Equipment***

Licensees must possess calibrated radiation detection/measurement instruments to perform, as necessary, the following:

- Package surveys
- Personnel and facility contamination measurements
- Sealed source leak tests
- Air sampling measurements
- Bioassay measurements
- Effluent release measurements
- Dose rate surveys

For the purposes of this document, radiation-monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the 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
- Hand and foot contamination monitors

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.). Radiopharmacies typically use a broad energy range of gamma and beta radiation emitters and need to use radiation detectors appropriate for those energies.

Applicants should discuss the types of instruments to be used for each type of survey to be performed and the availability of a sufficient quantity of these instruments at their facility.

Instrument calibrations may be performed by the pharmacy or by another person specifically authorized by NRC, an Agreement State, or a licensing state to perform that function. If the pharmacy utilizes the services of another person for instrument calibration, the pharmacy should ensure that person has been authorized by the NRC, an Agreement State, or a licensing State to perform that activity. The Calibration Regulatory Guide provides information about instrument specifications and model calibration procedures.

Licensees should provide a description of alternative minimum equipment to be used for radiation monitoring and/or alternative procedures for the calibration of radiation monitoring equipment.

#### ***Dosage Measurement Systems***

Due to the potential for radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured before transfer to provide high confidence that the correct amount of the radioactive drug is transferred in accordance with the customer's request. The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before their transfer for commercial distribution.

The procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. Performing periodic checks and tests before first use, followed by checks at specified intervals, and following repairs that could affect system performance accomplish this. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured.

Currently, no alpha-emitting nuclides are used in unsealed form in medicine; therefore, guidance is not provided in this document on the measurement of these radionuclides. For photon-emitters, activity measurement is a straightforward determination; however, for beta-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of beta-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST) traceable standard for all radionuclides currently in use. If radiopharmacies intend to *initially* distribute, i.e., measure, prepare, and label, beta-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to

accurately dispense such materials. If the applicant intends to use beta-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. In addition, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers).

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Appendix B contains a model procedure for dose calibrator testing.

The applicant must describe the types of systems (measurement or combination of measurement and calculation) it intends to use for the measurement of alpha-, beta-, and photon-emitting radioactive drugs.

Radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) beta-emitting radionuclides must provide the calculation to demonstrate its ability to accurately dispense such materials; however, a correction factor calculation is not required if radiopharmacy applicants intend to only redistribute beta-emitting radionuclides that were previously prepared and distributed by other licensees.

If applicable, the applicant must include a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers and a means for ensuring the accuracy of beta-correction factors.

#### **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 A through L. Review each appendix carefully. (Some of these appendices have been addressed in the preceding 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."

Appendix A	Typical Duties and Responsibilities of the Radiation Safety Officer
Appendix B	Dose Calibrator Testing Program
Appendix C	Suggested Commercial Radiopharmacy Audit Checklist
Appendix D	Ordering and Receiving Radioactive Material
Appendix E	Safely Opening Packages Containing Radioactive Material
Appendix F	Personnel Exposure Monitoring Program
Appendix G	Safe Use of Radiopharmaceuticals
Appendix H	Model Spill Procedures
Appendix I	Area Surveys
Appendix J	Monitoring, Calculating and Controlling Air Concentrations
Appendix K	Leak Testing Sealed Sources
Appendix L	Customer Return of Radioactive Wastes to Nuclear Pharmacies

### ***Audit Program***

Appendix C contains a suggested audit program that is specific to commercial radiopharmacies. Not all areas indicated in the Appendix may be applicable to every licensee, and not all items may need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to their activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Licensees must maintain records of audits and other reviews of program content and implementation for three years from the date of the record. NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

### ***Material Receipt and Accountability***

Licensed materials must be tracked from receipt to disposal in order to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their radiation protection program:

- Physical inventories of sealed sources at intervals not to exceed six months
- Ordering and receiving licensed material
- Package opening
- Maintaining material inventory within license possession limits
- Transfer of material, including distribution
- Disposal of material

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

MDH regulations state the requirements for monitoring packages containing licensed material. These requirements are described in Table 1, below.

**Table 1 Package Monitoring Requirements**

<b>PACKAGE</b>	<b>CONTENTS</b>	<b>SURVEY TYPE</b>	<b>SURVEY TIME<sup>6</sup></b>
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 3 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 3 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 3 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 3 hours after receipt of package

The licensee must immediately notify the final delivery carrier and MDH when removable radioactive surface contamination exceeds the limit of 22 disintegrations per minute per square centimeter (dpm/cm<sup>2</sup>) averaged over 300 cm<sup>2</sup>; or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

*Licensees must maintain records of receipt, transfer, and disposal of licensed material.* Licensees must secure and control licensed material and should have a means of promptly detecting losses of licensed material. MDH rules require licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

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. Sources in storage that are used infrequently may not require leak testing; however, the inventory must still be performed at the specified intervals.

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.

Table 2 lists the types and retention times for the records of receipt, use, transfer, and disposal (as waste) of all licensed material the applicant must maintain. Other records, such as transfer records, could be linked to radioactive material inventory records.

<sup>6</sup> 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.

**Table 3 - Record Maintenance**

<b>TYPE OF RECORD</b>	<b>HOW LONG RECORD MUST BE MAINTAINED</b>
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until MDH terminates the license
Important to decommissioning	Until the site is released for unrestricted use

Material accountability records typically contain the following information:

- Radionuclide and activity (in units of becquerels or curies), and the 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 radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number); and
- For licensed materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.).

The applicant should confirm that they will:

- Implement and maintain written procedures for safely opening packages.
- Conduct physical inventories of sealed sources of licensed material at intervals not to exceed six months.
- Develop, implement and maintain written procedures for licensed material accountability and control to ensure that:
  - license possession limits are not exceeded;
  - licensed material in storage is secured from unauthorized access or removal;
  - licensed material not in storage is maintained under constant surveillance and control; and
  - records of receipt, transfer, and disposal of licensed material are maintained.

***Occupational Dose***

The licensee should perform a prospective evaluation of the dose the individual is likely to receive before allowing the individual to receive the dose. When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. 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. For individuals who have received doses at other facilities in

the current year, the previous dose does not need to be considered in the prospective evaluation if monitoring was not required at the other facilities. 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 the prospective evaluation shows that an individual's dose is not likely to exceed ten percent of any applicable regulatory limit, the individual is not required to be monitored for radiation exposure and there are no recordkeeping or reporting requirements for doses received by that individual. If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required.

The types and quantities of radioactive material used at most commercial radiopharmacies provide a reasonable possibility for an internal intake by ANPs and radiopharmacy technologists. Uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing from vials containing millicurie quantities of radioiodine and other isotopes require particular caution. Precautionary measures for personnel to follow during iodine capsule preparation should involve the use of a fume hood and glove box or shoulder length gloves. To monitor internal exposure from such operations, most pharmacies institute a routine bioassay program to periodically monitor these workers.

A program for performing thyroid uptake bioassay measurements should include adequate equipment to perform bioassay measurements, procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units and should address the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue). Thyroid bioassay procedures should also specify the interval between bioassays, action levels, and the actions to be taken at those levels. Generally, thyroid bioassays at radiopharmacies are performed weekly for those workers who routinely handle radioiodine or are in the immediate vicinity when radioiodine is being handled.

Licensees should submit the written procedures for monitoring occupational dose.

#### ***Public Dose***

Public dose is defined as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation, sanitary sewerage discharges from licensees, and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual occupies when the dose is received.

Many possible internal dose pathways contribute to the total effective dose equivalent (TEDE). The TEDE can, however, be broken down into three major dose pathway groups:

1. Airborne radioactive material
2. Waterborne radioactive material
3. External radiation exposure

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure that the total effective dose equivalent from all exposure pathways arising from licensed activities does not exceed 100 mrem (1.0 mSv) to the maximally exposed member of the public. In addition, the licensee must control air emissions, such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level of 10 mrem (0.1 mSv) per year from those emissions. If exceeded, the licensee must report this to MDH and take prompt actions to ensure against recurrence.

Licensees should submit an outline of the monitoring program.

### **General Safety Procedures**

The written procedures should include the following elements:

- Contamination controls
- Waste disposal practices
- Personnel and area monitoring (including limits and frequency of personnel monitoring)
- Use of protective clothing and equipment (including use of appropriate shielding and frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the laboratory)
- Safe handling of radioactive materials (including special procedures for higher risk activities, such as use of radioiodine)
- Performing Molybdenum-99 breakthrough measurements on each elution from a generator
- Posting and labeling
- Recording requirements
- Reporting requirements
- Responsibilities

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

### **Emergency Procedures**

Accidents and emergencies can happen during any operation with radioisotopes, including their receipt, 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, and fires involving radioactive material can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize the potential 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 staff and the radiation safety officer. In addition, the licensee should develop procedures for routine contacts with its local fire department to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with systematic instructions and clear direction of whom to contact. The licensee should establish clear delineations between minor contamination events, minor spills, and major spills and events.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Applicants may adopt these procedures or develop their own incorporating the safety features included in these model procedures.

The licensee should submit the written procedures for the safe use of radioactive materials that address the following:

- Facility and personnel radioactive contamination minimization, detection, and control.
- Performing molybdenum-99 breakthrough measurements on all generator elutions used to prepare radioactive drugs for human medical use.
- Use of protective clothing and equipment by personnel.
- Identifying and responding to emergencies involving radioactive material, including:
  - Lost, stolen, or missing licensed material.
  - Exposures to personnel and the public in excess of MDH regulatory limits.
  - Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits.
  - Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas.
  - Radioactive spills and contamination.
  - Fires, explosions, and other disasters with the potential for the loss of containment of licensed material.
  - Routine contacts with local fire departments.

### **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 radioactivity should be understood in terms of its properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

Surveys are required to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate 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 radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g. radioiodine) or where licensed material is or could be released to unrestricted areas.
- Bioassays to determine the kinds, quantities or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe.
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers and returns from customers) and departing (e.g., prepared radiopharmaceuticals for shipment to customers).

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 workers from external and internal exposure.

#### ***Undetected Contamination and Loss of Control of Licensed Material***

Due to the large quantities of licensed material in liquid form often handled by radiopharmacy personnel, there can be a greater potential for radioactive material contamination. Radiation surveys, if properly conducted as outlined in this section, will normally detect contamination before it leaves the licensee's restricted area (e.g., radiopharmaceutical preparation and packaging areas). If detected within the restricted area during or shortly following radiopharmaceutical preparation, the licensee can normally complete standard decontamination activities to mitigate the spread of the contamination outside the restricted area.

Once the control of the radioactive material is lost, the contamination has a high probability of reaching public locations outside the radiopharmacy, including its customers. Contamination incidents can create public health, regulatory, and public relations problems for licensees.

Submit the written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring.

#### ***Transportation***

The types and quantities of radioactive materials shipped by commercial radiopharmacy licensees will nearly always meet the criteria for shipment in a "Type A" package, as defined by the DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For radiopharmacies who transport their own packages, the packages must be blocked and braced, and shipping papers must be used and located properly in the driver's compartment.

Packaging used by commercial radiopharmacies typically includes military ammunition boxes, briefcases, and cardboard/fiberboard boxes. These packages will normally meet the criteria for Type A quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions. The testing criteria for Type A packages are listed in 49 CFR 173.465. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, but must ensure that the testing was performed before use. Records of this testing must be maintained.

DOT regulations also require that individuals who perform functions related to the packaging and shipment of radioactive material receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for the individuals' duties, and safety training. DOT also specifies the frequency of the training and a record retention requirement for training.

The licensee should commit to transporting radioactive materials in accordance with US Department of Transportation (DOT) requirements.

#### ***Minimization of Contamination***

All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. In the case of commercial radiopharmacy applicants, these issues usually do not need to be addressed as a separate item, as they are included in responses to other items of the application.

The bulk of unsealed radioactive material utilized by radiopharmacies have short half-lives (under 120 days). These radionuclides do not pose a source of long-term contamination. Additionally, nearly all radioactive waste generated by radiopharmacies is stored for decay rather than transferred to a radioactive waste disposal facility.

The licensee may possess and redistribute sealed sources that contain radionuclides with long half-lives. These sealed sources have been approved by NRC or an Agreement State and, if used according to the respective SS&D Registration Certificate, usually pose little risk of contamination. Leak tests performed at the frequency specified in the SS&D Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to MDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

#### ***Radioactive Drug Labeling for Distribution***

The licensee must label each transport radiation shield to show the radiation symbol as described in 4731.2000. The label must also include the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The phrase transport radiation shield refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. The transport radiation shield should be constructed of material appropriate for the isotope to be transferred for commercial distribution. The transport radiation shield does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

The licensee must label each syringe, vial, or other container (e.g., generator or ampule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol. The label must include the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. The identifier must provide a correlation between the syringe, vial, or other container and the information on the label of its transport radiation shield. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

The applicant must describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the transport radiation shield or the container used to hold the radioactive drug); The applicant must also agree to affix the required labels to all transport radiation shields and each container used to hold the radioactive drugs.

#### ***Radioactive Drug Shielding for Distribution***

The applicant must provide appropriate transport radiation shields for the primary container of each radioactive drug that it intends to distribute. The shielding must be adequate for the types and quantities of radioactive materials that the applicant intends to distribute. Typically, transport radiation shields used by radiopharmacies have included two-piece, shielded syringe and vial containers (or "pigs"). Pharmacies have used lead and tungsten shields for gamma-emitting materials and plexiglass inserts for beta-emitters.

As general guidelines, transport radiation shields for Technetium-99<sup>m</sup> products have ensured surface radiation levels of not more than 3 mrem/hr (0.03 mSv/hr), due to the ease of shielding the low energy gamma emitted. For Iodine-131, surface dose rates on transport radiation shields have been approved up to 50 mrem/hr (0.5 mSv/hr) for diagnostic dosages and up to 150 mrem/hr (1.5 mSv/hr) for therapeutic dosages. The applicant should select appropriate shielding materials and dimensions to not only ensure that occupational doses are ALARA, but also that the transport radiation shield can be easily handled.

For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, syringe).

- Describe the type and thickness of the transport radiation shield provided for each type of container.
- Indicate the maximum radiation level to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.<sup>7</sup>

### ***Leak Testing of Sealed Sources***

When issued, a license will require performance of leak tests at intervals approved by the NRC or an Agreement State and specified in the SSD Registration Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 0.005 microcuries (185 Bq) of radioactivity.

Each sealed source must be tested for leakage at intervals not to exceed six months. The leak test should be performed at six-month intervals. The instrumentation should be sufficiently sensitive to detect 0.005 microcuries of radioactivity.

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. Use a commercial leak test kit. You take the smear and send the smear to the kit supplier, who will report the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurement.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier. In your application, you should state that the test samples will be taken by the individuals specified in Item 8 who are responsible for your radiation safety program. Commit to Appendix K.1.

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 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 K.1 and K.2.

Some radiopharmacies have been authorized to perform leak testing as a service for other licensees (customers). The subsection titled "service activities" addresses requests to perform leak testing as a service for other licensees. Applicants must specifically request authorization to perform leak testing as a service to other licensees. Requests to provide leak testing as a service to other licensees will be reviewed and, if approved, MDH staff will authorize via a license condition.

### **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.,

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<sup>7</sup> It is not acceptable to state that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the transport radiation shield.

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. Commercial radiopharmacies may request to receive certain radioactive waste returned from their customers.

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 commercial radiopharmacy licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-Storage (DIS);
- Transfer to an authorized recipient; and
- Release into sanitary sewerage.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. However, most commercial radiopharmacies dispose of radioactive waste by decay-in-storage because the majority of licensed materials used by these facilities have short half-lives.

Applicant's programs for management and disposal of radioactive waste should include procedures for handling, 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 permits licensed materials with half-lives of less than or equal to 120 days to be disposed by DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. Applicants should assure that adequate space and facilities are available for the storage of such waste. Procedures for management of waste by DIS should include methods of segregation, surveys before disposal, and maintenance of records of disposal.

Licensees can minimize the need for storage space if radioactive waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing radioisotopes of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and thus may be disposed in shorter periods, freeing storage space.

Used syringes/needles and vials returned from pharmacy customers (medical facilities) are considered both biohazardous and radioactive waste since these items may be contaminated with patients' blood or other body fluids. Following completion of decay-in-storage, such waste may be disposed of as biohazardous waste (medical waste) 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.

Radioactive material labels on the used syringes/needles cannot be defaced without exposing employees to the risk of injury from the needles. Additionally, exposing employees to the risk of injury from needles would place licensees in violation of the Occupational Safety and Health Administration regulations, which requires precautions to prevent contact with blood or other potentially infectious materials, including recommendations not to manipulate used syringes/needles by hand. Thus, radiopharmacy licensee's do not have to deface or remove radiation labels from individual containers and packages (e.g., syringes, vials) inside waste barrels/containers intended for disposal as medical waste, provided the following conditions are met:

- The radioactive material labels on the outer waste barrels/containers will be defaced or removed prior to transfer to waste disposal firm.
- Waste barrels are sealed prior to delivery to the waste disposal firm.

- Waste barrels/containers will be delivered directly from the licensee's facility to a waste disposal firm for disposal.
- Medical waste is incinerated and not sent to a medical waste landfill.
- The waste disposal firm is notified that the barrels must not be opened at any point, and for any reason, before incineration.

Other pharmacy radioactive waste that has not been returned from customers and has not otherwise been exposed to blood or body fluids should not have a biohazardous component. Following decay, if it contains no other hazardous components (e.g. needles, hazardous chemicals), such waste may be disposed 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 final 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.

Records of DIS 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, results of final survey before disposal as ordinary trash and results of the background survey;
- identification of the instrument used to perform the survey; and
- the signature or initials of the individual performing the survey.

#### ***Transfer to an Authorized Recipient***

Licensees may transfer radioactive waste to an authorized recipient for disposal. Most commercial radiopharmacies only dispose of radioactive wastes with half-lives greater than 120 days to authorized recipients (e.g., low-level radioactive waste disposal facilities). Since radiopharmacy licensees typically possess small quantities of these materials, the volume of materials disposed in this manner would also be minimal. Currently, radiopharmacies use this system for waste disposal infrequently; therefore, detailed guidance is not provided in this document on the specific requirements related to the transfer of wastes to authorized recipients for disposal.

#### ***Release into Sanitary Sewerage***

Licensees will not normally be authorized to dispose of radioactive waste by release into sanitary sewerage. However, consideration will be given to requests if each of the following conditions are 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 limits specified in 4731.2750, subpart 7, Table 3.
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit cannot exceed unity. Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed the limits specified 4731.2750, subpart 7, Table 3.

Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are indeed readily dispersible in water and are required to maintain accurate records of all releases of licensed material into the sanitary sewerage, if that method is approved by MDH.

#### ***Returned Wastes from Customers***

Commercial radiopharmacy licenses contain a license condition that permits radioactive waste, consisting of pharmacy-supplied items, to be received from their customers. The customer may return, and the radiopharmacy may accept for disposal, only items originating at the radiopharmacy that contained or contain radioactive material<sup>8</sup>. This is limited to pharmacy-supplied syringes and vials and their contents. It is *not* acceptable for customers to return items originating at their facilities that are contaminated with radioactive material supplied by the pharmacy (e.g., gloves, absorbent material, IV tubing, patient contaminated items). If an applicant wishes a broader authorization for radioactive waste retrieval, the applicant must apply for a separate license as a radioactive waste broker.

Radiopharmacy customers, who act as the shipper for returned materials, should be supplied with detailed written instructions on how to properly prepare and package radioactive waste for return to the radiopharmacy. These instructions should clearly indicate that only items supplied by the radiopharmacy may be returned. In addition, these instructions should be adequate to ensure that customers comply with Department of Transportation (DOT) and MDH regulations for the packaging and transport of licensed materials and for the radiation safety of drivers/couriers.

Since customers may return unused syringes and vials, which may contain significant quantities of licensed material, the radiopharmacy should do one of the following:

- Include in their instructions methods for determining that the activities of radioisotopes returned to the pharmacy are limited quantities.
- Otherwise ensure that customers prepare and offer packages for transport that meet MDH and DOT requirements if the packages contain greater than limited quantities of radioactive material.

The radiopharmacy should also have written instructions for pharmacy staff to address pick-up, receipt and disposal of the returnable radioactive waste.

If the pharmacy chooses to take the responsibility to act as the shipper for returned materials, the pharmacy must ensure that its customer follows DOT and MDH regulations for the packaging and transport of licensed materials and for the radiation safety of drivers/couriers in the return process. Submit the written procedures for customer return of pharmacy supplied syringes and vials and their contents, to specify that:

- Only pharmacy-supplied syringes and vials and their contents may be returned to the pharmacy.
- Instructions will be provided to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy.
- Instructions will be provided to pharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste.

#### **Item 12: License Fee**

If this is an application for a new license, the full fee 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

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<sup>8</sup> Retrieval, receipt and disposal of pharmacy-supplied syringes and vials from customers is authorized via a license condition.

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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

### **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

### **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of radioactive material are capable of complying with

MDH rules. This guide provides one set of methods approved by 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**  
**TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER**

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

- General surveillance is provided over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events.
- Incidents are responded to and investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.
- Proper authorities are notified of incidents such as damage, fire, or theft.
- Corrective actions are developed, implemented, and documented when violations of regulations or license conditions or program weaknesses are identified.
- All activities are immediately terminated following any unsafe condition or activity that is found to be a threat to public health and safety.
- He or she is the primary source of radiation protection information for personnel at all levels of responsibility.
- All radiation workers are properly trained.
- Procedures for the safe use of radioactive materials are developed and implemented.
- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit.
- Prospective evaluations are performed of occupational exposures, and those individuals likely to receive, in one year, a radiation dose in excess of ten percent of the allowable limits are provided personnel monitoring devices.
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- The performance of fume hoods and glove boxes used for volatile radioactive material work are monitored for proper operation.
- The receipt, opening, and delivery of all packages of radioactive material arriving at the nuclear pharmacy are overseen and coordinated.
- An inventory of all radioactive materials is maintained and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license.
- Sealed sources are leak tested at required intervals.
- There is effective management of the radioactive waste program, including effluent monitoring.

- Packaging and transport of radioactive material is in accordance with all applicable DOT requirements.
- An up-to-date license is maintained, and amendment, renewal requests, and notifications of new authorized nuclear pharmacists are submitted in a timely manner.
- Radiation safety program audits are performed at least annually and documented.
- He or she acts as liaison to the MDH.
- All required records are properly maintained.

**APPENDIX B  
MODEL DOSE CALIBRATOR TESTING PROGRAM**

This model procedure can be used by applicants and licensees for checking and testing dose calibrators.

**MODEL PROCEDURE**

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances.
  - 1.1 Constancy, at least once each day prior to assay of patient dosages (a safe margin is considered to be below + 10%).
  - 1.2 Linearity at installation and at least quarterly thereafter (a safe margin is considered to be below + 10%).
  - 1.3 Geometry dependence at installation (a safe margin is considered to be below +10%).
  - 1.4 Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below +10%).
2. After repair, adjustment, or relocation of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cesium- 137, Cobalt-60, Cobalt-57, or Radium-226 using a reproducible geometry each day before using the calibrator; however, Cobalt-57 and Radium-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material. Consider using two or more sources with different photon energies and activities.

Use the following procedure:

- 3.1 Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cesium-137 setting to assay Cesium-137).
  - 3.2 Measure background at the same setting, and subtract or confirm the proper operation of the automatic background circuit if it is used.
  - 3.3 For each source used, either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.
  - 3.4 Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
  - 3.5 Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the authorized nuclear pharmacist or the radiation safety officer of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator should be repaired or replaced if the error exceeds 10%.
4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. *Linearity* means that the calibrator is able to

indicate the correct activity over the range of use of that calibrator. This example uses a vial of Technetium-99<sup>m</sup> that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes your predetermined safety margin is ±5%.

**4.1 Time Decay Method**

- 4.1.1 Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).
- 4.1.2 Assay the Technetium-99<sup>m</sup> vial in the dose calibrator and subtract background to obtain net activity in millicuries.
- 4.1.3 Repeat step 4.1.2 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
- 4.1.4 Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

<u>Assay Time<sup>9</sup> (hours)</u>	<u>Correction Factor</u>
0	31.6
6	15.8
24	2.00
30	1.00
48	0.126

- 4.1.5 Plot both the measured net activity and the calculated activity versus time.
- 4.1.6 On the graph, the measured net activity plotted should be within ±5% of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.
- 4.1.7 If instrument linearity cannot be corrected, for routine assays it will be necessary to use either a portion of the eluate that can be accurately measured or the graph constructed in step 4.1.5 to relate measured activities to calculated activities.

**4.2 Shield Method:**

If a set of sleeves of various thicknesses is used to test for linearity, it will first be necessary to calibrate them.

- 4.2.1 Begin the linearity test by assaying the Technetium-99<sup>m</sup> syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time. After making the first assay, the sleeves can be calibrated as follows. (Steps 4.2.2 through 4.2.4 must be completed within 6 minutes.)

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<sup>9</sup> Assay times should be measured in whole hours and correction factors should be used to three significant figures as indicated. The half-life of T<sub>1/2</sub> = 6.02 hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.6 mCi, the calculated activities for 6 and 48 hours would be 15.6 mCi x 15.9 = 248 mCi and 15.6 mCi x 0.126 = 1.97 mCi, respectively.

- 4.2.2 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- 4.2.3 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- 4.2.4 Continue for all sleeves.
- 4.2.5 Complete the following decay method linearity test steps:
- 4.2.5.1 Repeat the assay at about noon, and again at about 4:00 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which the range is selected with a switch, select the range normally used for the measurement.
- 4.2.5.2 Convert the time and date information recorded to hours elapsed since the first assay.
- 4.2.5.3 On a sheet of semi log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.
- 4.2.5.4 Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  
 $(A - \text{observed} - A\text{-line}) / (A\text{-line}) = \text{deviation}$
- 4.2.5.5 If the worst deviation is more than +0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to true activity.
- 4.2.6 From the graph made in step 4.2.5.3, find the decay time associated with the activity indicated with sleeve 1 in place. This is the equivalent decay time for sleeve 1. Record that time with the data recorded in step 4.2.2.
- 4.2.7 Find the decay time associated with the activity indicated with sleeve 2 in place. This is the equivalent decay time for sleeve 2. Record that time with the data recorded in step 4.2.3.
- 4.2.8 Continue for all sleeves.
- 4.2.9 The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

- 4.2.10 Assay the Technetium-99<sup>m</sup> syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
- 4.2.11 Steps 4.2.12 through 4.2.14 below must be completed within 6 minutes.
- 4.2.12 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- 4.2.13 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- 4.2.14 Continue for all sleeves.

- 4.2.15 On a sheet of semi log graph paper, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
- 4.2.16 Plot the data using the equivalent decay time associated with each sleeve.
- 4.2.17 Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  
 $(A\text{-observed} - A\text{-line})/A\text{-line} = \text{deviation}$ .
- 4.2.18 If the worst deviation is more than  $\pm 0.05$ , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to "true activity."
5. *Geometry independence* means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following example assumes that injections are done with 3-cc plastic syringes, that radiopharmaceutical kits are made in 30-cc glass vials, and that the predetermined safety margin is  $\pm 5\%$ .
- 5.1 In a small beaker or vial, mix 2 cc of a solution of technetium-99<sup>m</sup> with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. Tap water may be used.
- 5.2 Draw 0.5 cc of the Technetium-99<sup>m</sup> solution into the syringe and assay it. Record the volume and millicuries.
- 5.3 Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- 5.4 Repeat the process until a volume of 2.0-cc has been assayed. The entire process must be completed within 10 minutes.
- 5.5 Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal error lines above and below the chosen standard volume.
- 5.6 If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow a conversion from indicated activity to true activity. If this is necessary, be sure to label the table or graph "syringe geometry dependence," note the date of the test, and indicate the model and serial number of the calibrator.
- 5.7 To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Technetium-99<sup>m</sup> solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
- 5.8 Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- 5.9 Repeat the process until a volume of 19.0-cc has been assayed. The entire process must be completed within 10 minutes.

- 5.10 Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 5% error lines drawn above and below the chosen standard volume.
- 5.11 If any correction factors are greater than 1.05, or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow conversion from indicated activity to true activity. If this is necessary, be sure to label the table or graph "vial geometry dependence," note the date of the test, and indicate the model number and serial number of the calibrator.
6. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Cobalt-57, Cobalt-60, Cesium-137) should be used. One source should have a principal photon energy between 100 keV and 500 keV. If a Radium-226 source is used, it should be at least 10 microcuries; other sources should be at least 50 microcuries.

Consider using at least one reference source whose activity is within the range of activities normally assayed.

- 6.1 Assay a calibrated reference source at the appropriate setting (i.e., use the Cobalt-57 setting to assay Cobalt-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.
- 6.2 Average the three determinations. The average value should be within the predetermined safety margin, which in this example is 5% of the certified activity of the reference source, mathematically corrected for decay.
- 6.3 Repeat the procedure for other calibrated reference sources.
- 6.4 If the average value does not agree within 5% with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be repaired or replaced if the error exceeds 10%.
- 6.5 At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.
- 6.6 Put a sticker on the dose calibrator noting when the next accuracy test must be performed.
7. The individual performing the tests will sign or initial the records of all geometry, linearity, and accuracy tests.

**APPENDIX C  
SUGGESTED COMMERCIAL RADIOPHARMACY AUDIT CHECKLIST**

*Note:* All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities and activities that have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit \_\_\_\_\_ Date of Last Audit \_\_\_\_\_

Auditor \_\_\_\_\_ Date \_\_\_\_\_  
(Signature)

Management Review \_\_\_\_\_ Date \_\_\_\_\_  
(Signature)

Next Audit Date \_\_\_\_\_

**Audit History**

- A. Last audit of this location conducted on:
- B. Were previous audits conducted at intervals not to exceed 12 months?
- C. Were records of previous audits maintained?
- D. Were any deficiencies identified during last two audits or two years, whichever is longer?
- E. Were corrective actions taken? (Look for repeated deficiencies.)

**Organization and Scope of Program**

- A. If the mailing address or places of use changed, was the license amended?
- B. If ownership changed or bankruptcy filed, was MDH prior consent obtained or was MDH notified?
- C. Authorized Nuclear Pharmacists
  - 1. New ANP since last audit? If so, does new ANP meet MDH training requirements?
  - 2. If an individual began work as an ANP, was MDH notified within 30 days or was license amended?
- D. Radiation Safety Officer
  - 1. New RSO since last audit? If so, does new RSO meet MDH training requirements?
  - 2. If the RSO was changed, was license amended?

3. Is RSO fulfilling his/her duties?

4. To whom does RSO report?

**E. Authorized Users**

1. New AU since last audit? If so, does new AU meet MDH training requirements?

2. If an AU was added, was license amended?

**F. If the designated contact person for MDH changed, was MDH notified?**

**G. Type and quantity of radioactive material**

1. Does the license authorize all of the MDH regulated radionuclides possessed?

2. Is actual possession of those radionuclides within the limits on the license?

**Facilities**

A. Are facilities as described in MDH license application?

B. If facilities have changed, has MDH license been amended?

**Equipment and Instrumentation**

A. Sufficient numbers of portable and fixed radiation monitors?

B. Do survey meters meet the MDH's criteria?

C. Are calibration records maintained?

D. Are there sufficient lead shields (L-block, etc.) for work with radionuclides?

E. Are generators housed in separate room and/or properly shielded to keep doses ALARA?

F. Are procedures established for identifying, evaluating and reporting safety component defects?

**G. Dose Calibrators for Photon-emitters**

1. Constancy, at least once each day prior to assay of patient dosages ( $\pm 10\%$ )?

2. Linearity, at installation and at required frequency ( $\pm 10\%$ )?

3. Geometry dependence, at installation ( $\pm 10\%$ )?

4. Accuracy, at installation and at required frequency ( $\pm 10\%$ )?

5. After repair, adjustment, or relocation of the dose calibrator, were appropriate tests above repeated?

**H. Dose Measurement Systems for Beta- and Alpha-emitters**

1. Calibrated for each isotope used, with that isotope?

2. Constancy, at least once each day prior to assay of patient dosages ( $\pm 10\%$ )?
3. Geometry dependence, at installation ( $\pm 10\%$ )?
4. Accuracy, at installation and at required frequency ( $\pm 10\%$ )?
5. Linearity, at installation and at required frequency ( $\pm 10\%$ )?
6. After repair, adjustment, or relocation of the dose calibrator, were appropriate tests above repeated?

#### **Area Surveys and Contamination Control**

- A. Are area surveys being performed at applicable locations and required frequencies? Are records maintained?
- B. Are removable contamination surveys being performed at applicable locations and required frequencies? Are records maintained?
- C. Is appropriate corrective action taken and documented when excess radiation or contamination levels are detected?

#### **Leak Tests**

- A. Was each sealed source leak tested every six months or at other prescribed intervals?
- B. Was the leak test performed according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking and if yes, was MDH notified?

#### **Sealed Source Inventory**

- A. Are records kept showing the receipt of each sealed source?
- B. Are all sealed sources physically inventoried every six months?
- C. Are records maintained of inventory results with appropriate information?

#### **Training and Instructions to Workers**

- A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed?
  1. Is refresher training provided, as needed?
  2. Are records maintained?
- B. Were other workers trained as needed (e.g., radiopharmacy technicians, authorized users, couriers/drivers, ancillary personnel)? Are records maintained?

- C. Are workers knowledgeable of applicable radiation protection procedures, emergency response procedures and license conditions?
- D. Is HAZMAT training provided, if required?

**Material Use Control and Transfer**

- A. Are restricted and unrestricted areas delineated?
- B. Are radioactive materials that are stored in a controlled or unrestricted area secured from unauthorized access or removal?
- C. Are radioactive materials that are in a controlled or unrestricted area and not in storage controlled and maintained under constant surveillance?
- D. Procedures for receiving and opening packages?
- E. Is the transfer of radioactive material only done by authorized recipients?
- F. Are records kept of receipt and transfer?

**Personnel Radiation Protection**

- A. Are ALARA considerations incorporated into the radiation protection program?
- B. Were prospective evaluations performed showing that unmonitored individuals receive 10% of the limit?
- C. Did unmonitored individuals' activities change during the year which could put them over 10% of the limit?
- D. If yes to C. above, was a new evaluation performed?
- E. Is external dosimetry required for individuals likely to receive >10% of the limit? Is dosimetry provided to these individuals?
  - 1. Is the dosimetry supplier NVLAP approved?
  - 2. Are the dosimeters exchanged at appropriate frequency?
  - 3. Are dosimetry reports reviewed by the RSO when they are received?
  - 4. Are the records kept on MDH Forms or equivalent?
    - a. Has "Cumulative Occupational Exposure History" been completed?
    - b. Has "Occupational Exposure Record for a Monitoring Period" been completed?
  - 5. Declared pregnant worker/embryo/fetus
    - a. If a worker declared her pregnancy, did licensee comply with MDH requirements?
    - b. Were records kept of embryo/fetus dose?

- F. Monitoring for internal dose if individuals likely to receive >10% of ALI?
- G. Are workers notified annually of their exposures?
- H. Are records of exposures, surveys, monitoring, and evaluations maintained?

### **Waste Management**

- A. Waste storage areas
  - 1. Is storage area properly posted?
  - 2. Are containers properly labeled?
- B. Decay-in-Storage
  - 1. Do stored radionuclides all have half-lives less than 120 days?
  - 2. Are radionuclides segregated for storage according to half-life?
  - 3. Is each radionuclide in radioactive waste stored for a minimum of ten half-lives?
  - 4. Before waste is disposed of:
    - a. Are surveys performed at the container surface with an appropriate survey instrument set on its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background?
    - b. Are all radiation labels removed or obliterated, as appropriate?
  - 5. Are proper records maintained?
- C. Transfer to Authorized Recipient
  - 1. Is waste transferred to a person specifically authorized to receive it?
  - 2. Is waste properly manifested?

### **Receipt of Radioactive Waste from Customers**

- A. Does waste returned consist only of items that contained radioactive materials that the radiopharmacy supplied (e.g. pharmacy supplied syringes, vials)?
- B. Are waste packages checked for removable contamination upon receipt?

### **Effluents**

- A. Are effluents from materials maintained as low as reasonably achievable (ALARA)?
- B. Are fume hoods checked to confirm an adequate airflow?

- C. Are effluents monitored to determine activity being released?
- D. Are filters maintained according to the manufacturer's instructions and pharmacy procedures?

#### **Public Dose**

- A. Is public access to radioactive materials and exposure to effluents controlled in a manner to keep doses below 1 mSv (100 mrem) in a year?
- B. Are air emissions maintained below the constraint limit of 0.1 mSv (10 millirem) in a year?
- C. Has a survey or prospective evaluation been performed? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Are unrestricted area radiation levels exceeding 0.02 mSv (2 mrem) in any one hour?
- E. Are proper records maintained?

#### **Use and Emergency Procedures**

- A. Are procedures for safe use of radioactive materials and emergency procedures developed and implemented?
- B. Do the procedures contain the required elements?
- C. Are radioactive materials being handled safely?
- D. Are staff wearing protective clothing and personnel monitors as appropriate?
- E. Has assistance been coordinated with outside agencies for emergency response (e.g., fire department)?
- F. Did any emergencies occur?
  - 1. If so, were they handled properly?
  - 2. Were appropriate corrective actions taken?
  - 3. Was MDH notification or reporting required?

#### **Transportation**

- A. Are DOT-7A or other authorized packages used?
- B. Are package performance test records on file?
- C. Do packages have two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class?
- D. Are packages properly marked?
- E. Are packages closed and sealed during transport?

- F. Are shipping papers prepared and used?
- G. Do shipping papers contain proper entries? (Shipping name, Hazard Class, Identification Number [UN Number], Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity [SI units required], category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Emergency Response Information, and Cargo Aircraft Only [if applicable].)
- H. Are shipping papers within drivers reach and readily accessible during transport?
- I. Are packages secured against movement? [49 CFR 177.834]
- J. Were any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]

**Auditor's Independent Survey Measurements (If Made)**

- A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits?

**Notification and Reports**

- A. Was any radioactive material lost or stolen? Were reports made?
- B. Did any reportable incidents occur? Were reports made?
- C. Did any overexposures and high radiation levels occur? Were they reported?
- D. Were any contaminated packages or packages with surface radiation levels exceeding 200 mrem received? Was this reported to MDH?
- E. If any events (as described in items A through D above) did occur, what was root cause? Were appropriate notifications made and corrective actions taken?

**Posting and Labeling**

- A. Is "Notice to Workers" posted?
- B. Are MDH rules and license documents posted, or is a notice posted?
- C. Is there other posting and labeling?

**Record Keeping for Decommissioning**

- A. Are records kept of information important to decommissioning?
- B. Do records include all information?

**Bulletins and Information Notices**

- A. Were MDH Bulletins and MDH Information Notices received?

- B. Was appropriate training and action taken in response?

**Special License Conditions or Issues**

- A. Did the auditor review special license conditions or other issues?

**Deficiencies Identified in Audit; Corrective Actions**

- A. Summarize problems/deficiencies identified during audit.
- B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken by the facility. Include date(s) when corrective actions are implemented.
- C. Provide any other recommendations for improvement.

**Evaluation of Other Factors**

- A. Is senior licensee management appropriately involved with the radiation protection program and/or RSO oversight?
- B. Does the RSO have sufficient time to perform his/her radiation safety duties?
- C. Does the licensee have sufficient staff to support the radiation protection program?

## **APPENDIX D ORDERING AND RECEIVING RADIOACTIVE MATERIAL**

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may state on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that is published in Appendix D to the MDH Regulatory Guide for Nuclear Pharmacies."

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

### **MODEL GUIDANCE**

1. The Radiation Safety Officer (RSO) or a designee should ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. For routinely used materials:
    - (1) Written records identifying
      - authorized user or department
      - isotope
      - chemical form
      - activity
      - supplier
    - (2) Verification that material received was ordered by an authorized user.
  - b. For occasionally used materials (e.g., therapeutic dosages):
    - (1) The authorized user who will perform the procedure will make a written request to confirm that the material received is what was ordered.
    - (2) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.

**APPENDIX E**  
**SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**  
In addition to 4731.2350

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages published in Appendix E to the MDH Regulatory Guide for Nuclear Pharmacies."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix E," and submit your procedure.

**MODEL PROCEDURE**

1. All labeled packages containing radioactive material must be monitored for radiation levels and radioactive surface contamination according upon receipt.
2. The following procedures for opening each package will be followed:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
  - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is more than 10 millirems per hour at 3 feet (1 meter), stop and notify the RSO. (The transport index noted on packages with Yellow II or Yellow III labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface).
  - d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with White I labels should be less than 0.5 millirem per hour on the external surface of the package.

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

- f. Open the package with the following precautionary steps:
  - (1) Remove packing slip.
  - (2) Open outer package following the supplier's instructions, if provided.
  - (3) Open inner package and verify that the contents match the packing slip.
  - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
  - (5) If anything is other than expected, stop and notify the RSO.
- g. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument [for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter] should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator

is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.

- h. Check the user request to ensure that the material received is the material that was ordered.
  - i. Monitor the packing material and the empty packages for contamination with a radiation survey meter before discarding.
    - (1) If contaminated, treat this material as radioactive waste.
    - (2) If not contaminated, remove or obliterate the radiation labels before discarding it.
  - j. Make a record of the receipt.
3. For packages received under the general license, the following procedure for opening each package will be followed.
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - b. Check to ensure that the material received is the material that was ordered.

## APPENDIX F PERSONNEL EXPOSURE MONITORING PROGRAM

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may state on your application, "We will establish and implement the model personnel exposure monitoring program published in Appendix F.1 and/or F.2 to the MDH Regulatory Guide for Nuclear Pharmacies."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of MDH rules. State on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix F" and submit your monitoring program.

### F.1. MODEL PROGRAM FOR EXTERNAL EXPOSURE

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or finger monitor.
4. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages and secretarial personnel who work in the nuclear pharmacy but do not work with radioactive materials.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

### F.2. Model Program for Internal Exposure

#### ***Conditions Under Which Bioassays Are Required***

Personnel who prepare substantial doses of radioiodine may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Routine<sup>10</sup> bioassays are required when an individual handles in open form unsealed quantities of radioactive iodine that exceed the quantities shown in Table E.2. The quantities shown in Table F.2 apply to the quantity handled at any one time or the total amount used in a process over any three-month period.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed ten percent (10%) of the limit in the year. Monitoring as it applies

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<sup>10</sup> "Routine" in this instance means that an individual is assigned on a scheduled and repeatable basis to submit specimens for bioassay or to report for in vivo measurements. Either radiochemical bioassay of urine or in vivo counting is acceptable for estimating internal radioactivity burdens or intakes. In some cases, the licensee may wish to corroborate estimates from urinalysis data with in vivo determinations. Each facility should adopt procedures or obtain services best suited to its own needs.

to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay.

When quantities handled in unsealed form are greater than ten percent (10%) of the values in Table E.2, routine bioassays may be necessary under certain circumstances. A written justification for not performing bioassays should be prepared and recorded for subsequent review during inspections whenever bioassays are not performed and the quantities handled exceed ten percent of the levels in Table 2.

All workers handling radioactive iodine or working sufficiently close to the process so that intake is possible (e.g., within a few meters and in the same room as the worker handling the material) should participate in bioassay programs.

#### ***Frequency***

A baseline measurement should be established for workers prior to beginning work with radioactive iodine in sufficient quantities that require bioassays.

A bioassay should also be performed within the last two weeks of the last possible exposure to radioactive iodine when operations are being discontinued or when the worker is terminating activities or potential exposure to these isotopes.

Follow-up bioassays should be performed within two (2) weeks of any measurements exceeding action point levels in order to confirm the initial results and, in the case of a single intake, to allow an estimate of the effective half-life of the radioiodine in the thyroid.

#### ***Timing***

Biological samples or measurements should be obtained no sooner than one day (24 hours) and no later than four days (96 hours) following an exposure to conditions that require bioassays and every two (2) weeks or more thereafter as long as those conditions exist. When work with radioiodine is infrequent, bioassays should be performed within ten (10) days of the end of the work period during which radioactive iodine was handled.

Table 2

**ACTIVITY LEVELS ABOVE WHICH BIOASSAYS FOR IODINE ARE NECESSARY**

	Activity Handled in Unsealed Form Making Bioassay Necessary	
	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1 mCi	10 mCi
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	10 mCi	100 mCi
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box or box leakage	100 mCi	1000 mCi

Notes: Quantities may be considered the cumulative amount in process handled by a worker during a three-month period. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that radioiodine will remain in nonvolatile form and diluted to concentrations less than 0.1 mCi/mg of nonvolatile agent.

Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in non-free form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped or crushed). However, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process. The left column may then be applicable in those laboratories working only with Iodine-125. In radioimmunoassay (RIA) kits, the quantities of Iodine-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right column.

Bioassay should be performed whenever an individual employee handles in open form (e.g., an open bottle or container) more than 50 mCi at any one time. Operations involving the routine use of Iodine-125 or Iodine-131 in an open room or bench should be discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1 mCi of Iodine-125 or Iodine-131 should be opened at least initially within hoods having adequate face velocities of 0.5 m/sec or more.

## APPENDIX G SAFE USE OF RADIOPHARMACEUTICALS

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 G to the MDH Regulatory Guide for Nuclear Pharmacies."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the MDH rules. State on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Appendix G," and submit your model rules for the safe use of radiopharmaceuticals.

### MODEL RULES

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
5. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
6. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
7. Wear a finger exposure monitor during the elution of generators; during the preparation and assay of radiopharmaceuticals.
8. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
9. Never pipette by mouth.
10. Wipe-test by-product material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
12. With a radiation survey meter, survey daily for contamination the generator storage and kit preparation areas. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A logbook should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each dosage in the dose calibrator.
15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
16. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should consider the use a cart or other device to move waste and other radioactive material.

## **APPENDIX H MODEL SPILL PROCEDURES**

You may use the following model procedures as they appear here, stating on your application, "We will establish and implement the model spill procedure published in Appendix H to the MDH Regulatory Guide for Nuclear Pharmacies."

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

### **MODEL PROCEDURES**

#### ***MINOR SPILLS OF LIQUIDS AND SOLIDS***

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

#### ***MAJOR SPILLS OF LIQUIDS AND SOLIDS***

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

**MAJOR SPILLS AND MINOR SPILLS**

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

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

**Table H-1 – Relative Hazards of Common Radionuclides**

Estimate the amount of radioactivity spilled. If the amount spilled is greater than the amount indicated below for that isotope, the spill is considered major. Below these limits, the spill is considered minor.	
RADIONUCLIDE	MILLICURIES
Co-60, Sr-89, I-125, I-131	1
F-18, P-32, Co-58, Fe-59, Se-75, Sr-85, Y-90, In-111, I-123, Sm-153, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99 <sup>m</sup> , Tl-201	100

## APPENDIX I AREA SURVEYS

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys that is published in Appendix I to the MDH Regulatory Guide for Nuclear Pharmacies."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure. State on your application, "We have developed survey procedures for your review that are appended as Appendix I" and submit your survey procedures.

### MODEL PROCEDURE

#### AMBIENT DOSE RATE SURVEYS

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

Quarterly surveys should be accomplished in areas

  - adjacent to restricted areas
  - through which radioactive materials are transferred
  - where radioactive material is temporarily stored before shipment

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

#### REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas:

In any area where the potential for spreading contamination is likely to occur, (cafeterias, snack bars, furniture and equipment), survey at least *quarterly*. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.
2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200 dpm/100 cm<sup>2</sup> for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).
3. Immediately notify the RSO if you find levels, which exceed the established action levels. See Table 1 below for guidance in establishing your action levels.

**RECORDS**

1. Records must include the information (e.g., survey meter manufacturer, model, calibration date, surveyor, date, etc.) as well as actions taken in the case of excessive dose rates or contamination and follow-up survey information.
2. The RSO will review and initial the record at least monthly and promptly in those cases in which action levels were exceeded.

**Table I-1**

<b>RECOMMENDED ACTION LEVELS IN DPM/100 CM<sup>2</sup> FOR SURFACE CONTAMINATION</b>		
	<b>P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198</b>	<b>Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201</b>
<b>1. Unrestricted areas, personal clothing</b>	<b>200</b>	<b>2,000</b>
<b>2. Restricted areas, protective clothing used only in restricted areas, skin</b>	<b>2,000</b>	<b>20,000</b>

3. Maintain records for three years.

**APPENDIX J**  
**MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS**

**ADEQUACY OF FACILITY FOR HANDLING XENON-133**

You must have adequate equipment and operating controls to ensure that radioactivity in air is maintained within regulatory limits. Describe the scope and extent of your operations involving Xenon-133. Include the form in which Xenon-133 will be received (e.g., ampoules containing .1 curie or more, unit-dose vials), the form in which Xenon-133 will be dispensed, and the manipulations involved between receipt and dispensing. This description should include an estimate of the fraction of Xenon-133 lost during storage and manipulation.

It is assumed that you will receive Xenon-133 in unit-dose vials and redistribute the product to your customers upon request. One manufacturer estimated a loss factor of 0.5% per day from its unit-dose vials. This value has been used by some applicants and the MDH staff has found this acceptable. If you will use a more complicated process than simply redistributing unit-dose vials, you should provide information about your methods for estimating the loss factor.

**J.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES IN WORK AREAS.**

For *restricted areas*, the limit derived air concentrations (DAC) for Xenon-133 in air is  $1 \times 10^{-4}$   $\mu\text{Ci/ml}$ . In order to demonstrate compliance with this regulation, you may state that Xenon-133 will be stored in a fume hood with adequate airflow and that all work involving Xenon-133 will be conducted in that fume hood. If you do not so state, you should submit calculations to demonstrate compliance.

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, OSD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the derived air concentration (DAC) for Xenon-133 (or other gas to be used) to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of five (5) rems (50 mSv) and divide this number by five (5) rems.
  - a. This yields the fraction of the dose limit of five (5) rems that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in 4731.2750 in Table 1, column 3.
  - b. If the highest annual external dose is 2 rems, and the listed DAC value for Xenon-133 is  $1\text{E-}4$  mCi/ml, then the modified DAC value should be based on 3 rems that could still be incurred from internal exposure.
3. The following calculations must be made:
  - a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
  - b. The estimated activity released to the restricted areas.
    - (1) The total activity released to the restricted area divided by the total air exhausted must be less than the applicable DAC for a restricted area. The total activity released to the

restricted area is activity used each week multiplied by estimated fractional loss per study. The total air exhausted is the sum of all exhaust rates multiplied by the length of the workweek.

- (2) If this is not the case, plan for fewer studies and do the calculations again. An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.

## J.2 PUBLIC DOSE FROM AIRBORNE EFFLUENT

If you are not directly venting gases to the atmosphere, you may respond by stating, "We will not directly vent gases to the atmosphere and, therefore, no effluent estimation is necessary."

Effluent release presents a potential dose to the public. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week. The quotient must be less than the applicable DAC value for an unrestricted area.

If you will follow the model procedure below for calculating release concentrations, you may respond by stating, "We will follow the model procedure for calculating airborne effluent concentration that is published in Appendix J.2 to the MDH Regulatory Guide for Nuclear Pharmacies."

If neither of the above applies, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully. State on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as Appendix J.2," and append your procedure for monitoring airborne effluent concentration.

The limit for Xenon-133 concentrations at the boundary of the unrestricted area to  $5 \times 10^{-7}$   $\mu\text{Ci/ml}$  when averaged over one year. The calculations to estimate the concentration of Xenon-133 in effluents to unrestricted areas may be performed as follows:

1. Estimate the maximum amount of Xenon-133 to be released per week, value "A." Your estimate should be based on your total possession limit multiplied by your estimated loss factor.
2. Determine the airflow rate of the exhaust system and describe the methods used for measuring the airflow rates. *The airflow rate should be determined by actual measurement.* Linear airflow (i.e., feet per minute) must be multiplied by the area of the fume hood opening (in square feet) to obtain the airflow rating in cubic feet per minute.
3. Calculate the airflow per week, value "V."
4. Calculate the average concentration for unrestricted areas. MDH rules require that

$$C = A/V \leq 5 \times 10^{-7} \mu\text{Ci/ml}$$

The following gives the amount of Xenon-133 that can be released per week without exceeding an average concentration of  $5 \times 10^{-7}$   $\mu\text{Ci/ml}$ :

EXHAUST RATE (FT <sup>3</sup> /MIN)	AVERAGE RELEASE OF XENON-133 PER WEEK (MCI)
100	14.3
500	71.4
1,000	142.7
1,500	214.1

Some Useful Conversions

1 mCi	$10^3 \mu\text{Ci}$
1 ft <sup>3</sup>	$2.832 \times 10^4 \text{ ml}$
1 ft <sup>3</sup> /min	$1.699 \times 10^6 \text{ ml/hr}$

*Airflow ratings should be measured periodically to ensure continued compliance. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application.*

### J.3 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, calculations should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

1. Collect the following data:
  - a. A, the highest activity of gas in a single container, in microcuries;
  - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser values), in milliliters per minute;
  - c. Q -- the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not recirculated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system.
  - d. C -- the modified derived air concentrations (DAC) in restricted areas.
  - e. V -- the volume of the room in milliliters.
  
2. For each room make the following calculations:
  - a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
  - b. The evacuation time  $t = -V/Q \times \ln(C \times V/A)$ .

3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted to
  - 2.0 mrem in any 1 hour from external sources, and
  - 100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.

Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

#### **J.4 RECORDS**

1. Measure ventilation rates in areas of use at intervals not to exceed six months.
2. Maintain records for three years.

## **APPENDIX K LEAK TESTING SEALED SOURCES**

You may use the following model procedure to leak test sealed sources. If you follow the model procedure for taking leak test samples for analysis by a contractor, you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources that was published in Appendix (K.1 and/or K.2) to the MDH Regulatory Guide for Nuclear Pharmacies."

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. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix K," and submit your leak test procedure.

### **TRAINING**

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

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

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

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests

### **K.1 MODEL PROCEDURE FOR TAKING LEAK 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.
  - b. For larger sealed sources and devices, 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.

## K.2. MODEL PROCEDURES FOR ANALYZING LEAK TEST SAMPLES

### *Facilities and Equipment*

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (e.g., NaI(Tl) well counter system for gamma-emitters, liquid scintillation for beta-emitters, gas-flow proportional counters for alpha-emitters).
- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{3 + 4.65 (bkg/t)^{1/2}}{E}$$

where:

MDA	=	minimum detectable activity in disintegrations per minute (dpm)
bkg	=	background count rate in counts per minute (cpm)
t	=	background counting time in minutes
E	=	detector efficiency in counts per disintegration

For example:

where:

bkg	=	200 cpm
E	=	10%, or 0.1
t	=	2 minutes

$$MDA = \frac{3 + 4.65 (200 \text{ cpm}/2 \text{ minutes})^{1/2}}{(0.1)}$$

$$= 495 \text{ dpm}$$

### *Frequency for Conducting Leak Tests of Sealed Sources*

Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

### *Procedure for Performing Leak Testing and Analysis*

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.

- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcuries) of the radionuclide.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within +5% of the stated value and traceable to primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

For example: 
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$$

where:

cpm	=	counts per minute
std	=	standard
bkg	=	background
Bq	=	becquerel

- Count each wipe sample. Determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or mCi).

For example:

$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$$

- Sign and date the list of sources, data and calculations. Retain records for three years. If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO so that the source can be withdrawn from use and disposed of properly. Also notify MDH.

## APPENDIX L CUSTOMER RETURN OF RADIOACTIVE WASTES TO NUCLEAR PHARMACIES

Return only items that contained or contain radioactive materials supplied by the radiopharmacy (e.g., pharmacy-supplied syringes and vials and their contents). Most return shipments to radiopharmacies will qualify as excepted packages of limited quantity, in accordance with DOT requirements. For those packages containing radioactive material in excess of the limited quantity, customers should ensure that all applicable DOT requirements are met for the packages. This includes, but is not limited to, certification packaging (Type A), package marking and labeling, and shipping papers. For specific guidance on preparing these types of packages, please follow your in-house procedures for shipping radioactive material packages or contact the pharmacy for guidance.

Preparation of radioactive materials for return as excepted package of limited quantity:

- Ensure that the activities of material being returned are limited quantities as defined by DOT (see table below). Special attention should be given for the return of unused doses that may still contain significant activities of radionuclides. The amount of radioactivity in unused doses may necessitate that a syringe or vial be held for decay to reduce the activity to that permitted for shipment of limited quantities.
- Place the syringe or vial in the original, labeled, lead shield in which it was delivered.
- Place shielded waste into the shipping package (e.g., padded briefcase or ammo box) in which it was delivered. Note: Packages used to ship radioactive material to customers meet the DOT package requirements for transport of limited quantities.

Preparation of package:

- Using a calibrated survey meter, measure the radiation levels at all points on the surface of the package to ensure that levels are less than or equal to 0.5 mrem/hr;
- Use contamination wipes on the surface of the package to ensure that the removable contamination does not exceed 22 dpm/cm<sup>2</sup> over a 300 cm<sup>2</sup> area.
- Label the package as "Excepted Package - Limited Quantity of Material."
- Seal the package so it will be evident upon receipt if the package accidentally opened during shipment.

Shipping papers are not required when shipping limited quantities. However, the statement specified in 49 CFR 173.422 ("This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN2910.") must be included in, on, or otherwise provided with the shipment.

Limited Quantities (49 CFR 173.421) For Typical Radionuclides as Liquid Used by Radiopharmacies (49 CFR 173.425 - Table 7)

**Table 1 - Limited Quantity Values for Liquid Radioactive Material Packages**

Liquid Radionuclides	A2 Value (Ci)	Limited Quantity Shipment (mCi) A2 X 10 <sup>-4</sup>
Co-57	216	21.6
Co-58	27	2.7
Cr-51	811	81.1
Ga-67	162	16.2
I-123	162	16.2
I-125	54.1	5.41
I-131	13.5	1.35
In-111	54.1	5.41
Mo-99	20 <sup>11</sup>	2
P-32	8.11	0.81
Se-75	81.1	8.1
Sr-89	13.5	1.35
Tc-99 <sup>m</sup>	216	21.6
Tl-201	270	27

**Table 2 - Limited Quantity Values for Gaseous Radioactive Material Packages**

Radionuclide Uncompressed Gas	A2 Value (Ci)	Limited Quantity Shipment (mCi) A2 X 10 <sup>-3</sup>
Xe-133 (uncompressed)	1541	1541

**Table 3 - Limited Quantity Values for Special Form Radioactive Material Packages**

Solid Radionuclide Special Form	A1 Value (Ci)	Limited Quantity Shipment (mCi) A1 X 10 <sup>-3</sup>
Ir-192	27	27
Cs-137	54.1	54.1

The values above are derived from 49 CFR 173.423, Table 7, and the Table of A1 and A2 values for radionuclides in 49 CFR 173.435. If shipping more than one radionuclide in the same package, the limits in 173.433(d) apply as follows: The sum of the ratios of the activity of each radionuclide divided by its respective A2 value must be less than or equal to one. For special form material, the sum of the ratios of the activities of each radionuclide divided by its respective A1 value must be less than, or equal to, one.

***Procedure for Driver or Courier for Pick-up of Radioactive Waste from Customers***

- Ensure that the shipping package is properly labeled "Excepted Package - Limited Quantity of Material."
- Ensure that the shipping package has been sealed.
- Do not accept any package that is not properly labeled and sealed.

***Procedure for Receipt and Opening of Packages from Customers Containing Radioactive Waste***

- Place all returned packages in an identifiable location within the radiopharmacy.
- Put on disposable gloves.

<sup>11</sup> For domestic use

- Monitor the package for removable contamination. If wipe tests indicate contamination levels greater than 22 dpm/cm<sup>2</sup> over a 300 cm<sup>2</sup> area, take the following actions:
  - Notify the customer and the MDH.
  - Survey the driver/courier who retrieved the waste and the vehicle used to transport the waste to the radiopharmacy.
  - Decontaminate the package or remove it from service for decay.

Open the package and identify each nuclide in the shielded containers.

Dispose of radioactive waste into the appropriate container for the half-life of the nuclide being disposed, in accordance with the radiopharmacy's procedures for disposal of waste by decay-in-storage.

Survey the dose shields for contamination with a low-level survey meter. Any dose shields that indicate activity exceeding background should be decontaminated or removed from service.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

**DEFINITIONS**

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

**ATTACHMENT II**  
**US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE**  
**ENHANCED SECURITY MEASURES**

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

### **Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

### **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one or more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

#### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

#### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## En Route

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR USE OF PORTABLE GAUGES

	<p><b>Radiation Control Unit</b> <b>Asbestos, Lead, Indoor Air &amp; Radiation Section</b> <b>Division of Environmental Health</b> <b>Minnesota Department of Health</b></p>
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January 2005

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## REGULATORY GUIDE FOR USE OF PORTABLE GAUGES

### 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 a license to use and possess sealed sources in portable gauging devices. An example of a portable gauging device is a moisture-density gauge that contains a gamma-emitting sealed source, Cesium-137, and a sealed neutron source, Americium-241: Beryllium.

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

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

### 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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**

Applicants must provide the manufacturer's or distributor's name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State. NRC or an Agreement State performs a safety evaluation of portable gauges before authorizing a manufacturer or distributor to distribute the gauges to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the SSD registration process was formalized, older gauges may not have been evaluated in a separate document; but were specifically approved on a license. Licensees can continue to use the gauges that are specifically listed on their licenses.

Consult with the proposed manufacturer or distributor to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with 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. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSD Registration Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by MDH, licensees are required to use gauges according to their respective SSD Registration Certificates. Accordingly, applicants may want to obtain a copy of the certificate and review it with the manufacturer or distributor or with NRC or the issuing Agreement State to ensure that it correctly reflects the radiation safety properties of the source or device.

Identify each radionuclide that will be used in each source in the gauging device(s).

Identify the manufacturer or distributor and model number of each type of 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 NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate.

Confirm that the activity per source and maximum activity per device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State<sup>1</sup>.

#### ***Financial Assurance and Recordkeeping for Decommissioning***

The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most portable gauge applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the possession thresholds. A licensee would need to possess many gauges before the financial assurance requirements would apply.

The standard gauge license does not specify the maximum number of gauges that a licensee may possess (allowing flexibility in obtaining additional gauges specifically authorized by the license as needed without amending its license). It contains a condition requiring the licensee to limit its possession of gauges to quantities not requiring financial assurance. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where gauges are used or stored and to leaking sources. Licensees must transfer these records important to decommissioning the new licensee before licensed activities are transferred or assigned or to MDH before the license is terminated. For portable gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each gauge was used or stored.

#### **Item 6: Purpose(s) For Which Licensed Material Will Be Used**

Gauges should be used only for the purposes for which they were designed, according to the manufacturer's or distributor's recommendations and instructions, as specified in an approved SSD Registration Certificate, and as authorized on an NRC or Agreement State license. Uses other than

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<sup>1</sup> For information on SSD registration certificates, contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.

those listed in the SSD Registration Certificate require review and approval by the NRC or an Agreement State. Requests to use portable gauges for purposes not listed in the SSD Registration Certificate will be reviewed on a case-by-case basis. Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety-critical components of the device. MDH will evaluate the radiation safety program for each type and use of gauge requested.

If the portable gauge(s) will be used for the purposes listed on the SSD Registration Certificate<sup>2</sup>, do the following:

- You should state, "The portable gauge(s) will be used for the purposes described on the SSD Registration Certificate(s)"
- Provide a specific description of use for each type of gauge requested, e.g., "for use in measuring moisture and density of soil, compaction of asphalt, etc."

If the portable gauge will be used for purposes other than those listed on the SSD Registration Certificate, specify these other purposes and submit safety analyses (and procedures, if needed) to support safe use.

#### **Item 7: Individual(s) Responsible for Radiation Safety Program**

##### ***Radiation Safety Officer (RSO)***

The person responsible for the radiation protection program is called the Radiation Safety Officer (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. MDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO<sup>3</sup>.

Radiation Safety Officers (RSOs) must have adequate training and experience. Successful completion of training of one of the following is evidence of adequate training and experience:

- Portable gauge manufacturer's or distributor's course for users or for RSOs
- An equivalent course that meets Appendix B criteria

The licensee should provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.

As an alternative, the licensee should state that:

- a. Before obtaining licensed materials, the proposed RSO will have successfully completed the training described in Appendix B of this guide; or
- b. The new RSO will receive training described in Appendix B of this guide within a specified time after being appointed.

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<sup>2</sup> Allowed uses of portable gauges normally include process control methods such as measuring the thickness of paper, the density of coal, the level of material in vessels and tanks, etc. Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

<sup>3</sup> It is important to notify MDH, as soon as possible, of changes in the designation of the RSO.

### **Authorized Users**

An authorized user (AU) is a person whose training and experience meet MDH criteria, who is named explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. Authorized users must ensure the proper use, security, and routine maintenance of portable gauges containing licensed material. Therefore, they must attend the training and instruction given at the time of installation or receive equivalent training and instruction.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Authorized users (AUs) must have adequate training and experience. Successful completion of a portable gauge manufacturer's or distributor's course for users will satisfy the training requirements.

### **Item 8: Training for Individuals Working In or Frequenting Restricted Areas**

Individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 100 mrem (1 mSv) in a year must receive training. The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

Licensees need to perform a prospective evaluation to determine radiation doses likely to be received by different individuals or groups. Authorized users would be most likely to receive doses in excess of 100 mrem (1 mSv) in a year.

Licensee personnel who work in the vicinity of a portable gauge but do not use gauges (ancillary staff) are not required to have radiation safety training as long as they are not likely to receive 100 mrem (1 mSv) in a year. However, to minimize potential radiation exposure when ancillary staff are working in the vicinity of a portable gauge, it is prudent for them to work under the supervision and in the physical presence of an AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the gauge and the meaning of the radiation symbol, and should be instructed not to touch the gauge and to keep away from it as much as their work permits.

Some ancillary staff, although not likely to receive doses over 100 mrem, should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments near the gauge to ensure the control and security of licensed material.

Submit the training program for individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 100 mrem (1 Sv) in a year (occupationally exposed workers) and ancillary personnel.

### **Item 9: Facilities and Equipment**

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

1. A diagram that shows where the gauge will be stored when not at field locations.
2. The security measures to be taken during storage when not at field locations.
3. The security measures taken when stored in the field. For example, locking gauges in the trunk of a car, hidden from view while in a locked van, or secured by a lock and chain while in an

open bed truck. A restricted area does not include areas used as residential quarters, motel rooms, or similar locations.

4. If the proposed permanent facility is under construction, or is planned for construction, include the estimated completion date.

You should state that the device will be stored in a locked enclosure such as the transport vehicle, store room, closet, shed, etc., in a way that will prevent access by unauthorized persons. You should keep in mind that the device needs to be in storage or physically watched by an authorized user at all times. It is not acceptable for a device to be chained to a post or left lying unattended at the place of use during lunch or breaks because the device would then be accessible to unauthorized persons.

Provide diagrams of the facility that include the building and the proposed restricted area(s). Indicate the use of the adjacent areas (e.g., storage, hallway, etc.). Include the spaces above and below the restricted areas.

If any proposed permanent facility is a private residence, confirm that the use of the gauge does not conflict with local codes or zoning laws. Provide commitments that restricted areas do not include residential quarters and explain how radiation levels in unrestricted areas will be controlled and monitored to comply with Chapter 40.

*Any change in permanent storage locations, unless approved by an amendment to the license, is prohibited.*

#### **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 A through K. Review each appendix carefully. (Some of these appendices have been addressed in the preceding 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."

Appendix A	Typical Duties and Responsibilities of the Radiation Safety Officer
Appendix B	Criteria for Acceptable Training for Radiation Safety Officers and Authorized Users
Appendix C	Information Needed to Support Applicant's Request to Perform Non-Routine Maintenance Operations
Appendix D	Leak Testing Sealed Sources
Appendix E	Suggested Portable Gauge Audit Checklist

#### ***Leak Testing of Sealed Sources***

Each sealed source must be tested for leakage at intervals not to exceed 6 months. The leak test should be performed at 6-month intervals. The instrumentation should be sufficiently sensitive to detect 0.005 microcuries of radioactivity.

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. Use a commercial leak test kit. You take the smear and send the smear to the kit supplier, who will report the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurements.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier. In your application, you should state that the test samples will be taken by the individuals specified in Item 8 who are responsible for your radiation safety program. Commit to Appendix D.1.

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 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 D.1 and D.2.

#### ***Routine Maintenance***

You should state that any maintenance you will perform (such as cleaning) will always be done with the radioactive source in the safe shielded position. You may not do any maintenance unless the source is safely shielded.

To take the radioactive source out of the device, you must have special training and procedures, use a radiation survey meter, and take appropriate radiation safety precautions. If you plan to remove the source from the device for exchange or maintenance, your license must specifically authorize those procedures. Review Appendix C and submit the requirements listed there.

#### ***Radiation Detection Equipment***

You do not need to have a radiation survey meter during routine use if you have made the commitment that personnel will wear a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD) when using the device. MDH must be contacted immediately for timely evaluation of any incident.

If you plan to perform gauge servicing that requires removal of the source from its shielded position or removal of the source rod from the gauging device, you must have a survey meter that is calibrated annually. Provide the manufacturer name, model number, and range of the survey instruments being used. For example:

<b>MANUFACTURER</b>	<b>MODEL NUMBER</b>	<b>RANGE</b>
Geotronics Industries	OMG-12	0.01 - 50 mr/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mr/hr

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide on survey instrument calibration from the MDH.

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

State that before using the survey meter, you will check the response of the instrument with a check source and, if the meter does not respond properly, you will not use the meter until it is repaired and operable.

### ***Personnel Monitoring Equipment***

Personnel monitoring equipment must be used by individuals who receive or are likely to receive occupational exposure in one year from sources external to the body, in excess of 10% of the dose specified in paragraph 4731.2000. Individuals under 18 years or declared pregnant women are required to use personnel monitoring equipment if they receive or are likely to receive a dose in excess of 10% of the specified dose.

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

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

### ***Inventories***

State that you will conduct inventories at intervals not to exceed six (6) months, to account for all sealed sources and gauges received and possessed under your license. You should maintain records of the inventories for at least five (5) years from the date of the inventory. The records should include the radionuclide and amount of material in each source, the manufacturer's name, model number and serial number of each gauge, the location of each, and the date of the inventory.

### ***Annual Audits***

Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure compliance with MDH rules and the terms and conditions of the license. Records of audits and other reviews of program content are maintained for three years.

As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

Once problems are identified, it is essential that they are corrected promptly and comprehensively. MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. MDH will normally exercise discretion and not to cite violations previously identified and corrected by the licensee. The licensees are encouraged to regulate their own compliance.

An audit program for a portable gauge should include a review of:

- ✓ leak test records and procedures
- ✓ inventory records
- ✓ training
- ✓ the operating and emergency procedures
- ✓ survey instrument calibration records and procedures (if applicable)

See Appendix E for questions to consider in an annual audit. You, as the licensee, are responsible for the content and implementation of your radiation safety program and for all actions of your employees.

### ***Operating Procedures***

Commit to providing the manufacturer's operating and emergency procedures; commit to the following procedures; or, submit your procedures to the MDH for review. The following topics should be addressed in your procedures:

1. Before removing the gauge from its place of storage, check to make sure that the gauge source rod is in the shielded, locked position, then lock the transport case if possible.
2. Sign the gauge out in a logbook, stating the dates of use, names of the authorized users who are responsible for the gauge, and the temporary job sites where the gauge will be used.
3. Never leave the gauge unattended.
4. Follow all applicable DOT requirements when transporting the gauge.
5. Do not touch the source rod with your fingers, hands, or any part of your body, and always make sure the source rod is in the shielded position after each measurement is made.
6. Always wear your assigned personnel-monitoring device (dosimeter) when using the gauge.
7. Never wear another person's dosimetry.
8. Never store your dosimetry near the gauge.
9. Always keep unauthorized persons away from the area where the gauge is to be used.
10. Always maintain constant surveillance and immediate control of the gauge when it is not in storage.
11. To make gauges more visible to operators of heavy equipment at construction sites, stake and flag each gauge, making sure the flags are tall enough to be seen by heavy equipment operators.
12. Never look under the gauge when the source rod is being lowered into the ground.
13. After each measurement, return the source to the shielded position and lock it there.
14. When the gauge is not in use at a temporary job site, place the gauge in a secured storage location (e.g., locked in the trunk of a car or locked in a storage shed).
15. Return the gauge to its proper storage location at the end of the work shift.
16. Indicate in the source logbook when the gauge is returned to storage.

### ***Emergency Procedures***

If the source fails to return to the shielded position or if any other emergency or unusual situation arises such as the gauge being struck by a moving vehicle, dropped, or in a vehicle involved in an accident:

1. Immediately secure the area around the gauge.
2. Prevent unauthorized personnel from entering the secured area.
3. If any heavy equipment is involved, detain the equipment until it is determined that there is no contamination present.

4. Notify management of the situation, calling company personnel.
5. List name, work, and home telephone numbers of company personnel.
6. Follow the directions provided by the person contacted.
7. Management should:
  - a. Arrange for a survey to be conducted as soon as possible by an approved person using an appropriate radiation detection instrument.
  - b. Make necessary notifications to local authorities and notify the MDH as required. Notification is required when gauges are lost, stolen, damaged, or involved in incidents that result in doses in excess of the dose limits specified in 4371.2000.
  - c. Ensure reports to the MDH are submitted in a timely manner.
  - d. Review and adhere to the reporting requirements of 4731.2000.

*You should state on your application that you will provide the operating and emergency procedures to each person who uses the device.*

#### **Transportation to Field Locations**

It is your obligation to obtain a copy of the DOT regulations on transportation of radioactive materials. The requirements for package labeling are in subpart E of 49 CFR Part 172 of the DOT regulations. General requirements for shipping and packaging radioactive material are in Subpart I of 49 CFR Part 173 of the DOT regulations. The address to write for a copy of these regulations is:

US Government Bookstore  
120 Bannister Road  
Kansas City, MO 64137  
(816) 765-2256

You should state in your application that packaging and transport of the device will be carried out in accordance with the applicable DOT regulations.

#### **Item 11: Waste Management**

The only option for disposal of the licensed material contained in portable gauges is to transfer the material to an authorized recipient. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it. Authorized recipients are the original suppliers of the device, a commercial firm licensed by an Agreement State or the NRC to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

#### **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

### **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

### **RENEWAL OF A 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 MDH. 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 rules 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 Minnesota Department of Health reviews each application to ensure that users of byproduct material are capable of complying with MDH rules. This guide provides one set of methods approved by 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**  
**TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER**

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

- Activities involving licensed material that the RSO considers unsafe are stopped.
- Radiation exposures are ALARA.
- Development, maintenance, distribution, and implementation of up-to-date operating and emergency procedures.
- Individuals that use portable gauges are properly trained.
- Possession, installation, relocation, use, storage, routine maintenance and non-routine operations of portable gauges are consistent with the limitations in the license, the SSD Registration Certificate(s), manufacturer's or distributors recommendations and instructions.
- Safety consequences of non-routine operations are analyzed before conducting any such activities that have not been previously analyzed.
- Non-routine operations are performed by the manufacturer, distributor or person specifically authorized by the NRC or an Agreement State.
- Prospective evaluations are performed demonstrating that individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices.
- Personnel monitoring devices, if required, are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit as specified in 10 CFR 20.1301.
- Portable gauges are properly secured.
- Notification of proper authorities of incidents such as damage to or malfunction of portable gauges, fire, loss, or theft.
- Investigation of unusual occurrences involving the portable gauge (e.g., malfunctions or damage), identification of cause(s), implement of appropriate and timely corrective action(s).
- Radiation safety program audits are performed at intervals not to exceed 12 months and development, implement, and documentation of timely corrective actions.
- When the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented.
- Licensed material is transported according to all applicable DOT requirements.
- Licensed material is disposed of properly.
- Appropriate records are maintained.

- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.
- Posting of documents or posting a notice indicating where these documents can be examined.

**APPENDIX B  
CRITERIA FOR ACCEPTABLE TRAINING FOR RADIATION SAFETY OFFICERS  
AND AUTHORIZED USERS**

Classroom training may be in the form of lecture, videotape, or self-study emphasizing practical subjects important to safe use of the gauge:

***Radiation Safety:***

- Radiation vs. contamination
- Internal vs. external exposure
- Biological effects of radiation
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure
- Location of sealed source within the gauge

***Regulatory Requirements:***

- Applicable regulations
- License conditions, amendments, renewals
- Locations of use and storage of radioactive materials
- Material control and accountability
- Annual audit of radiation safety program
- Transfer and disposal
- Recordkeeping
- Prior events involving portable gauges
- Handling incidents
- Recognizing and ensuring that radiation warning signs are visible and legible
- Licensing and inspection by regulatory agency
- Need for complete and accurate information
- Employee protection
- Deliberate misconduct
- Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee
- Operating and emergency procedures
- Routine vs. non-Routine maintenance
- Lock-out procedures

On-the-job training must be done under the supervision of an AU or RSO. Supervised hands-on experience should include performing the following:

- Operating procedures
- Test runs of emergency procedures
- Routine maintenance
- Lock-out procedures

***Training Assessment***

Management will ensure that proposed AUs are qualified to work independently with each type of gauge with which they may work. Management will ensure that proposed RSO's are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges to be possessed by the applicant. This may be demonstrated by written or oral examination or by observation.

**Course Instructor Qualifications**

Instructor should have:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of a portable gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of an 8 hour radiation safety course; and
- 8 hours hands-on experience with portable gauges

**OR**

- Successful completion of a portable gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of 40-hour radiation safety course and 30 hours of hands-on experience with portable gauges.

**OR**

- The applicant may submit a description of alternative training and experience for the course instructor.

Additional training is required for those applicants intending to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service. See Appendix C - "Non-Routine Operations."

**APPENDIX C  
INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST  
TO PERFORM NON-ROUTINE MAINTENANCE OPERATIONS**

You should state that any maintenance you will perform (such as cleaning) will always be done with the radioactive source in the safe shielded position. You may not do any maintenance unless the source is safely shielded.

To take the radioactive source out of the device, you must have special training and procedures, use a radiation survey meter, and take appropriate radiation safety precautions. If you plan to remove the source from the device for exchange or maintenance, your license must specifically authorize those procedures.

If you are considering performing maintenance or cleaning of gauges that requires the removal of the radioactive source or source rod from the shielded position, you should keep in mind the radiation levels you may encounter. A typical moisture-density gauge contains 10 millicuries of Cesium-137 and 40 millicuries of Americium-241. In about 9 minutes an unshielded Cesium-137 source of this activity can deliver 5 rems to a worker's hands or fingers (extremities), assuming the extremities are 1 centimeter from the source. The threshold for extremity monitoring is 5 rems per year.

Thus, to perform extended maintenance, you should have special training, authorization on your license, follow special procedures, use a radiation survey meter, use special shields, use special personnel monitoring devices, and take appropriate radiation safety precautions. Accordingly, provide the following information:

**1. Type of work to be performed**

Describe the types of work, maintenance, or cleaning that you wish to perform that necessitate removal of the radioactive source from the shielded position or the removal of the source rod from the device. For each type of device, specify the manufacturer's name and the model number of the gauge.

**2. Training and experience**

List the individuals who will perform extended maintenance and describe their training and experience in performing the maintenance. Individuals are considered on a case-by-case basis. For each individual that will perform extended maintenance, indicate that

- All radiation safety courses the individual has taken.
- The amount of hands-on experience the individual has had performing extended maintenance (include the manufacturer's name and model of the gauge in addition to the type and frequency of extended maintenance performed).
- Any additional factors to document that the individual is competent to perform extended maintenance safely.

**3. Handling procedures**

Submit your procedures for safe handling of the radioactive source while the source is outside the gauge. Your procedures should specify that

- The source rod will be handled only at the end opposite to the source end
- The source end will immediately be placed in a shielded container (e.g., lead shield).

- Unauthorized individuals will not be allowed into the areas where extended maintenance is performed.
- Containers shielding the source will be labeled "Caution Radioactive Material."
- The source will be under the constant surveillance of an authorized user when not in storage.
- The source will be secured against unauthorized removal or access when in storage.
- The manufacturer's instructions and recommendations for performing extended maintenance will be followed.

Indicate where the source rod will be located after it has been removed.

4. Personnel monitoring

Describe how you will ensure that radiation exposure to individuals performing extended maintenance will not exceed Chapter 40 limits. An acceptable response is that individuals performing extended maintenance on gauges will always wear both whole body and extremity monitoring devices. Like the whole body devices, extremity monitoring devices will be exchanged at least quarterly.

5. Survey instrumentation

If you have already provided detailed information on survey instruments in response to previous items, state "See response to item ---." Otherwise, list the type and ranges of survey instruments you will have available, state the frequency of calibration, and state who will perform the calibration. Include how you will ensure that the survey instrument is working properly.

For example, you may state that a survey instrument capable of measuring between 0.1 millirem per hour and 100 millirems per hour will be used to perform the surveys. You must also confirm that the survey instrument will be calibrated annually by the manufacturer. In addition, you may state that, before each use of the instrument, you will check the response of the instrument with a dedicated check source that was supplied with the instrument. You should commit that, if the instrument does not respond properly, you will not perform extended maintenance on the gauges until the survey instrument is repaired and operable or until you obtain an operable instrument.

6. Surveys

Describe how you will ensure that radiation levels in areas where extended maintenance will take place do not exceed exposure limits. For example, you may

- Commit to performing surveys with a survey instrument (as describe above).
- Specify where and when surveys will be conducted during extended maintenance.
- Commit to maintaining records of the survey for three (3) years from the date of the survey, as required by 4731.2510 of the Minnesota Rules. The survey record should include the name of the person who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements.

## **APPENDIX D LEAK TESTING SEALED SOURCES**

You may use the following model procedure to leak test sealed sources. If you follow the model procedure you may indicate on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix (D.1 and/or D.2) to the MDH Regulatory Guide for Portable Gauges."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Minnesota Rules. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix (D.1 and/or D.2)," and submit your leak test procedure.

### **D.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES**

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

### **D.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES**

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries. 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 either a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source. The source activity should be certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.

3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries 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 three (3) years.

**APPENDIX E  
SUGGESTED PORTABLE GAUGE AUDIT CHECKLIST**

All areas indicated in audit notes may not be applicable to every license 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 and activities that have not occurred since the last audit need not be reviewed at the next audit.

Licensee's name \_\_\_\_\_

License No. \_\_\_\_\_

Date of This Audit \_\_\_\_\_

Date of Last Audit \_\_\_\_\_

\_\_\_\_\_  
(Auditor Signature)

Date \_\_\_\_\_

\_\_\_\_\_  
(Management Signature)

Date \_\_\_\_\_

**Audit History**

- A. Last audit of this location conducted on:
- B. Were previous audits conducted at intervals not to exceed 12 months?
- C. Were records of previous audits maintained?
- D. Were any deficiencies identified during last two audits or two years, whichever is longer?
- E. Were corrective actions taken? (Look for repeated deficiencies).

**Organization and Scope of Program**

- A. If the mailing address or places of use changed, was the license amended?
- B. If ownership changed or bankruptcy filed, was MDH prior consent obtained or was MDH notified?
- C. Radiation Safety Officer
  - 1. If the RSO was changed, was the license amended?
  - 2. Does the new RSO meet MDH training requirements?
  - 3. Is the RSO fulfilling his/her duties?

4. To whom does the RSO report?

D. If the designated contact person for MDH changed, was MDH notified?

**E. Sealed Sources and Devices**

1. Does the license authorize all of the MDH regulated radionuclides contained in gauges?

2. Are the gauges as described in the Sealed Source and Device (SSD) Registration Certificate?

3. Are copies available of the manufacturer's or distributor's manuals for operation and maintenance?

4. Are the actual uses of gauges consistent with the authorized uses listed on the license?

**Training and Instructions to Workers**

A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed in accordance with 4731.1020?

Has refresher training been provided, as needed?

Are records maintained?

B. Did each authorized user (AU) receive training and instruction given at the time of gauge installation or equivalent training and instruction before using gauges?

C. Are training records maintained for each AU?

D. Did individuals who perform non-routine operations receive training before performing these operations?

E. Did interviews with AUs reveal that they know the emergency procedures?

F. Did this audit include observations of AUs using the gauge?

G. Did this audit include observations of workers performing routine cleaning and lubrication on the gauge?

H. Is HAZMAT training provided, if required? [49 CFR 172.700, 172.701, 172.702, 172.703, 172.704]

**Radiation Survey Instruments**

A. If the licensee is required to possess a survey meter, does it meet the MDH's criteria?

### **Gauge Inventory**

- A. Is a record kept showing the receipt of each gauge?
- B. Are all gauges physically inventoried every six months?
- C. Are records of inventory results with appropriate information maintained?

### **Personnel Radiation Protection**

- A. Are ALARA considerations incorporated into the radiation protection program?
- B. Were prospective evaluations performed showing that unmonitored individuals receive 10% of limit?
- C. Did unmonitored individuals' activities change during the year that could put them over 10% of limit?
- D. If yes to C. above, was a new evaluation performed?
- E. Is external dosimetry required for individuals likely to receive greater than 10% of limit?
- F. Relative to dosimetry provided to these individuals:
  - 1. Is the dosimetry supplier NVLAP approved?
  - 2. Are the dosimeters exchanged monthly for film badges and quarterly for TLDs or OSDs?
  - 3. Are dosimetry reports reviewed by the RSO when they are received?
  - 4. Are the records based on MDH Forms or equivalent?
    - a. Has MDH "Cumulative Occupational Exposure History" or equivalent been completed?
    - b. Has MDH "Occupational Exposure Record for a Monitoring Period" or equivalent been completed?
  - 5. For declared pregnant workers/embryo/fetus:
    - a. Was additional monitoring provided for a worker who declared her pregnancy?
    - b. Were records kept of the embryo/fetus dose?
- F. Are records of exposures, surveys, monitoring, and evaluations maintained?

### **Public Dose**

- A. Is public access to gauges controlled in a manner to keep doses below 1 mSv (100 mrem) in a year?
- B. Has a survey or evaluation been performed?  
  
Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- C. Do unrestricted area radiation levels exceed 2 mrem (0.02 mSv) in any one hour?
- D. Is gauge access controlled in a manner that would prevent unauthorized use or removal?
- E. Are records maintained?

### **Operating and Emergency Procedures**

- A. Have operating and emergency procedures been developed?
- B. Do they contain the required elements?
- C. Does each individual working with the gauges have a current copy of the operating and emergency procedures (including emergency telephone numbers)?
- D. Did any emergencies occur?
  - 1. If so, were they handled properly?
  - 2. Were appropriate corrective actions taken?
  - 3. Was MDH notification or reporting required?

### **Leak Tests**

- A. Was each sealed source leak tested every 6 months or at other prescribed intervals?
- B. Was the leak test performed according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking and if yes, was MDH notified?
- E. If yes to D. above, was MDH notified?

## **Maintenance of Gauges**

- A. Are manufacturer's or distributor's procedures followed for routine cleaning and lubrication of gauge?
- B. Are repair and maintenance of components related to the radiological safety of the gauge performed by the manufacturer, distributor or person specifically authorized by the MDH or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument)?
- C. Are labels, signs, and postings identifying gauges containing radioactive material, radiation areas, and lockout procedures/warnings clean and legible?

## **Transportation**

(This section will not apply if you have not transported gauges during the period covered by this audit.)

- A. Were DOT-7A or other authorized packages used? [49 CFR 173.415, 173.416(b)]
- B. Are package performance test records on file?
- C. Is special form sources documentation available? [49 CFR 173.476(a)]
- D. Did the package have two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [49 CFR 172.403, 173.441]
- E. Was the package properly marked? [49 CFR 172.301, 172.304, 172.310, 172.324]
- F. Was the package closed and sealed during transport? [49 CFR 173.475(f)]
- G. Were shipping papers prepared and used? [49 CFR 172.200(a)]
- H. Did shipping papers contain proper entries? (Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)) [49 CFR 172.200, 172.201, 172.202, 172.203, 172.204, 172.604]
- I. Were shipping papers within drivers reach and readily accessible during transport? [49 CFR 177.817(e)].
- J. Was the package secured against movement? [49 CFR 177.834]
- K. Were placards on vehicle, if needed? [49 CFR 172.504]
- L. Were there proper overpacks, if used? [49 CFR 173.25]
- M. Were any incidents reported to DOT? [49 CFR 171.15, 171.16]

**Auditor's Independent Survey Measurements (If Made)**

- A. Describe the type, location, and results of measurements.

Do any radiation level exceed regulatory limits?

**Notification and Reports**

- A. Was any radioactive material lost or stolen?

Were reports made?

- B. Did any reportable incidents occur?

Were reports made?

- C. Did any overexposures and high radiation levels occur?

Were reports made?

- D. If any events (as described in items a through c above) did occur, what was root cause?

Were corrective actions appropriate?

- E. Is the management/RSO/shift foreman licensee aware of telephone number for MDH?

**Posting and Labeling**

- A. Are MDH "Notice to Workers" posted?

- B. Are MDH regulations and license documents posted or is a notice posted?

- C. Is there other posting and labeling?

**Record Keeping for Decommissioning**

- A. Are records kept of information important to decommissioning?

- B. Do the records include all information?

**Bulletins and Information Notices**

- A. MDH Bulletins and MDH Information Notices received?
- B. Was appropriate training and action taken in response?

**Special License Conditions or Issues**

- A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?

**Deficiencies Identified in Audit; Corrective Actions**

- A. Summarize problems/deficiencies identified during audit.
- B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just location audited)?  
Include date(s) when corrective actions are implemented.
- C. Provide any other recommendations for improvement.

**Evaluation of Other Factors**

- A. Is senior licensee management appropriately involved with the radiation protection program and/or RSO oversight?
- B. Does the RSO have sufficient time to perform his/her radiation safety duties?
- C. Does the licensee have sufficient staff to support the radiation protection program?

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including:

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### Security Plan

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

#### Personnel Security

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one or more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

#### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

#### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR RESEARCH AND DEVELOPMENT, LABORATORY, AND INDUSTRIAL USE OF SMALL QUANTITIES OF RADIOACTIVE MATERIAL

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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# REGULATORY GUIDE FOR RESEARCH AND DEVELOPMENT, LABORATORY, AND INDUSTRIAL USE OF SMALL QUANTITIES 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 a laboratory and industrial use of small quantities of radioactive material license. It also provides the user with a synopsis of the by-product material regulations.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in the 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.

### ***Management Responsibilities***

MDH recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. MDH believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. MDH also believes that effective management will result in increased safety and compliance.

To ensure adequate management involvement, *a management representative must sign the submitted application acknowledging management's commitments and responsibility* for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations.
- Completeness and accuracy of the radiation safety records and all information provided to MDH.
- Knowledge about the contents of the license and application.
- Compliance with current MDH and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures.
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and that meticulous compliance with regulations is maintained.

- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program.
- Obtaining MDH's prior written consent before transferring control of the license.
- Notifying MDH in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

## **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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 both free and bound forms, then 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.

The Table below is a partial list of radioisotopes of  $T_{1/2} > 120$  days with their corresponding limits in excess of which Financial Assurance or a Decommissioning Funding Plan is required. Radioisotopes of  $T_{1/2} > 120$  days are listed in column 1. 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	LIMIT FOR FINANCIAL ASSURANCE (MILLICURIES)	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 AU 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 AU 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 AU 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 AU is considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the AU 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 AU with the types and quantities of licensed material to be used and information demonstrating that each proposed AU 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 A through K. 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."

Appendix A	Guidance on Decommissioning Funding Plan and Financial Assurance
Appendix B	Duties and Responsibilities of the Radiation Safety Officer
Appendix C	Model Training Program
Appendix D	Audit Program
Appendix E	Facilities and Equipment Considerations
Appendix F	Material Receipt and Accountability
Appendix G	Safe Use of Radioisotopes and Model Emergency Procedures
Appendix H	Safe Handling of Radioactive Materials
Appendix I	Radiation Safety Survey Topics
Appendix J	Leak Testing Sealed Sources
Appendix K	Considerations for Laboratory Animal and Veterinary Medicine Uses

### ***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:<sup>1</sup>

- 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.

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

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<sup>1</sup> Alternative responses will be reviewed by MDH staff.

inventory. The package is then delivered to the AU 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 by Receiving 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 <sup>2</sup>
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 3 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 3 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 3 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 3 hours after receipt of package

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

<sup>2</sup> 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.

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 an 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 (OSDs, TLDs, film, 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***

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

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.

### ***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 kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix J.1 or submit your own procedures.

For Option 3, indicate how the test sample will be taken. Specify the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for these measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application. Commit to Appendix 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, Table 3.
- 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, Table 3 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 Ci) 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 Ci) 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 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.

#### **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 by-product 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  $\mu\text{Ci}$ ) 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 Half-lives Greater Than or Equal to 120 Days**

ISOTOPE	UNSEALED ( $\mu\text{Ci}$ )	SEALED ( $\mu\text{Ci}$ )
Americium-241	10	$1 \times 10^8$
Antimony-125	10000	$1 \times 10^{11}$
Barium-133	10000	$1 \times 10^{11}$
Cadmium-109	10000	$1 \times 10^{11}$
Calcium-45	10000	$1 \times 10^{11}$
Carbon-14	100000	$1 \times 10^{12}$
Cerium-144	1000	$1 \times 10^{10}$
Cesium-134	1000	$1 \times 10^{10}$
Cesium-135	10000	$1 \times 10^{11}$
Cesium-137	10000	$1 \times 10^{11}$
Chlorine-36	10000	$1 \times 10^{11}$
Cobalt-60	1000	$1 \times 10^{10}$
Europium-152 13 yr	1000	$1 \times 10^{10}$
Europium-154	1000	$1 \times 10^{10}$
Europium-155	10000	$1 \times 10^{11}$
Gadolinium-153	10000	$1 \times 10^{11}$
Gold-198	100000	$1 \times 10^{12}$
Hydrogen-3	1000000	$1 \times 10^{13}$
Indium-115	10000	$1 \times 10^{11}$
Iodine-129	100	$1 \times 10^9$
Iron-55	100000	$1 \times 10^{12}$
Krypton-85	100000	$1 \times 10^{12}$
Manganese-54	10000	$1 \times 10^{11}$
Nickel-59	100000	$1 \times 10^{12}$
Nickel-63	10000	$1 \times 10^{11}$
Niobium-93 <sup>m</sup>	10000	$1 \times 10^{11}$
Platinum-193	100000	$1 \times 10^{12}$
Polonium-210	100	$1 \times 10^9$
Promethium-147	10000	$1 \times 10^{11}$
Rubidium-87	10000	$1 \times 10^{11}$
Ruthenium-106	1000	$1 \times 10^{10}$
Silver-110 <sup>m</sup>	1000	$1 \times 10^{10}$



**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 public 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***

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

### ***General Information***

- A. Radiation safety
  - o radiation vs. contamination
  - o internal vs. external exposure
  - o biological effects of radiation
  - o ALARA concept
  - o use of time, distance, and shielding to minimize exposure
- B. Regulatory issues
  - o RSO
  - o material control and accountability
  - o personnel dosimetry
  - o radiation safety program audits
  - o transfer and disposal
  - o record keeping
  - o surveys
  - o postings
  - o labeling of containers
  - o handling and reporting of incidents or events
  - o licensing and inspection by MDH
  - o need for complete and accurate information
  - o employee protection
  - o deliberate misconduct

### ***Licensee-Specific Program Elements***

- A. Authorized users and supervised users
- B. Ordering and receiving radioisotopes
- C. Applicable regulations and license conditions
- D. Areas where radioactive material is used or stored
- E. Potential hazards associated with radioactive material in each area where the individuals will work
- F. Appropriate radiation safety procedures

- G. Licensee's in-house work rules
- H. Each individual's obligation to report unsafe conditions to the RSO
- I. Appropriate response to spills, emergencies or other unsafe conditions
- J. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable
- K. 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.
- L. Emergency procedures:
  - o RSO name and telephone number
  - o immediate steps to prevent or control spread of contamination
  - o clean-up instructions, decontamination
- M. Survey program:
  - o survey instrument accessibility
  - o who is responsible
  - o types, contamination and area
  - o frequency
  - o levels of contamination
  - o personnel, hands, shoes
  - o records
- N. Waste
  - o liquid
  - o solids
  - o sanitary sewer
  - o burial (transfer to low level waste repository)
  - o storage
  - o decay-in-storage
  - o waste storage surveys
  - o incineration
  - o records
- O. Dosimetry
  - o whole body
  - o extremities
  - o lost or replacement badges and dose assessment
  - o bioassay procedures
  - o records
- P. Instrumentation
  - o survey meters-use, calibration frequency, use of check sources
  - o analytical instruments-gas chromatographs, liquid scintillation counters
- Q. Procedures for receiving packages containing radioactive materials
  - o normal
  - o off-duty
  - o notification of user and RSO
  - o security
  - o exposure levels

- o possession limit
  - o receipt of damaged packages
- R. Procedures for opening and examining packages
- o leakage and contamination
  - o monitoring packages
  - o monitoring packing materials
  - o gloves
  - o transferring material to users
- S. Animal experiments
- o description of facilities
  - o safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
  - o security
- T. Sealed sources
- o leak test requirements
  - o inventory requirements
  - o exempt quantities
  - o records
- U. Other topics, as applicable
- V. Question and answer period

***For Laboratory Safety and Use of Radioisotopes***

- A. 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.
- B. Protective clothing, laboratory apparel, and equipment.
- C. 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 gloveboxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma emitting licensed materials are handled.
- D. 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.
- E. Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.
- F. Decontamination procedures to use and whom to contact in case of an emergency.
- G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.
- H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are used.
- I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.

- J. 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.
- K. Records to be maintained on use and disposal of licensed materials.
- L. 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 4731.2020, 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, NMSS Newsletters, 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.



**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**

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

14. 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 calculations basic using and measuring radioactivity
- Biological effects of radiation
- Appropriate on-the-job-training consists of the following:
  - Observing authorized personnel using survey equipment, collecting samples, and analyzing samples
  - Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

### **FACILITIES AND EQUIPMENT**

To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.

A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cesium-137, Cobalt-60).

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

### **AMBIENT RADIATION LEVEL SURVEYS**

Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 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.

Table 1 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material in use at any one time at any particular location. If licensed material it has not been used for a period greater than the required survey frequency, then it is considered not in use.

**Table 1 - Suggested Contamination Survey Frequency**

	< 0.1 ALI	≥ 0.1 ALI < 1.0	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

## CONTAMINATION IN UNRESTRICTED AREAS

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table 2.

**Table 2 - Acceptable Surface Contamination Levels for Equipment**

Nuclide <sup>a</sup>	Average <sup>b, c</sup>	Maximum <sup>b, d</sup>	Removable <sup>b, e</sup>
I-125, I-129	1.7 Bq/100 cm <sup>2</sup> (100 dpm/100 cm <sup>2</sup> )	5.0 Bq/100 cm <sup>2</sup> (300 dpm/100 cm <sup>2</sup> )	0.3 Bq/100 cm <sup>2</sup> (20 dpm/100 cm <sup>2</sup> )
I-126, I-131, I-133, Sr-90	16.7 Bq/100cm <sup>2</sup> (1,000 dpm/100 cm <sup>2</sup> )	50.0 Bq/100cm <sup>2</sup> (3,000 dpm/100 cm <sup>2</sup> )	3.3 Bq/100cm <sup>2</sup> (200 dpm/100 cm <sup>2</sup> )
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 <sup>2</sup> (5,000 dpm/100 cm <sup>2</sup> )	250 Bq/100 cm <sup>2</sup> (15,000 dpm /100 cm <sup>2</sup> )	16.7 Bq/100 cm <sup>2</sup> (1,000 dpm/100 cm <sup>2</sup> )

<sup>a</sup> 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.

<sup>b</sup> 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.

<sup>c</sup> 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.

<sup>d</sup> The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup>.

<sup>e</sup> The amount of removable radioactive material per 100 cm<sup>2</sup> 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, Table 2 provides the maximum acceptable residual levels for equipment and Table 3 provides screening values for building surface contamination. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before 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<sup>2</sup> is acceptable to indicate levels of removable contamination.

**Table 3 - Screening Values for Building Surface Contamination<sup>1</sup>**

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

<sup>1</sup> 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.

Table 3 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 cm<sup>2</sup>). 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 for which monitoring is not practicable, 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.1 and/or J.2) 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.1 and/or J.2)," and submit your leak test procedure.

### J.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, they should also be checked for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

### J.2. 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 \_\_\_\_\_.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

## ATTACHMENT II

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### Security Plan

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### *Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

#### Personnel Security

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one of more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.



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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR SPECIAL NUCLEAR MATERIAL OF LESS THAN CRITICAL QUANTITIES

The logo is circular with a ram's head in the center. The text "Radioactive Materials Group" is written along the top arc, "Minnesota Department of Health" along the bottom arc, and "RAM" in the center.	<p>Radiation Control Unit Asbestos, Lead, Indoor Air &amp; Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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# **REGULATORY GUIDE FOR SPECIAL NUCLEAR MATERIAL OF LESS THAN CRITICAL MASS QUANTITIES**

## **INTRODUCTION**

This guide describes the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of special nuclear material. It is intended for applicants requesting authorization to possess and use up to 2,000 grams of plutonium as sealed plutonium-beryllium neutron sources, and any special nuclear material in quantities and forms not sufficient to form a critical mass.

Activities that involve the receipt, possession, use, and transfer of special nuclear material in quantities and forms sufficient to form a critical mass are not within the scope of this guide.

## **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. A model ALARA management program is contained in Appendix A to this guide.

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.

## **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 are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the 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 propriety information to the public or substantial delays in processing your application.

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

Submit one copy of your application to:

Radioactive Materials Unit  
Minnesota Department of Health  
Snelling Office Park  
1645 Energy Park Drive, Suite 300  
St. Paul, MN 55108-2970

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 Renewals to a License," section 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 or 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 and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. 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. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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**

The special nuclear material requested should be identified by isotope; chemical or physical form; activity in curies, millicuries, or, microcuries; and mass in grams. Specification of isotope should include principle isotope and significant contaminants. Major dose-contributing contaminants present or expected to build up are of particular interest. For example, the quantity of Plutonium-236 present in Plutonium-238 should be specified.

Possession limits requested should cover the total anticipated inventory, including stored materials and waste.

If the application is for a sealed or plated source, the special nuclear material content and manufacturer's name and model number of each source should be specified. If a sealed source will be used in a device (holder, gage, analyzer, etc.), the manufacturer's name and model number of the device should be identified. Each source should be keyed to the specific devices used with it.

You should indicate the material that is being irradiated (e.g., foils, salts, etc.). Estimate the maximum amount of activity for the activated isotopes. Your license will include authorization for small quantities of these isotopes. If you are irradiating loose material, you must address area surveys. See Appendix D of this guide.

#### **Item 6: Purpose For Which Radioactive Material Will Be Used**

Requested radioisotopes must be authorized by the Atomic Energy Act of 1954, as amended. All sealed sources and devices containing licensed material should be used only for the purpose for which they are designed, and according to manufacturer's or distributor's instructions and recommendations for use as specified in the SSD Registration Certificate.

Applicants should clearly specify the purpose for which each radioisotope will be used, and a general plan for carrying out the activity should be described. Each individual use should be described. The typical license authorizes persons to perform research, development, and student instruction using Pu-Be sealed sources in a neutron howitzer. In addition, it authorizes use in experiments utilizing sub-critical assemblies and calibration of radiation detection instruments. Non-typical uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

The described uses should contain sufficient information to enable the reviewers to have a clear understanding of each use and determine the potential for radiation exposure of workers and members of the public.

#### **Item 7: Individuals Responsible For The Radiation Safety Program**

##### ***Radiation Safety Officer (RSO)*<sup>1</sup>**

The person responsible for implementing the radiation protection program is called the Radiation Safety Officer (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 believes that to demonstrate adequate training and experience, the RSO should have: (1) sufficient knowledge of physical, chemical, or 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 special nuclear material to be used)
- MDH regulatory requirements and standards
- Hands-on use of radioactive materials

Provide the name of the proposed RSO and information about the proposed RSO's 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.

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<sup>1</sup> Facilities are required to notify MDH 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 Users (AU)**

An AU 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 AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements. The AU is also responsible to ensure that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

AUs must have adequate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of licensed material, and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination.

MDH believes that to demonstrate adequate training and experience the AU should have: (1) sufficient knowledge of physical, chemical, or biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following topics:

- 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 special nuclear material to be used)
- Hands-on use of radioactive materials

The length of training and experience described above will depend upon the type, form, quantity, and proposed use of the licensed material requested.

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

Applicants must name at least one qualified authorized user. In general, AUs must demonstrate training and experience with the type and quantity of material 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 times larger) quantities of the same substance. Applicants should also 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.

Provide the name of each proposed AU with the types and quantities of licensed material to be used and information about the proposed AU's 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.

### **Item 8: Training for Individuals Working In Or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)**

Individuals who, in the course of their employment, are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), must receive instruction commensurate with their duties and responsibilities.

Before beginning work with licensed material, individuals must 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 and waste processing. 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 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).

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.

#### **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 uses of the types and quantities of radioactive materials to be used.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed, in case changes are required as a result 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 cannot possess or use licensed material until after the facilities are approved and completed, equipment is procured and ready for use, 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 prior to release. Therefore, careful facility design is important to prevent contamination, facilitate decontamination, and reduce the costs needed for decommissioning.

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 A through L. 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."

Appendix A	Model Program for Maintaining Occupational Exposure ALARA
Appendix B	Duties and Responsibilities of the Radiation Safety Officer
Appendix C	Audit Program
Appendix D	Area Surveys
Appendix E	Leak Testing Sealed Sources

### ***Audit Program***

Appendix C contains a suggested audit program that is applicable to special nuclear material of less than critical mass licensees and is acceptable to MDH. However, all areas indicated in Appendix C may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit. Generally, audits are conducted at least once every 12 months to meet the annual requirement.

Currently, MDH's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of licensed material users to determine if, for example, Safe Use and Emergency 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 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 will exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

Licensees must 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 audit
- name of person(s) who conducted audit
- persons contacted by the auditor(s)
- areas audited
- audit findings, corrective actions
- follow-up

These records must 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 Multichannel Analyzers
- Liquid Scintillation Counters (LSC)
- Gamma Counters
- Proportional Counters
- ZnS Detectors
- Neutron Detectors
- Solid State Detectors

The choice of instrument should be appropriate for the type of radiation to be measured and the type of measurement to be taken (e.g., count rate, dose rate, etc.). The majority of the radioactive emissions from special nuclear material are alpha emissions, therefore the applicant's instrumentation should include instrumentation capable of detecting alpha emissions, such as ZnS detectors. Applications should include descriptions of the instrumentation available for use and any instrumentation applicants intend to purchase prior to starting licensed activities. The description should include the type of instrument and probe and the instrument's intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material, and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without a calibration with appropriate radioactive sources.

MDH requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations shall submit procedures for review.

Provide a description of the instrumentation (as described above) that will be used to perform required surveys.

***Material Receipt and Accountability***

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

Licensees need to make arrangements 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 AU, 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 containing radioactive material by labeling and shipping papers.
- Segregate the package from other incoming items in a secured area until released by the RSO.
- Notify the RSO.

When notified by Receiving 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 following table.

PACKAGE CONTENTS SURVEY TYPE SURVEY TIME <sup>2</sup>			
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 3 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 3 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 3 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 3 hours after receipt of package

The licensee must immediately notify the final delivery carrier and MDH by telephone or facsimile when removable radioactive surface contamination exceeds the limits of 49 CFR 173.443 or when external radiation levels exceed the limits of 4731.0465.

It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees must have in place an accountability and control system for promptly detecting losses 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 at least every six months that these sealed sources have not been disturbed. 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.

<sup>2</sup> 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 work day to perform the required surveys.

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).

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, use, 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 and describe the action taken.

Develop procedures for ensuring material accountability and either of the following:

- o 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.
- o A description of procedures for ensuring that no sealed sources have been lost, stolen, or misplaced and how often this inventory will be done.

#### ***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 prior to allowing the individual to receive the dose. This evaluation need not 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.<sup>3</sup> 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 determined that monitoring was not required and a subsequent evaluation indicates that the ten percent regulatory threshold may be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported. 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 "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 "ND" for "not detectable."

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 required.

A common method for dose evaluation is to monitor workers' dose with whole body and extremity dosimetry (OSDs, TLDs, film, ring badge, etc.) provided by a dosimetry service approved by the National

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<sup>3</sup> 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).

Voluntary Laboratory Accreditation Program (NVLAP). 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 or isotopes used.

Provide either of the following:<sup>4</sup>

- A statement that: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of ten percent of the allowable limits in 4731.2000, or we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose.'"
- A description of an alternate method for demonstrating compliance with the referenced regulations.

### ***Public Dose***

Public dose is defined as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

There are many possible dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

1. Airborne radioactive material
2. Waterborne radioactive material
3. External radioactive exposure

The licensee should review these major pathways and decide which, if any, are applicable to its operations.

### ***Operating and Emergency Procedures***

Operating and emergency procedures should be developed, maintained, and implemented to ensure that all licensed materials are used in accordance with licensed activities, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA. The operating procedures should include a description of the operations involving the special nuclear material and a general plan for carrying out the activity. 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. Each licensee must develop, implement, and maintain operating and emergency procedures containing the following elements:

- Contamination controls
- Personnel and area monitoring (including frequency and limits)
- Use of protective clothing and equipment
- Recording requirements
- Reporting requirements
- Waste disposal practices

A copy of the operating and emergency procedures should be posted in all laboratory or work areas where radioactive materials are used. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined. Also, copies of operating and emergency procedures should be provided to all authorized users. These instructions should describe immediate action to be taken in case of an emergency in order to prevent release of radioactive material or further contamination of work areas and personnel. Examples of emergency procedures involve

<sup>4</sup> Alternative responses will be evaluated by MDH staff.

turning off the ventilation systems, evacuation of the area, reentry, and containment of spills. The instructions should specifically state the names and telephone numbers of responsible persons to be notified.

*MDH must be notified when licensed material is lost, stolen, or other related conditions occur. The RSO must be proactive in evaluating whether MDH notification is required.*

The applicant must state that procedures for safe use of materials and emergencies have been developed or will be developed before receipt of licensed material. If you want the option to make changes in the procedures, include a statement that "Procedures may be revised only if 1) the changes are reviewed and approved in writing by the licensee management and the RSO; 2) the licensee staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the MDH regulations and the license; and 4) the changes do not degrade the effectiveness of the program."

### **Leak Tests**

When issued, a license will require performance of leak tests at intervals approved by MDH or an Agreement State and specified in the SSD Registration Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcuries) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. Appendix E outlines the options and response required by the licensee.

### **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 neutrons) and compared to the appropriate limits.

Radiation surveys are used to detect and evaluate contamination of the following:

- 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 when it is reasonable under the circumstances 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, equipment, and packages of radioactive material received or prepared for shipment.
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form, 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 are released to the environment or to the sanitary sewer.
- Bioassays to determine the kinds, quantities, concentration, and 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 (see Appendix D).

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. Table D.1 in Appendix D contains contamination limits that are acceptable to MDH.

#### ***Transportation***

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 4731.0465, but are As Low As Reasonably Achievable (ALARA).

#### ***Minimization of Contamination***

When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. When submitting new applications, applicants should consider the following:

- Implementation of and adherence to good health physics practices in operations.
- Minimization of areas, to the extent practicable, where licensed materials are used and stored.
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill.
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition.
- Appropriate filtration of effluent streams.
- Use of non-porous materials for laboratory bench tops, flooring, etc.
- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction.
- Use of appropriate plumbing materials with minimal pipe lengths and traps.
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed.

SNM Sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to MDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

#### **Item 11: Waste Disposal**

1. Wastes generated as a result of operations involving special nuclear material must be disposed of safely. Such wastes may include items such as contaminated tools, gloves, clothing, absorbent materials, filters, resin columns, decontamination solutions, or process wastes.
2. Wastes that are soluble or readily dispersible in water may be disposed of via the sanitary sewer system subject to monthly concentration limits.
3. The most commonly used method of disposal is transfer to a commercial firm licensed to accept such wastes. In dealing with such firms, prior contact is recommended to determine specific services provided.
4. Other methods of disposal may be considered and justified on a case-by-case basis. Information submitted to support a request for any alternate methods of disposal should include the quantities and kinds of materials, the levels of radioactivity, a description of the manner and conditions of disposal, an evaluation of environmental considerations, and the control procedures.
5. Indicate how the licensee will dispose of each waste.

#### **Item 12: License Fee**

If this is an application for a new license, the full fee 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**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

## **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. You may not place into effect any amendment until receiving 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 MDH has taken the final action on the application. 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 by-product 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  
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AT MEDICAL  
INSTITUTIONS ALARA**

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix A to the MDH Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities." Submit the signed commitment in Section 6 of this appendix.

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in Section 6 of this appendix.

**ALARA PROGRAM**

**1. Management Commitment**

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

**2. Review of Proposed Users and Uses**

- a. The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- b. When considering the use of radioactive material, the RSC will review efforts of the applicant to maintain exposure ALARA.
- c. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- d. The RSC will delegate authority for enforcement of an ALARA program to the RSO.

- e. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- f. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- g. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

**Table A-1 – Investigational Levels**

	Investigational Levels (mrems per month)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

- h. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

**3. Radiation Safety Officer Commitment**

- a. Annual and Quarterly Review
  - The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
  - The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.
- b. Education Responsibilities for ALARA Program
  - The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.
- c. Cooperative Efforts for Development of ALARA Procedures
  - Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
  - The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
  - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- d. **Reviewing Instances of Deviation from Good ALARA Practices:**
- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
- e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

**4. Authorized Users Commitment**

- a. **New methods of Use Involving Potential Radiation Doses**
- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
  - The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
- b. **Authorized User's Responsibility to Supervised Individuals**
- The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
  - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

**5. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses<sup>1</sup>**

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table A-1. These levels apply to the exposure of individual workers.

The RSO will review and record on MDH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table A-1:

- a. **Personnel dose less than Investigational Level I**
- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table A-1 values for the investigational Level I.

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<sup>1</sup> MDH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

- b. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II
  - The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality. This review will be recorded in the Committee minutes.
- c. Personnel dose equal to or greater than Investigational Level II
  - The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's "Occupational Exposure Record for Monitoring Period" and "Cumulative Occupational Exposure History," or its equivalent.
- d. Re-establishment of investigational levels to levels above those listed in Table I
  - In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

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

**6. Signature of Certifying Official<sup>1</sup> Sign and submit as part of Appendix A.**

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

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (Print or type)

\_\_\_\_\_  
Title

<sup>1</sup> The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

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

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for RSO duties published in Appendix B to the MDH Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. State on your application, "We have developed an RSO procedure for your review that is appended as Appendix B", and submit your procedure.

**MODEL PROCEDURE**

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Ensure that personnel monitoring devices are used as required. Ensure that exposure reports are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
  - a. The licensee is abiding by MDH regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained, approved users),
  - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA, and
  - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least four years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or the limits in 4731.2000 are investigated and reported to MDH within the required time limits.

10. Ensure that licensed material is disposed of properly.
11. Ensure that the facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.
12. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

## APPENDIX C AUDIT PROGRAM

### SAMPLE AUDIT PROGRAM

An audit is required to be 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 the MDH 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). If it is not, the auditor should 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 whether he or she fulfills the duties specified in the license. Ensure use by authorized individuals.

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

**Section 4: Audits.** Verify that audits are conducted and properly documented in accordance with licensee commitments.

**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 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 for three years.

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

**Section 9: Radiation Surveys.** Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are 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. 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 licensed material received from others are received, opened, and surveyed. Ensure that transfers are performed. Records of surveys, receipt, and transfer must be maintained for three years.

**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. 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. The RSO should review personnel monitoring records, compare exposures of individuals doing similar work, and 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.** Check on the licensee's 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, NMSS Newsletters, 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 D AREA SURVEYS**

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys published in Appendix D to the MDH Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 4731.2000. State on your application, "We have developed survey procedures for your review that are appended as Appendix D," and submit your survey procedures.

### **MODEL PROCEDURE**

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

### **AMBIENT DOSE RATE SURVEYS**

1. Survey Areas -- Restricted Areas
  - a. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
  - b. In sealed source storage areas, survey quarterly with a radiation survey meter.
  - c. The wearer should survey protective clothing after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the restricted areas. Any contamination above expected levels should be reported to the RSO.
2. Survey Areas -- Unrestricted Areas  
Quarterly surveys should be accomplished in areas
  - adjacent to restricted areas
  - through which radioactive materials are transferred
  - where radioactive material is temporarily stored before shipment

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

### **REMOVABLE CONTAMINATION SURVEYS**

#### **Survey Areas:**

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

The wipe sample<sub>2</sub> assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200 dpm/100 cm<sup>2</sup> for isotopes of iodine). You

must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).

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

**RECORDS**

1. Records must include the actions taken in the case of excessive dose rates or contamination and follow-up survey information.
2. The RSO will review and initial the record at least monthly and promptly in those cases in which action levels were exceeded.

**Table D-1**

<b>RECOMMENDED ACTION LEVELS IN DPM/100 CM<sup>2</sup> FOR SURFACE CONTAMINATION</b>		
	<b>P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198</b>	<b>Cr-51, Co-57, Ga-67, Tc-99<sup>m</sup>, Hg-197, Tl-201</b>
<b>1. Unrestricted areas, personal clothing</b>	<b>200</b>	<b>2,000</b>
<b>2. Restricted areas, protective clothing used only in restricted areas, skin</b>	<b>2,000</b>	<b>20,000</b>

## APPENDIX E LEAK TESTING SEALED SOURCES

You may use the following model procedure to leak test sealed sources. If you 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 (E.1 and/or E.2) to the MDH Regulatory Guide For Special Nuclear Material of Less Than Critical Mass Quantities."

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. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix (E.1 and/or E.2)," and submit your leak test procedure.

### E.1 MODEL PROCEDURE FOR TAKING TEST SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, you should also check for radon leakage. 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.

### E.2 MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries (185 Bq) for beta or gamma emitting radionuclides. For alpha emitting radionuclides, select an instrument that is sufficiently sensitive to detect 0.001 microcuries (37 Bq). 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 sodium-iodide crystal with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive. For alpha emitting radionuclides, a zinc-sulfide scintillation detector with a ratemeter or scaler is appropriate.
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. Wipes of alpha emitting radionuclides should be dry and the exposed, single layer of the wipe material should face the detector.
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 microcuries or greater for beta or gamma emitting radionuclides or 0.001 microcuries for alpha emitting radionuclides, notify the RSO. The source must be withdrawn from use to be repaired or disposed 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 records for three years.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

#### Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

#### 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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

**Training records must include:**

- 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.

## DEFINITIONS

**Hazardous Material** means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

**HAZMAT Employer** means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

**HAZMAT Employee** means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including:

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
  - loads, unloads, or handles HAZMAT;
  - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
  - prepares HAZMAT for transportation;
  - is responsible for safety of transporting HAZMAT; or
  - operates a vehicle used to transport HAZMAT.

**Training** means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

**ATTACHMENT II**  
**US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE**  
**ENHANCED SECURITY MEASURES**

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

**Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

*Begin with a list*

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

**Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one or more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

#### *Employees as a security risk*

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

#### **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

#### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

## **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

### **Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.

