# MINNESOTA DEPARTMENT OF HEALTH


# REGULATORY GUIDE FOR BROAD SCOPE LICENSES

**Division of Environmental Health**
**Indoor Environments & Radiation Section**
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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, 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 in 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, 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 satisfies 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 licensees staff is trained in the revised procedures prior to implementation; and

The licensees 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:

Radiation Control
Minnesota Department of Health
625 Robert St. N
PO Box 64975
St. Paul, MN 55164-0975

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

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

### Item 1: License Action Type

Check box A for a new license request.

Check box B for an amendment to an existing license and provide the license number. See "Amendments and 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, 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 MDH, 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 MDH, 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 MDH, 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 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, 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, 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 4731.3580, 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 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:[1]

- A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications."

- A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications. Additionally, we will implement the model survey meter calibration program published in MDH Instrument Calibration Regulatory Guide."

- A description of alternative 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.

[1] 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**

| PACKAGE | CONTENTS | SURVEY TYPE | SURVEY TIME[2] |
|---|---|---|---|
| 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

[2] 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 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 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 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 an Application for a Minnesota Radioactive materials License form or as a letter. The person indicated in Item 13 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 4731.3090. 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) | $^{3}H$ | $1.2 \times 10^{8}$ |
| Carbon-14 | $^{14}C$ | $3.7 \times 10^{6}$ |
| Sodium-22 | $^{22}Na$ | $9.5 \times 10^{3}$ |
| Sulfur -35 | $^{35}S$ | $1.3 \times 10^{7}$ |
| Chlorine-36 | $^{36}Cl$ | $5.0 \times 10^{5}$ |
| Manganese-54 | $^{54}Mn$ | $3.2 \times 10^{4}$ |
| Iron-55 | $^{55}Fe$ | $4.5 \times 10^{6}$ |
| Cobalt-60 | $^{60}Co$ | $7.1 \times 10^{3}$ |
| Nickel-63 | $^{63}Ni$ | $1.8 \times 10^{6}$ |
| Strontium-90 | $^{90}Sr$ | $8.7 \times 10^{6}$ |
| Technetium-99 | $^{99}Tc$ | $1.3 \times 10^{6}$ |
| Iodine-129 | $^{129}I$ | $3.5 \times 10^{4}$ |
| Cesium-137 | $^{137}Cs$ | $2.8 \times 10^{4}$ |
| Iridium-192 | $^{192}Ir$ | $7.4 \times 10^{4}$ |

* Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using D and D Version 1, based on site-specific re-suspension factor. For Unrestricted Release (dpm/100 $cm^2$) Units are disintegrations per minute per 100 square centimeters (dpm/100 $cm^2$). 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[3]

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**

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

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

| RADIOTOXICITY OF RADIONUCLIDES | MINIMUM QUANTITY | TYPE OF WORKING PLACE OR LABORATORY REQUIRED | | |
|---|---|---|---|---|
| | Ci | 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) |

[3] 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[1]**
**(Instruments used to measure radiological conditions at licensed facilities)**

| Portable Instruments Used for Contamination and Ambient Radiation Surveys | | | |
|---|---|---|---|
| *Detectors* | *Radiation* | *Energy Range* | *Efficiency* |
| 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% |
| NaI 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 | | | |
| *Detectors* | *Radiation* | *Energy Range* | *Efficiency* |
| 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.

**RADIONUCLIDE STORAGE AND USAGE LOG**

Investigator:

---

Nuclide: _____ Chemical Name/Form: _____

Manufacturer/Supplier _____ Lot Number: _____

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

Storage Location: _____ Location of Use _____

| DATE USED | AMOUNT (INDICATE UNITS) | SURVEY DATE | BACKGROUND (INDICATE UNITS) | MEASUREMENT (INDICATE UNITS) | SIGNATURE OR INITIALS |
|---|---|---|---|---|---|
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Date Consigned to Waste: _____

## 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 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** | | |

**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**

| | |
|---|---|
| **Group 1** | 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 |
| **Group 2** | 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$^{m}$ Cd-115$^{m}$ In-114$^{m}$ Sb-124 Sb-125 Te-127$^{m}$ Te-129$^{m}$ 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 |

| | |
|---|---|
| **Group 3** | Be-7 C-14 F-18 Na-24 C1-38 Si-31 P-32 P-33 S-35 Ar-41 K-42<br>K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55<br>Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 $Zn-69^{m}$ Ga-72 As-73<br>As-74 As-76 As-77 Se-75 Br-82 $Kr-85^{m}$ Kr-87 Rb-86 Sr-85 Sr-91<br>Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 $Tc-97^{m}$ Tc-97<br>Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111<br>Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 $Te-125^{m}$ Te-127 Te-129<br>$Te-131^{m}$ Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-131<br>La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149<br>Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166<br>Er-169 Er-171 (9.2 hr) Tm-171, Yb-175 Lu-177 W-181 W-185 W-187<br>Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-l91<br>Pt-193 Pt-197<br>Au-196 Au-198 Au-l99 Hg-197 $Hg-197^{m}$ Hg-203 Tl-200 Tl-201 Tl-202<br>Pb-203 Bi-206 Bi-212 Rn-220 Rn-222 Th-231 Pa-233 Np-239 |
| **Group 4** | H-3 O-15 Ar-37 $Co-58^{m}$ Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87<br>$Y-9l^{m}$ Zr-93 Nb-97 $Tc-96^{m}$ $Tc-99^{m}$ $Rh-103^{m}$ $In-113^{m}$ I-129 $Xe-131^{m}$<br>Xe-133 $Cs-134^{m}$ Cs-135 Sm-147 Re-187 $Os-191^{m}$ $Pt-193^{m}$ $Pt-197^{m}$<br>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**

| NUCLIDE[A] | AVERAGE[B, C] | MAXIMUM[B, D] | REMOVABLE[B, E] |
|---|---|---|---|
| I-125, I-129 | 1.7 Bq/100 $cm^2$ (100 dpm/100 $cm^2$) | 5.0 Bq/100 $cm^2$ (300 dpm/100 $cm^2$) | 0.3 Bq/100 $cm^2$ (20 dpm/100 $cm^2$) |
| I-126, I-131, I-133, Sr-90 | 16.7 Bq/100$cm^2$ (1,000 dpm/100 $cm^2$) | 50.0 Bq/100$cm^2$ (3,000 dpm/100 $cm^2$) | 3.3 Bq/100$cm^2$ (200 dpm/100 $cm^2$) |
| Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above. | 83.3 Bq/100 $cm^2$ (5,000 dpm/100 $cm^2$) | 250 Bq/100 $cm^2$ (15,000 dpm/100 $cm^2$) | 16.7 Bq/100 $cm^2$ (1,000 dpm/100 $cm^2$) |

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

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

[c] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

[d] The maximum contamination level applies to an area of not more than 100 $cm^2$.

[e] The amount of removable radioactive material per 100 $cm^2$ of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, 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 $cm^2$ is acceptable to indicate levels of removable contamination.

**Table 3 - Screening Values for Building Surface Contamination1**

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

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

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 cm2). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in 4731.2110. For radionuclides in a mixture, the sum of fractions rule applies.

**Survey Record Requirements**

Each survey record should include the following:

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

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of

work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

**Air Monitoring in the Workplace**

Air sampling can be used to do the following:

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

**Airborne Effluent Release Monitoring**

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

For release points 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 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.

**SUMMARY OF REVISIONS**

| REVISION | SECTION | DESCRIPTION |
|---|---|---|
| 9/16/05 | Title page and filing an application | Address and section name changes |
| 12/13/15 | Throughout | Removed “Schedule A” from the references to section 4731.3580. |
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