MINNESOTA DEPARTMENT OF HEALTH

REGULATORY GUIDE FOR SPECIAL NUCLEAR MATERIAL OF LESS THAN CRITICAL QUANTITIES

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REGULATORY GUIDE FOR SPECIAL NUCLEAR MATERIAL OF LESS THAN CRITICAL MASS QUANTITIES

INTRODUCTION

This guide describes the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of special nuclear material. It is intended for applicants requesting authorization to possess and use up to 2,000 grams of plutonium as sealed plutonium-beryllium neutron sources, and any special nuclear material in quantities and forms not sufficient to form a critical mass.

Activities that involve the receipt, possession, use, and transfer of special nuclear material in quantities and forms sufficient to form a critical mass are not within the scope of this guide.

AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

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

FILING AN APPLICATION

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

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

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

Submit one copy of your application to:

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

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

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

Item 1: License Action Type

Check box A for a new license request.

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

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

Item 2: Name and Mailing Address of Applicant

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

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

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

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

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

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

Item 4: Person to Be Contacted About This Application

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

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

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

Item 5: Radioactive Material

The special nuclear material requested should be identified by isotope; chemical or physical form; activity in curies, millicuries, or, microcuries; and mass in grams. Specification of isotope should include principle isotope and significant contaminants. Major dose-contributing contaminants present or expected to build up are of particular interest. For example, the quantity of Plutonium-236 present in Plutonium-238 should be specified.

Possession limits requested should cover the total anticipated inventory, including stored materials and waste.

If the application is for a sealed or plated source, the special nuclear material content and manufacturer's name and model number of each source should be specified. If a sealed source will be used in a device (holder, gauge, analyzer, etc.), the manufacturer's name and model number of the device should be identified. Each source should be keyed to the specific devices used with it.

You should indicate the material that is being irradiated (e.g., foils, salts, etc.). Estimate the maximum amount of activity for the activated isotopes. Your license will include authorization for small quantities of these isotopes. If you are irradiating loose material, you must address area surveys. See Appendix D of this guide.

Item 6: Purpose for Which Radioactive Material Will Be Used

Requested radioisotopes must be authorized by the Atomic Energy Act of 1954, as amended. All sealed sources and devices containing licensed material should be used only for the purpose for which they are designed, and according to manufacturer's or distributor’s instructions and recommendations for use as specified in the SSD Registration Certificate.

Applicants should clearly specify the purpose for which each radioisotope will be used, and a general plan for carrying out the activity should be described. Each individual use should be described. The typical license authorizes persons to perform research, development, and student instruction using Pu:Be sealed sources in a neutron howitzer. In addition, it authorizes use in experiments utilizing sub-critical assemblies and calibration of radiation detection instruments. Non-typical uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

The described uses should contain sufficient information to enable the reviewers to have a clear understanding of each use and determine the potential for radiation exposure of workers and members of the public.

Item 7: Individuals Responsible For the Radiation Safety Program

Radiation Safety Officer (RSO)[1]

The person responsible for implementing the radiation protection program is called the Radiation Safety Officer (RSO). The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are described in Appendix B.

MDH believes that to demonstrate adequate training and experience, the RSO should have: (1) sufficient knowledge of physical, chemical, or biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

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

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

Authorized Users (AU)

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

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

[1] Facilities are required to notify MDH of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to MDH as part of an amendment request.

MDH believes that to demonstrate adequate training and experience the Authorized User should have: (1) sufficient knowledge of physical, chemical, or biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following topics:

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

The length of training and experience described above will depend upon the type, form, quantity, and proposed use of the licensed material requested.

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

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

Provide the name of each proposed Authorized User with the types and quantities of licensed material to be used and information about the proposed Authorized User's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

Item 8: Training for Individuals Working In or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)

Individuals who, in the course of their employment, are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), must receive instruction commensurate with their duties and responsibilities.

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

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

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

Item 9: Facilities and Equipment

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

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

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

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

These records are required to be maintained in an identifiable location. Facilities are required to meet MDH criteria prior to release. Therefore, careful facility design is important to prevent contamination, facilitate decontamination, and reduce the costs needed for decommissioning.

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

Item 10: Radiation Safety Program

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

Audit Program
Appendix C contains a suggested audit program that is applicable to special nuclear material of less than critical mass licensees and is acceptable to MDH. However, all areas indicated in Appendix C may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit. Generally, audits are conducted at least once every 12 months to meet the annual requirement.

Currently, MDH's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of licensed material users to determine if, for example, Safe Use and Emergency Procedures are available and are being followed.

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

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

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

These records must be maintained for inspections by MDH.

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

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

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

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

The choice of instrument should be appropriate for the type of radiation to be measured and the type of measurement to be taken (e.g., count rate, dose rate, etc.). The majority of the radioactive emissions from special nuclear material are alpha emissions; therefore the applicant's instrumentation should include instrumentation capable of detecting alpha emissions, such as ZnS detectors. Applications should include descriptions of the instrumentation available for use and any instrumentation applicants intend to purchase prior to starting licensed activities. The description should include the type of instrument and probe and the instrument's intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material, and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without a calibration with appropriate radioactive sources.

MDH requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations shall submit procedures for review.

Provide a description of the instrumentation (as described above) that will be used to perform required surveys.

Material Receipt and Accountability

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

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

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

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

- Identify the package as containing radioactive material by labeling and shipping papers.
- Segregate the package from other incoming items in a secured area until released by the RSO.
- Notify the RSO.

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

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

PACKAGE CONTENTS	SURVEY TYPE	SURVEY TIME[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

The licensee must immediately notify the final delivery carrier and MDH by telephone or facsimile when removable radioactive surface contamination exceeds the limits of 49 CFR 173.443 or when external radiation levels exceed the limits of 4731.0412.

It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees must have an accountability and control system for promptly detecting losses of licensed material.
Licensees who use and/or possess sealed sources are required by license condition to perform inventories of sealed sources every six months. Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm at least every six months that these sealed sources have not been disturbed. Licensees are also required to conduct leak tests of sealed sources at six-month intervals (or at longer intervals as specified in the SSD Registration Certificate). Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.
To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside the normal channels (e.g., through the loan or other transfer of materials without purchase).

Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components including refrigerators and freezers will

[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 work day to perform the required surveys.

become contaminated. Removal of these items for maintenance, repair, or disposal should also be carefully controlled.

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

Develop procedures for ensuring material accountability and either of the following:

- A statement that: "Physical inventories will be conducted at intervals not to exceed six months, to account for all sealed sources and devices received and possessed under the license.
- A description of procedures for ensuring that no sealed sources have been lost, stolen, or misplaced and how often this inventory will be done.

Occupational Dose

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

If this prospective evaluation shows that the individual's dose is not likely to exceed ten percent of any applicable regulatory limit, there are no recordkeeping or reporting requirements.[3] For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. When determining the need for monitoring, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered, including any recordkeeping and reporting requirements. If an evaluation determined that monitoring was not required and a subsequent evaluation indicates that the ten percent regulatory threshold may be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

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

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

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

[3] 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).

Provide either of the following:[4]

- A statement that: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of ten percent of the allowable limits in 4731.2020, or we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose.'"
- A description of an alternate method for demonstrating compliance with the referenced regulations.

Public Dose

Public dose is defined as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

There are many possible dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

- Airborne radioactive material
- Waterborne radioactive material
- External radioactive exposure

The licensee should review these major pathways and decide which, if any, are applicable to its operations.

Operating and Emergency Procedures

Operating and emergency procedures should be developed, maintained, and implemented to ensure that all licensed materials are used in accordance with licensed activities, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA. The operating procedures should include a description of the operations involving the special nuclear material and a general plan for carrying out the activity. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public. Each licensee must develop, implement, and maintain operating and emergency procedures containing the following elements:

- Contamination controls
- Personnel and area monitoring (including frequency and limits)
- Use of protective clothing and equipment
- Recording requirements
- Reporting requirements
- Waste disposal practices

A copy of the operating and emergency procedures should be posted in all laboratory or work areas where radioactive materials are used. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined. Also, copies of operating and emergency procedures should be provided to all authorized users. These instructions should describe immediate action to be taken in case of an emergency in order to prevent release of radioactive material or further contamination of work areas and personnel. Examples of emergency procedures involve turning off the ventilation systems, evacuation of the area, reentry, and containment of

[4] Alternative responses will be evaluated by MDH staff.

spills. The instructions should specifically state the names and telephone numbers of responsible persons to be notified.

MDH must be notified when licensed material is lost, stolen, or other related conditions occur. The RSO must be proactive in evaluating whether MDH notification is required.

The applicant must state that procedures for safe use of materials and emergencies have been developed or will be developed before receipt of licensed material. If you want the option to make changes in the procedures, include a statement that "Procedures may be revised only if 1) the changes are reviewed and approved in writing by the licensee management and the RSO; 2) the licensee staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the MDH regulations and the license; and 4) the changes do no degrade the effectiveness of the program."

Leak Tests

When issued, a license will require performance of leak tests at intervals approved by MDH or an Agreement State and specified in the SSD Registration Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcuries) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. Appendix E outlines the options and response required by the licensee.

Surveys

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

Radiation surveys are used to detect and evaluate contamination of the following:

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

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

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

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

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

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

Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Table D.1 in Appendix D contains contamination limits that are acceptable to MDH.

Transportation

Licensees should consider the safety of all individuals who may handle or may come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the package integrity is not compromised during transport, and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of 4731.0412, but are As Low As Reasonably Achievable (ALARA).

Minimization of Contamination

When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. When submitting new applications, applicants should consider the following:

- Implementation of and adherence to good health physics practices in operations.
- Minimization of areas, to the extent practicable, where licensed materials are used and stored.
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill.
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition.
- Appropriate filtration of effluent streams.
- Use of non-porous materials for laboratory bench tops, flooring, etc.
- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction.
- Use of appropriate plumbing materials with minimal pipe lengths and traps.
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed.

SNM Sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to MDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Item 11: Waste Disposal

- Wastes generated as a result of operations involving special nuclear material must be disposed of safely. Such wastes may include items such as contaminated tools, gloves, clothing, absorbent materials, filters, resin columns, decontamination solutions, or process wastes.
- Wastes that are soluble or readily dispersible in water may be disposed of via the sanitary sewer system subject to monthly concentration limits.
- The most commonly used method of disposal is transfer to a commercial firm licensed to accept such wastes. In dealing with such firms, prior contact is recommended to determine specific services provided.
- Other methods of disposal may be considered and justified on a case-by-case basis. Information submitted to support a request for any alternate methods of disposal should include the quantities and kinds of materials, the levels of radioactivity, a description of the manner and conditions of disposal, an evaluation of environmental considerations, and the control procedures.
- Indicate how the licensee will dispose of each waste.

Item 12: License Fee

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

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

Item 13: Certification

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

AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. You may not place into effect any amendment until receiving written verification from the MDH that the amendment has been approved.

RENEWAL OF LICENSE

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before MDH has taken the final action on the application. The application for the renewal should not reference material that was previously submitted.

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the

radioactive material. The renewal is necessary to avoid violating MDH regulations that do not allow you to possess licensable material without a valid license.

IMPLEMENTATION

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

INSPECTIONS

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

APPENDIX A
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix A to the MDH Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities." Submit the signed commitment in Section 6 of this appendix.

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

ALARA PROGRAM

Management Commitment

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

Review of Proposed Users and Uses

- The qualifications of each applicant will be thoroughly reviewed. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- When considering the use of radioactive material, the efforts of the applicant to maintain exposure ALARA will be reviewed.
- The users will justify their procedures and ensure that individual and collective doses will be ALARA.
- The authority for enforcement of an ALARA program will be the RSO.
- All users will be encouraged to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- A quarterly review of occupational radiation exposure will be completed with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

Table A-1 – Investigational Levels		
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

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

Radiation Safety Officer Commitment

- Annual and Quarterly Review
  - The RSO or a designee will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
  - The RSO or a designee will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA.

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

- Cooperative Efforts for Development of ALARA Procedures
  - Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
  - The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
  - The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
  - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

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

Authorized Users Commitment

- New methods of Use Involving Potential Radiation Doses
  - The authorized user will consult the RSO during the planning stage before using radioactive materials for new uses.

- The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

- Authorized User's Responsibility to Supervised Individuals
  - The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
  - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses[1]

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

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

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

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

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

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

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for RSO duties published in Appendix B to the MDH Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities."

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

MODEL PROCEDURE

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

- Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
- Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
- Ensure that personnel monitoring devices are used as required. Ensure that exposure reports are reviewed in a timely manner.
- Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
- Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
- Ensure that audits are performed at least annually to ensure that:
    - The licensee is abiding by MDH regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained, approved users),
    - The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA, and
    - The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least four years. Ensure prompt action is taken to correct deficiencies.
- Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or the limits in 4731.2020 are investigated and reported to MDH within the required time limits.
- Ensure that licensed material is disposed of properly.
- Ensure that the facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.
- Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

APPENDIX C
AUDIT PROGRAM

SAMPLE AUDIT PROGRAM

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

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

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

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

Section 4: Audits. Verify that audits are conducted and properly documented in accordance with licensee commitments.

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

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

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

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

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

Section 10: Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing licensed material received from others are received, opened, and surveyed. Ensure that transfers are performed. Records of surveys, receipt, and transfer must be maintained for three years.

Section 11: Transportation. Determine compliance with Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49

CFR Parts 172 and 173. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport (49 CFR 172.200, 201, 202, 203, 204 and 177.718).

Section 12: Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. The RSO should review personnel monitoring records, compare exposures of individuals doing similar work, and determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 4731.2080. Check whether records are maintained as required.

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

Section 14: Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements.

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

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

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

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

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

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

APPENDIX D
AREA SURVEYS

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys published in Appendix D to the MDH Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 4731.2020. State on your application, "We have developed survey procedures for your review that are appended as Appendix D," and submit your survey procedures.

MODEL PROCEDURE

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

Ambient 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% of the occupational dose limits.

Dose-rate surveys, at a minimum, should be performed in locations where members of the public could receive a total effective dose equivalent of 1 mSv (100 mrem) in a year, or the dose in any unrestricted area from external sources could exceed 0.02 mSv (2 mrem) in any one hour.

Dose-rate surveys should be performed in a manner and frequency that is representative of the use of radioactive materials. At a minimum, these surveys should be conducted daily in areas of radioactive material use, where exposures to workers could reasonably occur, (e.g. generator storage/elution and dose preparation stations). Other areas, where radiological conditions are not expected to change appreciably from day-to-day, should be surveyed weekly, (e.g. radioactive waste storage areas).

Contamination Surveys
Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in unacceptable levels of exposure 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 wipe tests, which should be analyzed using an appropriate counting instrument. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. See Table H.1 for examples of appropriate instruments.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, or equipment;
- After any spill or contamination event;
- To evaluate contamination of users and the immediate work area at the end of each day when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use;
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency
All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily. All other areas where radioactive materials are used or stored should be surveyed weekly.

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.

Recommended Action Levels for Surface Contamination				
P-32, Se-75, Sr-85, Sr-89, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Re-186, Au-198, Cr-51, $Tc\text{-}99^{m}$, Tl-201, Natural Uranium, U-235, U-238 and associated decay products, Plutonium				
	Type of Radioactive Material			
	Alpha ($dpm/100\ cm^2$)		Beta – Gamma ($dpm/100\ cm^2$)	
Unrestricted areas, personal clothing	20	1,000	200	2,000
Restricted areas, protective clothing used only in restricted areas, skin	200	10,000	2,000	20,000

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, Row 1 of the above table provides the maximum acceptable residual levels. Where both alpha and beta-gamma emitting nuclides exist, the limits established for alpha and beta-gamma emitting nuclides should be applied independently. To the extent practicable, it is appropriate to decontaminate below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released.

A standardized method for wipe testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A wipe taken from an area of approximately 100 cm^2 is acceptable to indicate levels of removable contamination.

Survey Record Requirements
Each survey record should include the following:

- Diagram of the area identifying specific locations surveyed;
- 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;
- Corrective actions taken for elevated levels identified and results of repeated surveys.
- 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 recurrence of contamination, times and dates, and surveyor's signature.

Air Sampling[5]

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.

Air Effluent Monitoring[6]

Airborne radioactive effluents should be monitored at the release points (e.g., stack) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration of equipment and checks of filtration to ensure their reliability.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), "*Document to Sampling Airborne Radioactive Materials in Nuclear Facilities*," and ANSI N42.18, "*Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents*."

Sanitary Sewerage Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in 4731.2090 and 4731.2420, respectively.

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 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:

- Presence of unusually high levels of facial and/or nasal contamination;
- 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;

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[5] Refer to NRC Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NRC NUREG-1400, "Air Sampling in the Workplace," dated September 1993, for further guidance on air sampling.

[6] NRC Regulatory Guide 4.20, "*Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors*," dated December 1996, provides guidance on methods acceptable to MDH for compliance with the constraint on air emissions to the environment. In addition, NRC Regulatory Guide 8.37, "*ALARA Levels for Effluents from Materials Facilities*," dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

- Incidents that result in contamination of wounds or other skin absorption;

APPENDIX E
LEAK TESTING SEALED SOURCES

You may use the following model procedure to leak test sealed sources. If you follow the model procedure you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix E to the MDH Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities."

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

MODEL PROCEDURE FOR TAKING TEST SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

   b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.

   c. If you are testing radium sources, you should also check for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

The samples will be analyzed as follows:

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

2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a certified check source that has the same isotope as the sealed source. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries for beta or gamma emitters or 0.001 microcuries for alpha emitters, a different instrument must be used.

3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source. Wipes of alpha emitting radionuclides should be dry and the exposed, single layer of the wipe material should face the detector.

4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

5. Continue the same analysis procedure for all wipe samples.

6. If the wipe sample activity is 0.005 microcuries or greater for beta or gamma emitting radionuclides or 0.001 microcuries for alpha emitting radionuclides, notify the RSO. The source must be withdrawn from use to be repaired or disposed in accordance with MDH rules.

7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain records for three years.

APPENDIX F
US DEPARTMENT OF TRANSPORTATION TRAINING REQUIREMENTS

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

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

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

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

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

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

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

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

Training records
Training records must include the following information:

- HAZMAT employee's name;

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

49 CFR References

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

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

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

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION
9/16/05	Title page and filing an application	Address and section name change.