MINNESOTA DEPARTMENT OF HEALTH

REGULATORY GUIDE FOR DIAGNOSTIC MEDICAL PROCEDURES
(INCLUDING NUCLEAR MEDICAL VANS)

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April 2, 2007

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REGULATORY GUIDE FOR
DIAGNOSTIC MEDICAL PROCEDURES

INTRODUCTION

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

MDH defines "medical use" as "the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user." An Authorized User is defined as "a physician, dentist, or podiatrist" who meets the training and experience requirements specified in the board certification pathway or who is identified as an authorized user on an NRC or Agreement State license; on a permit issued by an NRC master material licensee or an NRC master material permittee that is authorized to permit the medical use of radioactive material; or on a permit issued by the NRC or Agreement State broad scope licensee authorized the medical use of radioactive material.

The use of radioactive material for certain *in vitro* clinical or laboratory testing may be authorized by a general license; however, that use may not involve internal or external administration of radioactive material, or the radiation to human beings or animals.

MDH usually issues a single radioactive material license to cover an entire radionuclide program. (Note, however, that nuclear-powered pacemakers are licensed separately.) A license may include authorization for possession of sealed sources to be used to calibrate dose calibration devices.

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the regulations identified in 4731.4400 through 4731.4527 before completing the application form. The MDH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program

This guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for a medical use license and to describe the radioactive material requirements for medical use.

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with MDH, when incorporated into a license by reference;
- Terms and conditions of the license; and
- MDH rules.

MDH requires that the information in the application be complete and accurate in all material aspects. Information is considered relevant if it has the ability to change or affect an agency decision on issuing the license.

Specific Limited Scope License
MDH issues specific medical licenses of limited scope to private or group medical practices and to medical institutions. A medical institution is an organization in which more than one medical discipline is practiced. In general, individual physicians or physician groups located within a licensed medical facility (e.g., hospital) may not apply for a separate license. Since a physician group does not normally have control over the facilities, the hospital remains responsible for activities conducted on its premises and must apply for the license. On specific licenses of limited scope, the authorized users are specifically listed in the license.

Radioactive material may be administered to patients on an inpatient (i.e., hospitalized) or outpatient basis. For patients to whom radioactive material is administered and who are not releasable under MDH guidelines, inpatient facilities are required. In general, facilities for private and group practices do not include inpatient rooms and, therefore, procedures requiring hospitalization of the patient cannot be performed.

A specific limited scope license may also be issued to an entity requesting to perform mobile medical services. A medical institution or a private or group practice may apply for authorization to use radioactive material in a mobile medical service.

Specific Broad Scope License
Generally, MDH issues specific broad scope licenses for medical use (i.e., licenses authorizing multiple quantities and types of radioactive material for medical as well as other uses) to institutions that

- have experience successfully operating under a specific limited scope license; and
- are engaged in medical research and routine diagnostic and therapeutic uses of radioactive material.

Medical institutions that provide patient care and conduct research programs that use radionuclides for *in vitro*, animal, and medical procedures may request a specific broad scope license. No medical use of radioactive material, including research involving human subjects, may be conducted without an authorization in a license from the MDH. The criteria for the various types of broad scope licenses are found in 4731.3530 through 4731.3570.

Research Involving Human Subjects
Medical use is defined to include the administration of radioactive material or radiation incidental to the administration to human research subjects. Furthermore, 4731.4401, “Provisions for the protection of human research subjects,” addresses the protection of the rights of human subjects involved in research by medical use licensees. For these licensees, prior MDH approval is not necessary if the research is conducted, funded, supported, or regulated by another Federal Agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, the licensee must apply for a specific amendment and receive approval for the amendment before conducting such research. Whether or not a license amendment is required, licensees must obtain informed consent from human subjects and prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of those terms under the Federal Policy. Research involving human subjects shall be conducted only with radioactive materials listed in the license for the uses authorized in the license.

General *In Vitro* License
In accordance with 4731.3245, a general license can be issued authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use small quantities of certain radioactive material for *in vitro* clinical or laboratory tests not involving "medical use" (i.e., not involving administration to humans). An MDH Form 483 should be used when applying for a general license for *in vitro* clinical or laboratory tests not involving medical use. MDH limits possession to a total of 200 microcuries of photon-emitting materials at any one time, at any one location of storage or use.

An applicant needing more than 200 microcuries of these materials must apply for a specific license and may request the increased inventory limit as a separate line item. If requesting an increased inventory limit, the applicant will be subject to the requirements Chapter 4731, including the requirements for waste disposal.

As Low As Reasonably Achievable (ALARA) Philosophy

Each licensee must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and the licensee must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. Applicants should consider the ALARA philosophy when developing plans to work with licensed radioactive materials.

Licensees are also required to review the content of the radiation protection program and its implementation at least annually. The RSO is responsible for the day-to-day operation of the radiation protection program.

Appendix A provides a model ALARA program.

Timely Notification of Transfer of Control

Licensees must provide full information and obtain MDH's *written consent* before transferring control of the license, or, as some licensees refer to the process, "transferring the license." Control may be transferred as a result of mergers, 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 MDH's written consent before transferring control of the license. 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 the material;
- Public health and safety are not compromised by the use of such materials.

If only the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license, a licensee must file a written notification with MDH no later than 30 days after the date(s) of the change(s). Otherwise, prior MDH written consent must be given prior to the transfer.

Timely Notification of Bankruptcy Proceedings

Immediately following filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee is required by to notify MDH, in writing, identifying the bankruptcy court in which the petition was filed and the date of the filing.

Even though the licensee may have filed for bankruptcy, the licensee remains responsible for compliance with all regulatory requirements. MDH needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). MDH shares the results of its determinations with other entities involved (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.

Recordkeeping for Decommissioning and Financial Assurance

All licensees are required to maintain records important to decommissioning in an identified location. These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is a reasonable likelihood that contaminants may have spread) and leaking sealed sources. As an alternative to the potential need for site characterizations, some licensees prefer to maintain information on surveys and leak tests on an ongoing basis and as a low-cost means of providing evidence and assurance of an appropriate decommissioning status upon the termination of licensed activities and/or release of a site for non-licensed use. Licensees must transfer the records important to decommissioning either to the new licensee before licensed activities are transferred or assigned and must transfer records to MDH before the license is terminated.

Licensees using sealed sources authorized generally use licensed material in a manner that would preclude releases into the environment, would not cause the activation of adjacent materials, or would not contaminate work areas. The licensee's most recent leak test should demonstrate that there has been no leakage from the sealed sources while the sealed sources were in the licensee's possession. However, any leakage of the sealed source in excess of the regulatory limits would warrant further MDH review of decommissioning procedures on a case-by-case basis.

Licensees authorized to possess radioactive material in excess of the limits specified in 4731.3080 must also provide evidence of financial assurance for decommissioning. The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Some medical use applicants and licensees may not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 4731.3080 or because the half-life of the unsealed radioactive material used does not exceed 120 days. Applicants requesting licensed material with a half-life in excess of 120 days should determine whether financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed.

Applications for authorization to possess and use unsealed radioactive material with a half-life exceeding 120 days must be accompanied by a decommissioning funding plan or certification of financial assurance when the trigger quantities given in 4731.3080 Subpart 2 are exceeded. Acceptable methods of providing financial assurance include trust funds, escrow accounts, government funds, certificates of deposit, deposits of government securities, surety bonds, letters of credit, lines of credit, insurance policies, parent company guarantees, self guarantees, external sinking funds, statements of intent, special arrangements with government entities, and standby trust funds.

MDH will authorize sealed source possession exceeding the limits given in 4731.3080 Subpart 4 without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange, for no more than 30 days.

Determining Need for Financial Assurance for Decommissioning

The half-lives of unsealed radioactive material used by medical licensees have traditionally been less than 120 days. Therefore, most medical use applicants need only consider licensed material in sealed sources to evaluate the need for financial assurance. Use the following table as a worksheet to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed radioactive material with a half-life greater than 120 days, refer to 4731.3080 and 4731.3160 for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in the following table and must be used to determine the need for financial assurance for both sealed and unsealed radioactive material.

WORKSHEET FOR DETERMINING NEED FOR FINANCIAL ASSURANCE

FOR SEALED SOURCES				
Step	**Description**	**Cobalt-60**	**Cesium-137**	**Strontium-90**
1	Activity possessed, in curies*			
2	Activity requiring financial assurance, in curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

* This table uses only conventional units. The conversion to the International System of units (SI) is: 1 Curie = 37 gigabecquerels.

As 4731.3080 describes, if the sum of the fractions is greater than or equal to 1, the applicant will need to submit a decommissioning funding plan or financial assurance, as applicable.

FILING AN APPLICATION

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

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

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

Submit one copy of your application to:

Radioactive Materials Unit
Minnesota Department of Health
625 Robert Street North
P.O. 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.

Item 3: Address(es) Where Licensed Material Will Be Used or Possessed
Applicants must provide a specific address for each location where radioactive material will be used or stored, or dispatched. Specify the street address, city, and state or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each permanent storage or use facility and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. A Post Office Box address is insufficient because MDH needs a specific address to allow an MDH inspector to find the use and/or storage location. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

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

Item 4: Person to Be Contacted About This Application
Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer (RSO) or knowledgeable management official. The MDH will contact this individual if there are questions about the application.

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

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

Item 5: Radioactive Materials
The applicant should indicate the radioactive material requested. The amount and type of information necessary will vary according to the type of use requested.

When determining both individual radionuclide and total quantities of sealed sources, all materials to be possessed at any one time under the license should be included (i.e., materials received awaiting use, materials in use or possessed, material used for shielding, and materials classified as waste awaiting disposal or held for decay-in-storage).

For 4731.4432 (Uptake, Dilution, and Excretion Studies) and 4731.4434 (Imaging and Localization Studies), the chemical/physical form may be "Any" unsealed radioactive material permitted by 4731.4432 or 4731.4434, as appropriate. For 4731.4432 and 4731.4434 use, the total amount requested may be "As needed." The following format may be used:

RADIOACTIVE MATERIAL	CHEMICAL OR PHYSICAL FORM	AMOUNT
Any radioactive material authorized in 4731.4432	Any	As needed
Any radioactive material authorized in 4731.4434	Any	As needed

For 4731.4440 (Unsealed Radioactive Material Requiring a Written Directive), the chemical/physical form may be "Any" unsealed radioactive material permitted by 4731.4440. The total amount requested must be specified. The following format may be used:

RADIOACTIVE MATERIAL	CHEMICAL OR PHYSICAL FORM	AMOUNT
Any radioactive material authorized in 4731.4432	Any	300 mCi

For 4731.4460 (Sealed Sources for Diagnosis) and 4731.4404 (Other Medical Uses), the radionuclide, the chemical/physical form (i.e., sealed source or device identified by manufacturer and model number), the total amount in Becquerel (Bq), microcuries (µCi), millicuries (mCi), or curies (Ci), and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor. The following format may be used:

RADIOACTIVE MATERIAL	CHEMICAL OR PHYSICAL FORM	AMOUNT
Gadolinium 153 (i.e., specific diagnostic sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 500 millicuries per source and 1 curie total

Authorization for Calibration, Transmission, and Reference Sources: The maximum activity for these sources is listed in 4731.4423. Facilities that receive, possess, and use a calibration, transmission and reference source with activity level below the amounts indicated should not include those sources as part of the license application.

Shielding Material/Depleted Uranium: Some high activity radionuclide generators used to produce radioactive materials for 4731.4434 and 4731.4440 uses (e.g., Tc-99m generators) may include depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) as shielding material. If a generator has depleted uranium shielding, an applicant should request authorization to possess depleted uranium as shielding material. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange and shielding for other devices.

The applicant should review the manufacturer's specifications for each device specified in the license request to determine: (1) if depleted uranium is used to shield the source(s) within the device; and (2) the total quantity of depleted uranium present in the device (in kilograms). The applicant should also consult

the manufacturer's specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers (in kilograms).

The following format may be used:

RADIOACTIVE MATERIAL	CHEMICAL OR PHYSICAL FORM	AMOUNT
Depleted Uranium	Metal	999 kilograms

Other Material: The applicant should make a separate entry for other items that need to be listed (e.g., more radioactive material for *in vitro* testing than is allowed under 4731.3245, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal, or human research studies). The following format may be used:

RADIOACTIVE MATERIAL	CHEMICAL OR PHYSICAL FORM	AMOUNT
Any radioactive material permitted by 4731.3245	Prepackaged kits	50 millicuries

Item 6: Purpose for Which Licensed Material Will Be Used
Radioactive material for medical use is divided into seven types of use as follows:

- 4731.4432 Medical Use of Unsealed Radioactive material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
- 4731.4434 Medical Use of Unsealed Radioactive material for Imaging and Localization Studies for Which a Written Directive is Not Required
- 4731.4440 Medical Use of Unsealed Radioactive material for Which a Written Directive is Required
- 4731.4460 Medical Use of Sealed Sources for Diagnosis
- 4731.4404 Other Medical Uses of Radioactive material or Radiation from Radioactive material

For 4731.4432, 4731.4434, and 4731.4440 Use, the applicant should define the purpose of use by stating the applicable rule (e.g., 4731.4432, 4731.4434) and the description of the applicable modality (e.g., any uptake, dilution, and excretion procedure for which a written directive is not required).

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

4731.4404 Use, applicants must apply for authorization to use radioactive material, or radiation there from, in medical applications under 4731.4404. When applying for use under provisions of 4731.4404, applicants should describe the purpose of use and submit the information required, review regulatory requirements in other parts of Chapter 4731, and use them as a guide on how to determine what should be included in an application. It is anticipated that many of the uses of radioactive material under the provisions of 4731.4404 may involve research or product development; thus, applicants should ensure review and compliance with 4731.4401, "Provisions for the protection of human research subjects." Use of radioactive material in a source or device after approval by U.S. Food and Drug Administration, e.g.,

under an IDE (Investigational Device Exemption) or an IND (Investigational New Drug Exemption), does not relieve individuals of the responsibility to obtain a license to use the radioactive material in medicine.

Non-Medical Uses, applicants may also describe non-medical uses (e.g., survey meter calibrations with NIST traceable sources) and reference the applicable radioactive material provided in response to Item 5.

Item 7: Parties Responsible for the Radiation Safety Program

4731.4405 provides the requirements regarding the authority and responsibilities for the radiation protection program, including those of the licensee's management and the Radiation Safety Officer (RSO) appointed by licensee management. Other personnel who have a role in the radiation protection program are Authorized Users (AUs) and members of the Radiation Safety Committee (RSC), if the licensee is required to establish a RSC. MDH requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Chapter 4731 provides specific criteria for acceptable training and experience for Authorized Users for medical use and the RSO.

A résumé or curriculum vitae is likely to be insufficient because such documents usually do not supply all the information needed to evaluate an individual's training and experience for MDH purposes. Applicants should ensure that they submit the specific training information required by MDH rules. The applicable MDH Form 483 provides a format for submitting this information.

Licensees may contract for medical use services, including those involving patient services. However, the licensee should not assume that by hiring a contractor to provide certain services it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program, including training of contractor staff, is effectively implemented by the appropriate individuals.

Management Responsibilities

MDH endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with MDH regulatory requirements. "Management" refers to the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities or that person's delegate or delegates.

To ensure adequate management involvement, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for the following:

- Radiation protection, security, and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation protection records and all information provided to MDH;
- Knowledge about the contents of the license application;
- Compliance with current MDH and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Provision of adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;
- Approval of qualified individual(s) to serve as Authorized Medical Physicists (AMPs), and Authorized Nuclear Pharmacists (ANPs), and Authorized Users (AUs) for licensed activities.

It is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee's management must appoint an RSO, who agrees in writing to be responsible for implementing the radiation protection program, and must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding MDH rules and license provisions, including:

- identifying radiation safety problems;
- initiating, recommending, or providing corrective actions;
- stopping unsafe operations; and
- verifying the implementation of corrective actions.

However, the management retains the ultimate responsibility for the conduct of licensed activities.

Radiation Safety Officer (RSO)

The training and experience requirements for the RSO are described in 4731.4411 allow for the following training pathways:

- Certification as provided in 4731.4411 Subpart 1. Item A. by a specialty board whose certification process has been recognized by the NRC or an Agreement State, plus written attestation signed by a preceptor RSO as provided in 4731.4411 Subpart 1. Item B. (2) and training as specified in 4731.4411 Subpart 1. Item B. (3); or

- Completion of classroom and laboratory training (200 hours) and 1 year of full time radiation safety experience as described in 4731.4411(b)(1) plus written attestation signed by a preceptor RSO as provided in 4731.4411 Subpart 1. Item B. (2) and training as specified in 4731.4411 Subpart 1. Item B. (3); or

- Certification as provided in 4731.4411 Subpart 1. Item C. as a medical physicist under 4731.4412, plus written attestation signed by a preceptor RSO as provided in 4731.4411 Subpart 1. Item B. (2) and training as specified in 4731.4411 Subpart 1. Item B. (3); or

- Identification as provided in 4731.4411 Subpart 1. Item D. on the licensee's license as an Authorized User with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities, plus training as specified in 4731.4411 Subpart 1. Item B. (3).

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by 4731.4405 Subpart 1. Item E.

The RSO is responsible for day-to-day oversight of the radiation protection program. The licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in 4731.4405 to ensure that radioactive materials are used in a safe manner. The NRC requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

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

Appendix B contains a model RSO Delegation of Authority as well as a detailed list of the typical duties and responsibilities of an RSO.

Radiation Safety Officer Responsibilities
Some of the typical duties and responsibilities of a Radiation Safety Officer include ensuring the following:

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

RSO applicants must have successfully completed the applicable training and experience criteria described in Chapter 4731 within seven years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other pathways to meeting requirements for training and experience.

Licensees should provide the following:

- Name of the proposed RSO.

AND

For an individual previously identified as an RSO on an NRC or Agreement State license or permit:

- A copy of the license or a copy of a permit issued by an NRC master material licensee, a permit issued by a NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee that authorized the uses requested and on which the individual was named as the RSO.

For an individual qualifying under 4731.4411(a):

- Copy of certification by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

AND

- Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

AND

- Description of the training and experience specified in 4731.4411 Subpart 1. Item B. (3). demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

For an individual qualifying in accordance with 4731.4411 Subpart 1. Item B.:

- Description of the training and experience specified in 4731.4411 Subpart 1. Item B. demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

AND

- Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

AND

- Description of the training and experience specified in 4731.4411 Subpart 1. Item B. (3). demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

For an individual qualifying under 4731.4411(c):

- Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized by the NRC or an Agreement State under 4731.4412 Subpart 1. Item A. and description of the experience specified in 4731.4411 Subpart 1. Item C. demonstrating that the proposed RSO is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

AND

- Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval; has satisfactorily completed and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

AND

- Description of the training and experience specified in 4731.4411 Subpart 1. Item B. (3). demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

OR

- Copy of the licensee's license indicating that the individual is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the applicant seeks approval of an individual to serve as RSO.

AND

- Description of the training and experience specified in 4731.4411 Subpart 1. Item B. (3). demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

AND

- If applicable, description of recent related continuing education and experience as required by 4731.4415.

The licensee must notify the MDH within 30 days if an RSO permanently discontinues his or her duties under the license or has a name change and to request an amendment to change an RSO.

An Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist may be designated as the RSO on the license if the individual has experience with the radiation safety aspects of similar types of radioactive material use for which he or she has RSO responsibilities and, as required by 4731.4405 Subpart 1. Item G, has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.

Descriptions of training and experience will be reviewed using the criteria listed above. MDH will review the documentation to determine if the applicable criteria are met. If the training and experience do not appear to meet the criteria, the MDH may request additional information from the applicant.

Authorized Users (AUs)

The responsibilities of Authorized Users involved in medical use include the following:

- Radiation safety commensurate with use of radioactive material;
- Administration of a radiation dose or dosage and how it is prescribed;
- Direction of individuals under the Authorized User's supervision in the preparation of radioactive material for medical use and in the medical use of radioactive material;
- Preparation of written directives, if required.

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

Technologists, therapists, or other personnel may use radioactive material for medical use under an Authorized User's supervision in accordance with 4731.4407, “Supervision,” and in compliance with applicable FDA, other Federal, and State requirements. Examples include FDA requirements for conduct of certain types of clinical research after submission of applications for Investigational New Drugs (INDs) and under the auspices of a Radioactive Drug Research Committee.

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

Authorized User's for Non-Medical Uses

For *in vitro* studies, animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed Authorized Users should include the individuals who will actually be responsible for the safe use of the radioactive material for the requested use.

An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and providing information about the user’s training and experience.

Authorized non-medical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, and dosimetry research) will be reviewed on a case-by-case basis.

Provide the following:

- Name of the proposed Authorized User and uses requested.

AND

For an individual previously identified as an Authorized User on an NRC or Agreement State license or permit:

- A copy of the license or a copy of a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee on which the physician, dentist, or podiatrist was specifically named as an Authorized User for the uses requested.

For an individual who is board certified:

- Copy of the certification(s) by a specialty board(s) whose certification process has been recognized by the NRC or an Agreement State as applicable to the use requested.

AND

- Written attestation, signed by a preceptor physician Authorized User, that the training and experience specified for certification has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized User for the medical uses authorized has been achieved.

AND

- If applicable, description of recent related continuing education and experience as required by 4731.4415.

For an individual who is not board certified:

- A description of the training and experience demonstrating that the proposed Authorized User is qualified by training and experience for the use requested.

AND

- Written attestation, signed by a preceptor physician Authorized User, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized User for the medical uses authorized has been achieved.

AND

- If applicable, description of recent related continuing education and experience as required by 4731.4415.

Descriptions of training and experience will be reviewed using the criteria listed above. MDH will review the documentation to determine if the applicable criteria are met. If the training and experience do not appear to meet the criteria, the MDH may request additional information from the applicant.

Item 8: Safety Instruction for Individuals Working In or Frequenting Restricted Areas

Individuals working with or in the vicinity of licensed material must have adequate safety instruction. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 100 millirem (mrem) [1 millisievert (mSv)], the licensee must provide safety instructions as

required by 4731.1020. Additional requirements for training in radiation safety for individuals are described in 4731.4441. The licensee's authorized users are required by 4731.4407 to provide safety instruction to all personnel using radioactive material under their supervision.

Authorized Users, RSOs, and their supervised employees are most likely to receive doses in excess of 100 mrem (1 mSv) in a year. However, licensees also must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. All individuals working with or around licensed materials should receive safety instruction commensurate with their assigned duties, and if it is likely that they could receive doses over 100 mrem (1 mSv) in a year, they must receive instruction as specified by 4731.1020. For example, a licensee might determine that housekeeping staff, while not likely to receive doses over 100 mrem (1 mSv), should be informed of the nature of the licensed material and the meaning of the radiation symbol, and instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in controlling abnormal events, such as loss of radioactive material.

Individuals working with licensed material under the supervision of an Authorized User must receive instruction on the licensee's written radiation protection procedures, written directive procedures, and MDH regulations and license conditions with respect to the use of radioactive material.

A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an Authorized User, shall instruct supervised individuals in the preparation of radioactive material for medical use and require the individuals to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and MDH regulations. A licensee that permits supervised activities is responsible for the acts and omissions of the supervised individuals.

Appendix C provides a model training program that provides one way to satisfy the requirements referenced above.

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

Item 9: Facilities and Equipment

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

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

For use of unsealed radioactive material for uptake, dilution, or excretion, or for imaging and localization (4731.4432 or 4731.4433), applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described. Licensees planning to use F-18 for PET studies should include the shielding design for the rooms where patients are required to "rest" between the injection and the scan.

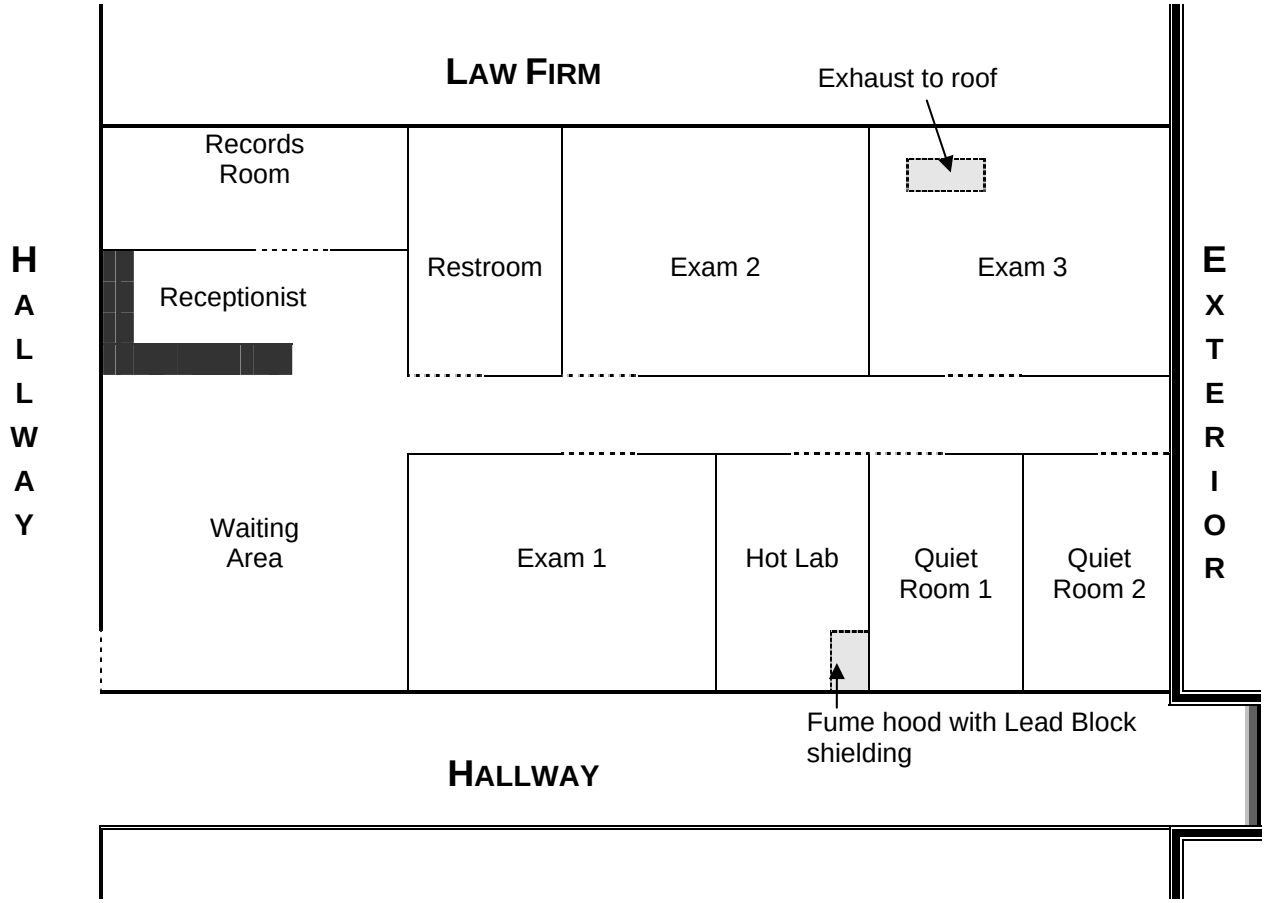
The applicant should demonstrate that the dose limits for individual members of the public (4731.2090) would not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant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

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

- Requesting prior MDH authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv) and demonstrating that the requirements will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits. A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA must be developed.

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

Sample Facility Design for Nuclear Medicine Suite



Annotated Drawings
Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used.

- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored.

- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below rooms; indicate whether the room is a restricted or unrestricted area as defined in 4731.0100.

- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used.

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

The radiation protection program that licensees are required to develop, document, and implement in accordance with 4731.2010 must include provisions for survey instrument calibration (4731.2200). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used.

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

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

Provide one or both of the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."

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

Also provide both of the following:

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

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

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

Dose Calibrator and Other Equipment Used to Measure Dosages
As described in 4731.4422, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or a nuclear pharmacy and does not split, combine, or otherwise modify unit dosages, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

- If the licensee performs direct measurements of dosages in accordance with 4731.4422 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

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

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

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

Item 10: Radiation Protection Program

Each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of Chapter 4731 and all additional license requirements and conditions that MDH deems appropriate or necessary to, in part, protect health or to minimize danger to life and property. The licensee is also responsible for the conduct of all individuals handling licensed material.

Applicants/licensees must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation protection program during the licensing process.

Annual Audit of the Radiation Safety Program

All licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with MDH and applicable DOT regulations and the terms and conditions of the license; and
- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101).

The applicant should develop and implement procedures for the required review or audit of the radiation protection program's content and implementation.

Appendix D contains model procedures that are only a suggested guide and are one way to meet this requirement. Some sections of Appendix D may not be pertinent to every licensee or to each review or audit. For example, licensees do not need to address areas that do not apply to their activities, and activities that have not occurred since the last review or audit need not be reviewed at the next review or audit. Reviews or audits of the content and implementation of the radiation protection program must be conducted at least annually.

MDH encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff about the radiation protection program, and spot-checking required records. As part of their review programs, licensees should consider performing unannounced audits of authorized and supervised users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, violations and radiation safety concerns are corrected comprehensively and in a timely manner. The following three-step corrective action process has proven effective:

- Conduct a complete and thorough review of the circumstances that led to the violation.
- Identify the root cause of the violation.
- Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation.

MDH's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Area Surveys

Licensees are required to make surveys of potential radiological hazards in their workplace. For example, licensees must perform surveys to:

- Ensure that licensed material will be used, transported, and stored in such a way that doses to members of the public do not exceed 100 millirem/year (1 mSv per year) and that the dose in any unrestricted area will not exceed 2 mrem (0.02 mSv) in any 1 hour from licensed operations;
- Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in 4731.2020; and
- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.
- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in 4731.2010.

The radiation protection program that licensees are required to develop, document, and implement must include provisions for area 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), calculations, 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 radiological conditions.

There are many different kinds of surveys performed by licensees:

- Contamination:
  - Fixed;
  - Removable.
- Air Effluent;
- Water Effluent;
- Leak Test;
- Bioassays;
- Air Sample;
- Restricted Areas;
- Unrestricted Areas; and
- Personnel (during use, transfer, or disposal of licensed material).

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 appropriate regulations. The most important types of surveys are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas;
- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas; and
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective barriers, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. Appendix E contains model procedures that represent one acceptable method of establishing survey frequencies for ambient radiation level and contamination surveys. For example, licensees are required to perform daily surveys in all areas used for the preparation and administration of radiopharmaceuticals for which a written directive is required; when the licensee administers

radiopharamaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey of the patient's room. Licensees should perform surveys after the patient's release. Licensees must perform surveys prior to the release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate the public dose limits are not exceeded.

Applicants must describe the various aspects of their survey program.

Dose to Occupational Workers

Applicants must demonstrate that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 percent of the following allowable limits or monitor external and/or internal occupational radiation exposure, if required by 4731.2210.

ANNUAL DOSE LIMITS FOR OCCUPATIONALLY EXPOSED ADULTS		
Eyes	15 rem	0.15 Sv
Extremities (hands to elbows and feet to knees)	50 rem	0.5 Sv
Skin	50 rem	0.5 Sv
Internal Organs	50 rem	0.5 Sv
Total Effective Dose Equivalent TEDE (whole body)	5 rem	0.05 Sv

The radiation protection program that licensees are required to develop, document, and implement in accordance with 4731.2010, must include provisions for monitoring occupational dose. The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required. Licensees must consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure. Review of dosimetry histories for workers previously engaged in similar duties may be helpful in assessing potential doses.

When evaluating external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within the limits of Chapter 4731.

Appendix G provides a model procedure for monitoring external occupational exposure.

If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSL), and thermoluminescent dosimeters (TLDs), that personnel will use. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors, which are required if workers are likely to receive a dose in excess of 0.05 Sv (5 rem) shallow-dose equivalent (SDE), in addition to whole-body badges. Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the regulatory requirements are met. See American National Standards Institute (ANSI) N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration (10 CFR 20.1501(b)).

When personnel monitoring is needed, most licensees use either film badges or TLDs that are supplied by a processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory

Accreditation Program (NVLAP). Licensees must verify that the processor is accredited by NVLAP for the type of radiation for which monitoring will be performed. Consult the NVLAP-accredited processor for its recommendations for exchange frequency and proper use.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 4731.2050 and 4731.2210. If internal dose assessment is necessary, the applicant shall measure the following:

- Concentrations of radioactive material in air in work areas; or
- Quantities of radionuclides in the body; or
- Quantities of radionuclides excreted from the body; or
- Combinations of these measurements.

The applicant should describe in its procedures the criteria used to determine the type of bioassay and the frequencies at which bioassay (both *in vivo* and *in vitro*) will be performed to evaluate intakes. The criteria also should describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments, i.e., the empirical models used to interpret the raw bioassay data. The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. If a commercial bioassay service will be used, the applicant should ensure that the service is licensed by MDH, the NRC or another equivalent Agreement State or provide another alternative for MDH to review.

If personnel monitoring is required, provide the following:

> A commitment to perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or to provide dosimetry.
>
> **OR**
>
> A description of an alternative method for demonstrating compliance with the MDH rules.

Dose to Members of the Public
Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 100 mrem (1 mSv) in 1 year, and the dose in any unrestricted area will not exceed 2 mrem (0.02 mSv) in any one hour from licensed operations.
- Ensure air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 10 mrem (0.1 mSv) TEDE in one year from these emissions.
- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Members of the public include persons who are not radiation workers. This includes workers who live, work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored. Public dose is controlled, in part, by ensuring that licensed material is secure (e.g., located in a locked area) to prevent unauthorized access or use by individuals coming into the area. Some medical use devices containing licensed material are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only authorized users and personnel using radioactive material under their supervision should have access to these keys.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and non-radioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security.

For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to show compliance.

The definition of "public dose" in 4731.0100 Subpart 180 does not include doses received due to exposure to patients released in accordance with 4741.4427. The provisions of 4731.2090 should not be applied to radiation received by a member of the general public from patients released in accordance with 4741.4427. If a patient is released pursuant to 4741.4427, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 2 mrem (0.02mSv) in any one hour. Patient waiting rooms need only be controlled for those patients not meeting the release criteria in 4741.4427.

Licensees may permit visitors to a patient who cannot be released under 4741.4427 to receive a dose greater than 0.1 rem (1 mSv) provided the dose does not exceed 0.5 rem (5 mSv) and the authorized user has determined before the visit that it is appropriate. In assessing adequacy of facilities to control public dose, licensees should consider the design factors discussed under "Facilities and Equipment" and may find confirmatory surveys to be useful in assuring compliance with 4731.2090.

The licensee must control emissions of radioactive material to air such that the individual member of the public likely to receive the highest total effective dose equivalent (TEDE) does not exceed the constraint level of 10 mrem (0.10 mSv) per year from those emissions. If exceeded, the licensee must report this in accordance with 4731.2620, and take prompt actions to ensure against recurrence.

Mobile Medical Service (Nuclear Van Service)

In addition to the requirements in 4731.4428 and 4731.4475 as applicable, mobile medical service licensees must comply with all other applicable regulations. Applicants for licensure of mobile medical services should use the MDH Regulatory Guide for Mobile Nuclear Medical Service for information to be submitted as part of their applications; however, many of the requirements in this guide are relevant to use of radioactive material by mobile medical service providers with details being dependent upon the scope of such programs. "Temporary job site" means a location, other than specific location(s) of use authorized on the license, where mobile medical services are conducted. Mobile medical service licensees may transport licensed material and equipment into a client's building, or may bring patients into the transport (e.g., van). In either case, the van should be located on the client's property that is under the client's control.

Self-contained mobile medical service involves a mobile treatment or administration facility that provides ready-to-deliver mobile medical services on arrival at a client's site. Companies providing only transportation of radioactive material will not be licensed for medical use. The general types of services provided as mobile medical services are:

- Mobile medical services (radioactive material and trained personnel) that provide the device/facility (e.g., in-van use) and treatment of (or administration to) patients at the client site. These mobile medical service providers are responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).
- Mobile medical service providers (radioactive material and trained personnel) that provide the transportation to and use of the radioactive material within the client's facility. These mobile medical service providers are also responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).

Mobile medical services within the client's facility must ensure that all radioactive materials are removed at the end of the business day. Otherwise, the licensee must apply for a separate license that authorizes

the client's facility as a place of use. Refer to Appendix H for additional guidance on information to provide in applications.

Material Receipt and Accountability
To maintain accountability of licensed material, licensees must do the following:

- Secure licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material; and
- Conduct physical inventories at required frequencies to account for licensed material.

Licensed materials must be tracked from “cradle to grave” to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded.

Ordering and Receiving
4731.2350 contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by 4731.2290, must be considered for all receiving areas. Licensees are required to maintain records showing the receipt of radioactive material.

Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized.

Appendix I contains model procedures that are one method for ordering and receiving licensed material.

Sealed Source Inventory
MDH requires the licensee in possession of a sealed source to conduct a semi-annual physical inventory of all such sources in its possession.

According to 4731.4424, the licensee must conduct a semi-annual physical inventory of all sealed sources in its possession. Records of inventories must be retained for at least three years from the date of the inventory. The record should include:

- Model number of each source
- Serial number if one has been assigned
- Identity of each source radionuclide
- Estimated activity
- Location of each source
- Date of inventory
- Initials or name of individual performing the inventory

Operating and Emergency Procedures
This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document.

- Develop, implement, and maintain specific operating and emergency procedures containing the following elements:
    - Instructions for opening packages containing licensed material;
    - Using licensed material and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements;
    - Instructions for conducting area radiation level and contamination surveys;
    - Instructions for administering licensed material in accordance with the WD;
    - Steps to ensure appropriate release of patients;
    - Instructions for calibration of survey and dosage measuring instruments;

- Periodic spot checks of sources;
- Instructions for radioactive waste management;
- Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred:
  (a) leaking or damaged source,
  (b) device malfunction and/or damage,
  (c) licensed material spills,
  (d) theft or loss of licensed material, or
  (e) any other incidents involving licensed material;
- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s);

AND

The licensee should consider the following:

- Make operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of procedure storage);
- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).
- When developing the procedures described above, the licensee is reminded that, to the extent practical, the licensee must use procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.
- When receiving and using radioactive material, the licensee is reminded that it must be licensed to possess the radioactive material and that the radioactive material must be secured (or controlled) and accounted for at all times.

Some sealed sources and unsealed radioactive material can deliver significant doses in a short time; therefore, the licensee must control to high and very high radiation areas and ensure the security of licensed material. Unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Many licensees achieve access control by permitting only trained individuals to have access to licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

After its occurrence becomes known to the licensee, MDH must be notified when an incident involving licensed material occurs.

Spill Procedures

Before using licensed material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of licensed material. The radiation protection program that licensees are required to develop, document, and implement must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material.

Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, state and local authorities, and MDH, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, containment of spills and other releases, appropriate methods for reentering, and for decontaminating facilities (when necessary).

Provide the written procedures for safe response to spills of licensed material.

Appendix J provides model procedures that are one method for responding to some types of emergencies.

Leak Tests

MDH requires testing to determine if there is any radioactive leakage from sealed sources. Licensees must perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources in accordance with 4731.4424.

Appendix K provides model procedures that are one way to perform leak testing.

4731.4424 requires licensees to perform leak tests at six-month intervals or at other intervals approved by the NRC, MDH, or another Agreement State and specified in the SSDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past six months. 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 µCi) of radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

The leak test may be performed in-house or by a contractor who is authorized by MDH, the NRC or an Agreement State to perform leak tests as a service to other licensees. The licensee or contractor does not need to leak-test sources if:

- Sources contain only radioactive material with a half-life of less than 30 days;
- Sources contain only radioactive material as a gas;
- Sources contain 3.7 MBq (100 µCi) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 µCi) or less of alpha-emitting material;
- Sources contain Ir-192 seeds in nylon ribbon; or
- Sources are stored and not being used. The licensee, shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within six months before the date of use or transfer.

Minimization of Contamination

Applicants for new licenses must describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed radioactive material. Cleanup procedures should be implemented for contamination events.

Sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired, or disposed of according to MDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Safe Use of Unsealed Licensed Materials

Before using licensed material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed licensed material. The radiation protection program that licensees are required to develop, document, and implement must include provisions for safe use of licensed material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

In addition, licensees must develop, implement, and maintain procedures for protective measures to be taken by occupational workers to maintain their doses ALARA. Protective measures may include:

- Use of syringe shields and/or vial shields;
- Wearing laboratory coats and gloves when handling unsealed radioactive material; and
- Monitoring hands after handling unsealed radioactive material.

Appendix L contains model procedures that provide one method for safe use of unsealed licensed material.

Licensee must describe the procedures for safe use of unsealed radioactive material.

Opening Packages

Licensees must ensure that packages are opened safely and that the requirements of 4731.2350 are met. Licensees must retain records of package surveys in accordance with 4731.2510.

Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of 4731.2350 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA.

Appendix M contains model procedures that represent one method for safely opening packages containing radioactive materials.

Applicants are reminded that 4731.2350 requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within three hours of receipt if it is received during normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

Procedures for Administrations When A Written Directive Is Required

4731.4408 sets forth the requirements for written directives (WDs) and 4731.4409 requires medical use licensees to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

The procedures do not need to be submitted to MDH. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining MDH approval. Appendix N provides guidance on developing the procedures.

Transportation

Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with MDH and DOT regulations.

Most packages of licensed material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in 49 CFR 173.421 and are therefore excepted from certain DOT requirements, provided certain other less restrictive requirements are met (e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.5 mrem per hour (0.005 mSv per hour)).

The general license in 10 CFR 71.12, "General license: NRC-approved package," provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by MDH. This general license is subject to certain conditions. 71.5 establishes the requirements for transportation of licensed material. 10 CFR 71.9 exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under 10 CFR Part 35 or the equivalent Agreement State regulations from the requirements in 10 CFR 71.5. This exemption applies to transport by the physician of licensed material for use in the practice of medicine.

Some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with an MDH, NRC, or Agreement State license, who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with MDH and DOT regulations.

Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the licensed material.
- Actually takes possession of the licensed material under its license.

Licensees should also ensure that the manufacturer (or service licensee) is authorized to possess the material at temporary job sites (e.g., the licensee's facilities).

Appendix O lists major DOT regulations that apply to medical licensees.

Item 11: Waste Management

Licensed materials must be disposed of in accordance with MDH requirements by:

- Transfer to an authorized recipient (4731.3105 Subpart 2);
- Decay-in-storage;
- Release in effluents within the limits in 4731.2090; or
- As authorized under 4731.2010 through 4731.2440.

The radiation protection program that licensees are required to develop, document, and implement must include provisions for waste disposal of licensed material. Appendix P contains model procedures that represent one way to provide for decay-in-storage and generator or other licensed material return. Applicants are reminded to take into account the following information when they develop procedures (as applicable):

Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with 4731.2400 Subpart 2, 4731.2450, or in applicable rules in Chapter 4731. Licensees should follow the packaging instructions received from the transfer agent and the burial site operator. The consignment sheet from the transfer agent should be kept as the record of disposal.

- When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives

(e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- Waste from *in vitro* kits (except mock Iodine-125) that are generally licensed is exempt from waste disposal rules, as set forth in 4731.3245(f). Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.
- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under 4731.2095 and 4731.2420, respectively.
    - Regulations for disposal in the sanitary sewer appear in 4731.2420. Material must be readily soluble or dispersible in the water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis are not subject to these limitations.)
    - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in 4731.2750 Subpart 4. These limits apply at the boundary of the restricted area.
    - Liquid scintillation-counting media containing 1.85 KBq (0.05 µCi) per gram of H-3 or C-14 may be disposed of without regard to its radioactivity.
- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must comply with 4731.2430.
- Applicants that wish to use waste volume reduction operations (e.g., compactors) should provide a detailed description (as outlined below), along with their facility diagram:
    - A description of the compactor to demonstrate that it is designed to safely compact the waste generated (e.g., manufacturer's specifications, annotated sketches, photographs);
    - The types, quantities, and concentrations of the waste to be compacted;
    - An analysis of the potential for airborne release of radioactive material during
    - compaction activities;
    - The location of the compactors in the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors, and procedures for monitoring filter blockage and exchange;
    - Methods used to monitor worker breathing zones and/or exhaust systems;
    - The types and frequencies of surveys that will be performed for contamination control in the compactor area;
    - The instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling waste that has not been compacted, and examining containers for defects.

Provide a statement that verifies that written waste disposal procedures for licensed material has been developed, implemented and will be maintained.

Nuclear pacemakers

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases and when the licensee is not responsible for control or disposal of the pacemaker, notify MDH and attempt to contact the hospital where the pacemaker was implanted to arrange for removal. The licensee that implanted the device is responsible for the follow-up, removal, and return of the pacemaker to the manufacturer for proper disposal.

Item 12: License Fees

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

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

Item 13: Certification
Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

AMENDMENTS TO A LICENSE

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

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

Except for areas of use where radioactive material is used in accordance with 4731.4432 (unsealed radioactive material; uptake, dilution, and excretion studies) or 4731.4434 (unsealed radioactive material; imaging and localization studies), licensees are required to obtain a license amendment before adding to or changing an area of use identified in the application or on the license. Licensees are required to notify MDH within 30 days following changes in areas of use for radioactive material authorized in 4731.4432 or 4731.4434.

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

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

RENEWAL OF A LICENSE

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

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating MDH rules that do not allow you to possess licensable material without a valid license.

IMPLEMENTATION

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

INSPECTIONS

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

APPENDIX A
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

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

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.

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 hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
- 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

If the licensee has established a Radiation Safety Committee, the RSC duties should include the following:

- The RSC should thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- When considering the use of radioactive material, the RSC should review efforts of the applicant to maintain exposure ALARA.
- The RSC should ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- The RSC should delegate authority for enforcement of an ALARA program to the RSO.
- The RSC should support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it should record the basis for its action in the minutes of the quarterly meeting.
- The RSC should encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

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

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.

The RSO is also responsible for assisting the RSC in the performance of its duties.

Authorized Users Commitment

New methods of Use Involving Potential Radiation Doses

- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
- The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

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.

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

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

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

Model Procedure

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

- Stopping unsafe activities involving licensed material;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Training for personnel is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to MDH, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the radiation protection program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radioactive materials. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations.

You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and termination operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Minnesota Department of Health at any time.

It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Your signature below indicates acceptance of the above responsibilities.

_____	_____
Signature of Radiation Safety Officer	Signature of Management Representative
_____	_____
Date	Date

cc: Effected Department Heads

APPENDIX C
MODEL TRAINING PROGRAM

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen from for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and the state of learning (background knowledge) of the audience. These models also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and requires reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet MDH requirements. Guidance on requirements for training and experience for Authorized Medical Physicists and Authorized Users who engage in certain specialized practices is also included.

Model Training Program for Medical Uses of Radionuclides, Sealed Sources, And Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material. Records of worker training will be maintained for at least three years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved In the Usage of Radioactive Material

Training for professional staff (e.g., nurses, dosimetrists, technologists, and therapists) may contain the following elements for those who provide or are involved in the care of patients during diagnostic procedures in the following topics, *commensurate with their duties*:

- Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues;
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA (4731.2010);
- Risk estimates, including comparison with other health risks;
- Posting requirements (4731.2310);
- Proper use of personnel dosimetry (when applicable);
- Access control procedures (4731.2220 and 4731.2290);
- Proper use of radiation shielding, if used;
- Patient release procedures (4731.4427);
- Instruction in procedures for notification of the RSO and Authorized User, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care;
- Occupational dose limits and their significance (4731.2020);
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (4731.2080);
- Worker's right to be informed of occupational radiation exposure (4731.1030);
- Each individual's obligation to report unsafe conditions to the RSO (4731.1020);
- Applicable regulations, license conditions, information notices, bulletins, etc. (4731.1020);
- Where copies of the applicable regulations, the MDH license, and its application are posted or made available for examination (4731.1010);
- Proper recordkeeping required by MDH regulations (4731.1020);
- Appropriate surveys to be conducted (4731.1500);
- Proper calibration of required survey instruments (4731.2200);
- Emergency procedures;

- Decontamination and release of facilities and equipment (4731.2150 and 4731.3085);
- Dose to individual members of the public (4731.2090); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (4731.4407).

Training for Staff Directly Involved In Administration Or To Care Of Patients Administered Radioactive Material For Which A Written Directive Is Required

In addition to the topics identified above, the following topics may be included in instruction for staff involved with patients (e.g., the RSO and nursing staff) in the following topics, *commensurate with their duties*:

- Leak testing of sealed sources (4731.4424);
- Emergency procedures (including emergency response drills) (4731.4441);
- Operating instructions (4731.4407);
- Detailed pretreatment quality assurance checks (4731.4407);
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (4731.4441, 4731.4453);
- Patient control procedures (4731.4441);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (4731.4441);
- Licensee's Written Directive Procedures, to ensure that each administration is in accordance with the Written Directive, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (4731.4409);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (4731.4441);
- Size and appearance of different types of sources and applicators (4731.4441);
- Previous incidents, events, and/or accidents; and

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security and life-safety services. The training program for ancillary staff that performs duties that are likely to result in a dose in excess of 1 mSv (100 mrem) will include instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Topics of instruction may include the following:

- Storage, transfer, or use of radiation and/or radioactive material (4731.1020);
- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding)
- The applicable provisions of MDH regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (4731.1020);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of MDH regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues);
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material;
- Radiation exposure reports that workers may request, as per 4731.1030.

APPENDIX D
MODEL ANNUAL AUDIT CHECKLIST

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities and activities that have not occurred since the last audit need not be reviewed at the next audit.

Audit History	**4731**	**N/A**	**Yes**	**No**
Were previous audits conducted annually?	2010	☐	☐	☐
Are records of previous audits maintained?	2500	☐	☐	☐
Deficiencies identified?		☐	☐	☐
Were the deficiencies corrected?		☐	☐	☐

Organization and Scope of Program	**4731**	**N/A**	**Yes**	**No**
Radiation Safety Officer		☐	☐	☐
1. If the RSO was changed, was license amended?	4403	☐	☐	☐
2. Does new RSO meet MDH training requirements?	4411 4414 4415	☐	☐	☐
3. Is RSO fulfilling all duties?	4405	☐	☐	☐
4. Is the written agreement in place for a new RSO?	4405	☐	☐	☐
Are there multiple locations of use?		☐	☐	☐
Are all locations listed on the license?		☐	☐	☐
If multiple locations authorized, list locations audited.				
Were annual audits performed at each location? If no, explain.		☐	☐	☐

Licensed Material	**4731**	**N/A**	**Yes**	**No**
Isotope, chemical form, quantity and use as authorized?		☐	☐	☐
Does total amount of radioactive material possessed require financial assurance?	3080	☐	☐	☐
If so, is financial assurance adequate?		☐	☐	☐
Calibration, transmission, and reference sources				
Sealed sources manufactured and distributed by a person licensed pursuant to 4731.3400 or equivalent NRC or Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources and sources do not exceed 30 millicuries?	4423	☐	☐	☐
Any radioactive material with a half life of less than 120 days in individual amounts not to exceed 15 millicuries?	4423	☐	☐	☐
Any radioactive material with a half life of greater than 120 days in individual amounts not to exceed 200 microcuries or 1000 times the quantities in 4731.3260?	4423	☐	☐	☐
Technetium-99^m in individual amounts as needed?	4423	☐	☐	☐
Unsealed materials used in 4731.4432, 4731.4434, and 4731.4440 are:		☐	☐	☐
Obtained from a manufacturer or preparer licensed under 4731.3395? or		☐	☐	☐

Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of a physician authorized user or authorized nuclear pharmacist? or		☐	☐	☐
Obtained and prepared for research in accordance with 4731.4432, 4731.4434, and 4731.4440, as applicable?		☐	☐	☐
Are sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate?	4460	☐	☐	☐
Are copies of the SSDR Certificates possessed or accessible?		☐	☐	☐
Are manufacturer's manuals for operation of medical devices possessed?		☐	☐	☐
Are the actual uses of the medical devices consistent with the authorized uses listed on the license?		☐	☐	☐
If places of use changed, was the license amended?		☐	☐	☐
If control of license was transferred, was MDH consent obtained prior to the transfer?		☐	☐	☐
Radiation Safety Program	**4731**	**N/A**	**Yes**	**No**
Minor changes to program?	4405	☐	☐	☐
Records of changes maintained for five years?	4500	☐	☐	☐
Content and implementation reviewed annually by the licensee?	2020	☐	☐	☐
Records of reviews maintained?		☐	☐	☐
Use by Authorized Individuals	**4731**	**N/A**	**Yes**	**No**
Authorized User	4414			
Certified by specialty board	4415	☐	☐	☐
Identified on MDH, NRC or other Agreement State License	4433	☐	☐	☐
Identified on permit issued by a broad scope or NRC master materials license	4436	☐	☐	☐
Listed on a facility license	4443 4444 4461	☐	☐	☐
Training, Retraining, and Instruction to Workers	**4731**	**N/A**	**Yes**	**No**
Have workers been provided with required instructions?	1020 4407 4441 4453 4466	☐	☐	☐
Is the individual's understanding of current procedures and regulations adequate?		☐	☐	☐
Training program implemented?		☐	☐	☐
Operating procedures?	4407	☐	☐	☐
Emergency procedures?	4441	☐	☐	☐
Periodic training required and implemented?		☐	☐	☐
Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed?	1020	☐	☐	☐
Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate?	4407	☐	☐	☐
Are initial and periodic training records maintained for each individual?	4510	☐	☐	☐
Workers cognizant of requirements for:				
Radiation Safety Program?	2010 4405	☐	☐	☐
Annual dose limits?	2020 2090 2095	☐	☐	☐

10% monitoring threshold?	2210	☐	☐	☐
Dose limits to embryo/fetus and declared pregnant worker?	2080	☐	☐	☐
Grave danger posting?	2310			
Procedures for opening packages?	2350	☐	☐	☐
Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with 4731.4407?		☐	☐	☐
Facilities	**4731**	**N/A**	**Yes**	**No**
Facilities are as described in the license application?		☐	☐	☐
Storage areas:				
Materials secured from unauthorized removal or access?	2290	☐	☐	☐
Licensee controls and maintains constant surveillance of licensed material not in storage?	2290	☐	☐	☐
Dose Calibrator:		☐	☐	☐
Constancy checked?		☐	☐	☐
Linearity tested quarterly?		☐	☐	☐
Accuracy tested annually?		☐	☐	☐
Geometry dependence test?		☐	☐	☐
Readings mathematically corrected if linearity error is greater than 10%?		☐	☐	☐
Records maintained and include required information?	4502	☐	☐	☐
Determination of dosages of unsealed radioactive material:				
Each dosage determined and recorded prior to medical use?	4422	☐	☐	☐
Measurement of unit dosages made by direct measurement or by decay correction?		☐	☐	☐
For other than unit dosages, dose determined by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation?		☐	☐	☐
Licensee uses generators?		☐	☐	☐
First eluate after receipt is tested for Molybdenum-99 breakthrough?	4509	☐	☐	☐
No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 µCi per mCi of Tc-99^m?		☐	☐	☐
Records maintained?		☐	☐	☐
Radiation Protection And Control Of Radioactive Material	**4731**	**N/A**	**Yes**	**No**
Use of radiopharmaceuticals				
Protective clothing worn?		☐	☐	☐
Personnel routinely monitor their hands?		☐	☐	☐
No eating/drinking in use/storage areas?		☐	☐	☐
No food, drink, or personal effects kept in use/storage areas?		☐	☐	☐
Proper dosimetry worn?		☐	☐	☐
Radioactive waste disposed of in proper receptacles?		☐	☐	☐
Syringe shields and vial shields used?		☐	☐	☐
Radiation Survey Instruments	**4731**	**N/A**	**Yes**	**No**
Appropriate, operable survey instruments possessed or available?	4421	☐	☐	☐
Calibrations completed before first use?		☐	☐	☐
Instrument calibrated annually (intervals not to exceed 12 months)?		☐	☐	☐
Calibrations within 20 percent on each scale or decade of interest?		☐	☐	☐
Calibration records maintained?		☐	☐	☐

Area Surveys	**4731**	**N/A**	**Yes**	**No**
Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements?	2200 4426	☐	☐	☐
Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms)?	4426	☐	☐	☐
Weekly in all areas where radiopharmaceuticals or waste is stored?		☐	☐	☐
Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?		☐	☐	☐
Trigger levels established?		☐	☐	☐
Corrective action taken and documented if trigger level exceeded?		☐	☐	☐
Techniques can detect 0.1 mR/hr, 2000dpm?		☐	☐	☐
Leak Tests	**4731**	**N/A**	**Yes**	**No**
Was each Sealed Source leak tested every six months or at prescribed intervals?		☐	☐	☐
Were leak teats performed according to the license?		☐	☐	☐
Records maintained?		☐	☐	☐
MDH notified of any leaking sources?		☐	☐	☐
Sealed Source Inventory	**4731**	**N/A**	**Yes**	**No**
Records of receipt for sources maintained?		☐	☐	☐
Sealed sources physically inventoried at intervals not to exceed six months?		☐	☐	☐
Records of inventories retained?		☐	☐	☐
Public Dose	**4731**	**N/A**	**Yes**	**No**
Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year?	2090	☐	☐	☐
Has a survey or evaluation been performed?	2200	☐	☐	☐
Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?		☐	☐	☐
Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour?	2090	☐	☐	☐
Is licensed material used or stored in a manner that would prevent unauthorized access or removal?	2290	☐	☐	☐
Records maintained?		☐	☐	☐
Patient Release	**4731**	**N/A**	**Yes**	**No**
Individuals released when TEDE less than 0.5 rem?	4427	☐	☐	☐
Instructions to the released individual, including breast-feeding women, include required information?		☐	☐	☐
Release records maintained?		☐	☐	☐
Records of instructions given to breast-feeding women maintained, if required?		☐	☐	☐
Unsealed Radioactive Material For Which A Written Directive Is Required	**4731**	**N/A**	**Yes**	**No**
Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls?	4442	☐	☐	☐
RSO and Authorized User promptly notified if patient died or had a medical emergency?		☐	☐	☐

Radioactive Waste	**4731**	**N/A**	**Yes**	**No**
Disposal:		☐	☐	☐
Decay-in-storage	4429	☐	☐	☐
Procedures followed?		☐	☐	☐
Labels removed or defaced?	2330 4429	☐	☐	☐
Special procedures performed as required?		☐	☐	☐
Authorized disposals?	2400	☐	☐	☐
Records maintained?	2510 2560	☐	☐	☐
Effluents:		☐	☐	☐
Release to sanitary sewer?	2420	☐	☐	☐
Material is readily soluble or readily dispersible?	2420	☐	☐	☐
Monthly average release concentrations do not exceed 2750 Subpart 4?		☐	☐	☐
No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year?	2420	☐	☐	☐
Procedures to ensure representative sampling and analysis implemented?	2200	☐	☐	☐
Release to septic tanks? (Note: Release to septic tanks is not authorized.)		☐	☐	☐
Waste incinerated?		☐	☐	☐
License authorizes?	2430	☐	☐	☐
Directly monitor exhaust?		☐	☐	☐
Airborne releases evaluated and controlled?	2095 2200	☐	☐	☐
Air effluents and ashes controlled?	2010 2020 2090 2200 2400	☐	☐	☐
Air effluent less than 10 mrem constraint limit?	2010	☐	☐	☐
If no, reported appropriate information to MDH.		☐	☐	☐
Corrective actions implemented and on schedule?		☐	☐	☐
Description of effluent program:		☐	☐	☐
Monitoring system hardware adequate?		☐	☐	☐
Equipment calibrated, as appropriate?		☐	☐	☐
Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?		☐	☐	☐
Waste storage		☐	☐	☐
Protection from elements and fire?		☐	☐	☐
Control of waste maintained?	2290	☐	☐	☐
Containers properly labeled and area properly posted?	2310 2320	☐	☐	☐
Package integrity adequately maintained?		☐	☐	☐
Waste disposal:		☐	☐	☐
Sources transferred to authorized individuals?	2400 2450 3105	☐	☐	☐
Name of organization:				
Records of surveys and material accountability are maintained?	2510 2560	☐	☐	☐

Receipt And Transfer of Radioactive Material	**4731**	**N/A**	**Yes**	**No**
Describe how packages are received and by whom.		☐	☐	☐
Written package opening procedures established and followed?	2350	☐	☐	☐
All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form)?		☐	☐	☐
Incoming packages surveyed?		☐	☐	☐
Monitoring in (C) and (D) performed within time specified?		☐	☐	☐
Transfer(s) performed per?	3105	☐	☐	☐
All sources surveyed before shipment and transfer?	2200	☐	☐	☐
Records of surveys and receipt/transfer maintained?	2510 3115	☐	☐	☐
Package receipt/distribution activities evaluated for compliance with 4731.2090?		☐	☐	☐
Transportation (10 CFR 71.5(a) and 49 CFR 171-189)	**4731**	**N/A**	**Yes**	**No**
Shipments are:		☐	☐	☐
delivered to common carriers;		☐	☐	☐
transported in own private vehicle;		☐	☐	☐
both;		☐	☐	☐
no shipments since last audit.		☐	☐	☐
Return radiopharmacy doses or sealed sources?		☐	☐	☐
Licensee assumes shipping responsibility?		☐	☐	☐
NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:		☐	☐	☐
Packages:		☐	☐	☐
Authorized packages used?		☐	☐	☐
Performance test records on file?		☐	☐	☐
DOT-7A packages		☐	☐	☐
Special form sources		☐	☐	☐
Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class?		☐	☐	☐
Properly marked (Shipping Name, UN Number, Package Type, RQ, “This End Up” (liquids), Name and Address of consignee)?		☐	☐	☐
Closed and sealed during transport?		☐	☐	☐
Shipping Papers:		☐	☐	☐
Prepared and used?		☐	☐	☐
Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper’s Name, Certification and Signature, Emergency Response Phone Number, “Limited Quantity” (if applicable), “Cargo Aircraft Only” (if applicable)?		☐	☐	☐
Readily accessible during transport?		☐	☐	☐
Personnel Radiation Protection	**4731**	**N/A**	**Yes**	**No**
Exposure evaluation performed?	2200	☐	☐	☐
ALARA program implemented?	2010	☐	☐	☐
External Dosimetry:				
Monitors workers per 4731.2210?		☐	☐	☐
External exposures account for contributions from airborne activity?	2040	☐	☐	☐
Supplier Frequency		☐	☐	☐

Supplier is NVLAP-approved?	2200	☐	☐	☐
Dosimeters exchanged at required frequency?		☐	☐	☐
Internal Dosimetry				
Monitors workers per 4731.2210?		☐	☐	☐
Briefly describe program for monitoring and controlling internal exposures?	2240	☐	☐	☐
Monitoring/controlling program implemented (includes bioassays)?		☐	☐	☐
Respiratory protection equipment?		☐	☐	☐
Review of Records and Reports				
Reviewed by Frequency		☐	☐	☐
Auditor reviewed personnel monitoring records for period to _____		☐	☐	☐
Prior dose determined for individuals likely to receive doses?	2520	☐	☐	☐
Maximum exposures TEDE Other		☐	☐	☐
Maximum CDEs Organs		☐	☐	☐
Maximum CEDE		☐	☐	☐
Internal and external summed?	2030	☐	☐	☐
Were occupational limits met?	2020	☐	☐	☐
MDH Form 5 or equivalent provided to all monitored employees?	2520 2540	☐	☐	☐
If a worker declared her pregnancy during the audit period, then was the dose in compliance and were the records maintained?	2030 2540	☐	☐	☐
Who performed any planned special exposures at this facility (number of people involved and doses received)?	2060 2520 2530 2630	☐	☐	☐
Records of exposures, surveys, monitoring, and evaluations maintained?	2500 2510 2540	☐	☐	☐
Confirmatory Measurements	**4731**	**N/A**	**Yes**	**No**
Detail location and results of confirmatory measurements.		☐	☐	☐
Medical Events	**4731**	**N/A**	**Yes**	**No**
If medical events have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.	4525	☐	☐	☐
Event date		☐	☐	☐
Information Source		☐	☐	☐
Notifications		☐	☐	☐
MDH		☐	☐	☐
Referring Physician Patient		☐	☐	☐
In writing/By telephone		☐	☐	☐
If notification did not occur, why not?		☐	☐	☐
Written Reports Submitted to MDH within 15 days?	4525	☐	☐	☐
Notification and Reports	**4731**	**N/A**	**Yes**	**No**
In compliance with 4731.1030, 4731.3110 (reports to individuals, public and occupational, monitored to show compliance)?		☐	☐	☐
In compliance with 4731.2600, 4731.3110 (theft or loss)?		☐	☐	☐
In compliance with 4731.2610, 4731.3110 (incidents)?		☐	☐	☐

In compliance with 4731.2620, 4731.3110 (overexposures and high radiation levels)?		☐	☐	☐
Aware of MDH phone number?		☐	☐	☐
In compliance with 4731.2620 (Constraint on air emissions)?		☐	☐	☐
Posting and Labeling	**4731**	**N/A**	**Yes**	**No**
MDH Form, "Notice to Workers" is posted [19.11]?	1010	☐	☐	☐
Other posting and labeling per 4731.2310, 4731.2330 and not exempted by 4731.2320, 4731.2340?		☐	☐	☐
Recordkeeping for Decommissioning	**4731**	**N/A**	**Yes**	**No**
Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination?	3080	☐	☐	☐
Records include all information outlined in?	3080	☐	☐	☐
Mobile Medical Service	**4731**	**N/A**	**Yes**	**No**
Operates services per 4731.4428 and 4731.4475?				
Compliance with 4731.2090 evaluated and met?				
Letter signed by management of each client?	4428			
Licensed material was not delivered to client's address (unless client was authorized)?	4428			
Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent?	4428			
Survey instruments checked for proper operation before used at each address of use?	4428			
Survey of all areas of use prior to leaving each client address?	4428			
Amendments Since Last Audit	**4731**	**N/A**	**Yes**	**No**
Any Amendments since last audit?	4403			
Notifications Since Last Audit	**4731**	**N/A**	**Yes**	**No**
Any Notifications since last audit?	4403			
Appropriate documentation provided to MDH for authorized nuclear pharmacist, authorized medical physicists, or authorized user no later than 30 days after the individual starts work?	**4403**			
MDH notified within 30 days after any of the following stops work or changes name:				
Authorized User;				
Radiation Safety Officer (RSO)				
MDH notified within 30 days after:				
licensee's mailing address changes;				
licensee's name changes without a transfer of control of the license; or				
licensee has added to or changed an area of use for 4731.4432 or 4731.4434 use?				

Bulletins and Information Notices	**4731**	**N/A**	**Yes**	**No**
Bulletins, Information Notices, etc., received?		☐	☐	☐
Appropriate action in response to Bulletins, Information Notices, Generic Letters, etc.?		☐	☐	☐

Special License Conditions or Issues	**4731**	**N/A**	**Yes**	**No**
Special license conditions or issues to be reviewed:				
Evaluation:				

Audits and Findings	
Summary of findings:	
Corrective and preventive actions:	
Audit conducted by: _____	Date: _____

APPENDIX E
AREA SURVEYS

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

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

MODEL PROCEDURE

This model provides acceptable procedures for area surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 4731.2020, 4731.2200, 4731.4426. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

Radiation Dose Rate Surveys
Perform surveys of dose rates 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
- an individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).

4731.2090 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Appropriate surveys will be conducted to assure that the requirements of 4731.2090 are met.

Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:

- Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas when using radiopharmaceuticals requiring a written directive.
- Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 µCi at a time).
- Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99^m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- Survey quarterly all sealed source storage areas.

If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted and unrestricted areas are presented in the following table.

AREA SURVEYED TRIGGER LEVEL		
Type of Survey	Ambient Dose Rate	Trigger Levels
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, 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 are performed in areas where unsealed forms of materials are used:

- 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 contamination of users and the immediate work area, at the end of the day, when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly;
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables R.2 for restricted areas and R.3 for unrestricted areas (e.g., 200 dpm/100 cm2 for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:

- Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (i.e., bone scan injections, Tc-99^m heart agents, etc.), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
- Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcuries at a time).
- Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.

A radioactive source with a known amount of activity should be used to convert sample measurements, which are usually in counts per minute (cpm), to dpm.

The area should be decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted areas are presented in the following table.

Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

SURFACE CONTAMINATION LEVELS IN RESTRICTED AREAS (DPM/100 CM^2)							
Area, clothing	P-32 Se-75 I-123 Yb-169	Co-58 Sr-85 I-125 Lu-77	Fe-59 Y-90 I-131 Au-198	Co-60 In-111 Sm-153	Cr-51 Tc-99^m	Co-57 Hg-197	Ga-67 Tl-201
Restricted areas, protective clothing used only in restricted areas	2,000				20,000		

SURFACE CONTAMINATION LEVELS IN UNRESTRICTED AREAS (DPM/100 CM^2)			
Nuclide[1]	Average[2,3,6]	Maximum[2,4,6]	Removable[2,5,6]
I-125, I-126, I-131, I-133, Sr-90	1,000	3,000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000	15,000	1,000

1 Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

2 As used in this table, dpm 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.

3 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.

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

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

6 The average and maximum radiation levels associated with surface contamination resulting from beta/gamma emitters should not exceed 0.2 mR/hour at one centimeter and 1.0 mR/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Contents of Survey Records

- A diagram of the area surveyed;
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe tests were 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.

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

APPENDIX F
RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND MODEL SURVEY INSTRUMENT CALIBRATION PROGRAM

Model procedures for describing the specifications for monitoring instruments appear below. Applicants may either adopt these model procedures or adopt alternative procedures. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for Radiation Monitoring Instruments and the Instrument Calibration Program that was published in Appendix F to the MDH Regulatory Guide for Diagnostic Medical Procedures."

If you develop your own guidelines for review, you should consider for inclusion all the features in the model and carefully review the requirements of the Minnesota Rules. State on your application, "We have developed a procedure for Radiation Monitoring Instruments and the Instrument Calibration Program for your review that is appended as Appendix F," and submit your procedure.

Equipment Selection

Low-energy beta emitters, such as Carbon-14 and Sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2 percent for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.

Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15 to 40 percent, depending on the beta energy.

Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.

Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.

The following table (except for items marked with an asterisk (*), extracted from “The Health Physics & Radiological Health Handbook,” Revised Edition, 1992, may be helpful in selecting instruments:

TYPICAL SURVEY INSTRUMENTS			
Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma X-ray	mR-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
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma	All energies	Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Model Procedure for Calibrating Survey Instruments
This model provides acceptable procedures for survey instrument calibrations. You may either adopt these model procedures or develop your own procedures to meet MDH requirements.

Procedures for calibration of survey instruments:

- Radiation survey instruments will be calibrated with a radioactive source in accordance with 10 CFR 35.61. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually, before first use and after servicing or repairs which affect calibration. (Battery changes are not considered “servicing.”) Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured. An ideal calibration source would emit the applicable radiation (e.g., alpha, beta, or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.
- Use radioactive sealed source(s) that:
    - Approximates a point source;
    - Is certified, NIST-traceable, standard source that has an activity or exposure rate accurate to within 5 percent; if the activity or exposure rate is determined by measurement, document the method used to make the determination and traceability to NIST;

    - Emit the type of radiation measured;
    - Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed; and
    - Provide a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- Use the inverse square and radioactive decay laws, as appropriate, to correct for changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 35.2061).
- Before use, perform daily check (with a dedicated check source) and battery checks.
- Instrument readings should be within ± 10 percent of known radiation values at calibration points; however, readings within ± 20 percent are acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters should be calibrated as follows:
    - Calibrate Linear-Readout Instruments at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20percent and 80percent).
    - Calibrate Logarithmic-Readout Instruments at two points on each decade.
    - Calibrate Digital-Readout Instruments with either manual or automatic scale switching for indicating exposure rates at no fewer than two points on each scale. Check calibrations near the ends of each scale (at approximately 20percent and 80percent of each scale).
    - Calibrate Digital-Readout Instruments without scale switching for indicating exposure rates at two points on each decade.
    - Calibrate Integrating instruments at two dose rates (at approximately 20percent and 80percent of the dose rate range).
- Readings above 1000 mR/hr (250 micro-coulomb/kilogram of air per hour) need not be calibrated; however, such scales may be checked for operation and approximately correct response.
- Include in survey meter calibration records the procedure used and the data obtained. Record the following:
    - A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
    - A description of the NIST-traceable calibration source, including the calibration procedure, exposure rate, distance at which is was measured and date of measurement;
    - For each calibration point, the calculated exposure rate, the indicated exposure rate, the calculated correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
    - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument);
    - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
    - For instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument;
    - For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
    - The exposure rate from a check source, if used;
    - The name of the person who performed the calibration and the date it was performed.
- The following information should be attached to the instrument as a calibration sticker or tag:
    - The source that was used to calibrate the instrument;
    - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
    - Special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated);
    - The date of calibration and the next calibration due date;
    - The apparent exposure rate from the check source, if used.

Determining the Efficiency of NaI(Tl) Uptake Probes
Sodium iodide (thallium doped) [NaI(Tl)] uptake probes are commonly used for bioassays of personnel administering I-131 radionuclides in the form of sodium iodide. Refer to 4731.2750 for the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) for occupational exposure to radionuclides. Convert count rates (e.g., in cpm) to units of activity (dpm, µCi) when performing bioassays to determine thyroid burdens of radio-iodine. Use the following procedure to calibrate probe for uptake measurements:

- Frequency: perform calibrations annually, before first use and after repairs that affect calibrations;
- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5 percent of the stated value and traceable to a primary radiation standard such as those maintained by NIST.

Calculate efficiency of the instrument. For example:

$$\textit{Efficiency}^{1} = \frac{\textit{[(counts per minute from standard) – (counts per minute from background)]}}{\textit{(activity of standard in microcurie)}}$$

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due;
- Results of efficiency calculation(s).

Calculating the Gamma Well Efficiency of Counting Equipment
Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed radioactive material is prepared, administered, or stored. Converting counts per minute (cpm) to disintegrations per minute (dpm) using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5 percent of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument. For example,

$$\textit{Efficiency} = \frac{\textit{[(counts per minute from standard) – (counts per minute from background)]}}{\textit{(activity of standard in microcurie)}}$$

Where *Efficiency* is in cpm / microcurie,

[1] The absolute efficiency is dependent on the counting geometry. Applicants may elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and has much less of a dependence on the counting geometry.

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due and
- Results of efficiency calculation(s).

Model Procedure for Calibrating Dose Calibrators

Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of ±5 percent may be more restrictive than the manufacturer's recommendation, however, the limit is suggested to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

Constancy

Constancy means reproducibility in measuring a source over a long period. Constancy tests should be completed daily prior to use on days when radiopharmaceutical dosages are administered. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.

3. Plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

5. Establish an action level at which the individual performing the test will automatically notify the supervision of the suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds ±10 percent.

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

Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99^{m} whose activity is at least as large as the maximum activity normally assayed. Linearity should be tested quarterly.

Decay Method

a. Assay the Tc-99^{m} syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time (to the nearest minute), and net activity. This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity used. For dose calibrators with a range selection switch, select the range you would normally use for the measurement.

c. Convert the recorded time and date to hours elapsed.

d. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.

e. Draw a best-fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

Shield Method

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

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

Geometry Independence

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

1. In a small beaker or vial, mix 2.0 cc of a solution of Tc-99^{m} with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.

2. Draw 0.5 cc of the Tc-99^{m} solution into the syringes and assay. Record the column and millicuries.

3. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

4. Repeat the process until you have assayed a 2.0 - cc volume.

5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.

6. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent

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

7. To test the geometry dependence of a 30-cc glass vial, draw 1.0 cc of the Tc-99^{m} solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

8. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries indicated.

9. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

10. Select as a standard the volume closest to that normally used for mixing radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.

11. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure to label the table or graph, note the date of the test, and indicate the model number and serial number of the calibrator.

Accuracy

Accuracy means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier. Accuracy tests should be completed at intervals not to exceed one year. The supplier must compare that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. Consider using at least one reference source whose activity is within the range of activities normally assayed.

1. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for three determinations.

2. Average the three determinations. The average value should be within five (5) percent of the certified activity of the reference source, mathematically corrected for decay.

3. Repeat the procedure for other calibrated reference sources.

4. If the average value does not agree, within five (5) percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

5. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values.

APPENDIX G
MODEL PROCEDURE FOR AN OCCUPATIONAL DOSE MONITORING PROGRAM

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

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

“Dosimetry” is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of 4731.2210. 4731.2020 provides the occupational dose limits for adults. Adults likely to receive in one year a dose in excess of 10 percent of those dose limits must be provided with dosimetry. If monitoring is required, each licensee shall maintain records of doses received and individuals must be informed on at least an annual basis of their doses.

If an individual is likely to receive more than 10 percent of the annual dose limits, MDH requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his/her dose.

The As Low As Reasonably Achievable “ALARA” Program

4731.2020 states that “each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities…” and, “the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).” Additionally, licensees are required to periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels. Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in 4731.2020 that apply to external exposure: deep dose to the whole body (5 rem or 0.05 Sv), shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). The (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm2), and eye dose equivalent at 0.3 cm (300 mg/cm2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

4731.2210 requires the use of individual monitoring devices for the following:

- Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in 4731.2020. Monitoring devices are accordingly required for adults with an annual dose in excess of
    - 0.5 rem (0.005 Sv) DDE
    - 1.5 rem (0.015 Sv) eye dose equivalent

    - 5 rem (0.05 Sv) shallow-dose equivalent to the skin
    - 5 rem (0.05 Sv) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of
    - rem (1.0 mSv) DDE
    - 0.15 rem (1.5 mSv) eye dose equivalent
    - 0.5 rem (5 mSv) shallow-dose equivalent to the skin
    - 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.
- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.
- Individuals entering a high or a very high radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, MDH does not require licensees to monitor radiation doses for this class of worker. The following methods may be used to demonstrate that doses are expected to be within 10% of regulatory limits:

- Prior Experience: Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;
- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable 'accident' scenarios should also be evaluated);
- The licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters (OSLs), or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP) approved, as required by 4731.2200.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose must be placed near the location expected to receive the highest dose during the year. When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso. If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

4731.2540 requires that the recording for individual monitoring be done on MDH Form 5 or equivalent. MDH Form 5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees should be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

In order to demonstrate compliance with occupational dose limits, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record, if an individual's dosimeter is lost. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

The investigational levels in this program are not new dose limits. As noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in the following table (i.e., 10 percent of the annual limit for occupational exposure), the Radiation Safety Officer or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in Table 1 (i.e., 30 percent of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Investigational Levels		
	Investigational Levels (mrem per year)	
	Level I	Level II
whole body; head and trunk; arms above the elbows; legs above the knee; active blood-forming organs; or gonads	500 (5 mSv)	1500 (15 mSv)
Skin of whole body, extremities	5,000 (50 mSv)	15,000 (150 mSv)
Lens of eye	1,500 (15 mSv)	4,500 (45 mSv)

The results of personnel monitoring should be review and recorded. The actions listed below should be taken when the investigation levels in Table 1are reached:

- Personnel dose less than Investigational Level I.

  Except when deemed appropriate by the RSO or the RSO's designee, no further action must be taken if an individual's dose is less than Table 1 values for Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

  When the dose of an individual whose dose equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO or the RSO's designee. Factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks should be considered to determine if improvements additional safety measures are needed to reduce exposures. The results of investigations and evaluations should be documented.

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

  The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. Actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

- Re-establishment of Investigational Level II to a level above that listed in Table 1.

Declared Pregnancy and Dose to Embryo/Fetus

4731.2080 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:

- The deep-dose equivalent to the declared pregnant woman; and
- The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

Internal Exposure

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in one year.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The derived air concentration (DAC) for each class of radionuclide is the concentration of airborne radioactivity in µCi/ml that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in 4731.2750.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The ALI and DAC numbers reflect the

doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (WT), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." When an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

- adequate equipment to perform bioassay measurements,
- procedures for calibrating the equipment, including factors necessary to convert counts per minute into Becquerel or microcurie units,
- the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
- the interval between bioassays,
- action levels, and
- the actions to be taken at those levels.

Controlling Air Concentrations and Worker Doses from Noble Gases

Noble gases such as xenon in the air present could contribute to a worker's exposure. To ensure that the doses to workers from gases are minimized, licensees should:

- administer gases in an area that has negative ventilation;
- check the area's negative ventilation flow rate every six months or when changes are made to the area's ventilation systems; and
- collect the spent gases in a shielded trap and monitor the trap regularly. (Licensees do not have to monitor the trap effluent of single-use devices.)

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

- If the trap effluent is continuously monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions. Keep a record of the checks.
- If the trap effluent is not continuously monitored, check the trap upon receipt and once each month. Keep a record of the date, background radiation level, and trap radiation level. If there is a significant increase in the measured activity, the trap must be replaced.

Summation of External and Internal Doses

Pursuant to 4731.2030, the external and internal doses must be summed if the licensee is required to monitor both under 4731.2210.

APPENDIX H
MOBILE MEDICAL SERVICES

Mobile medical service providers must comply with all applicable sections of Chapter 4731 as well as DOT regulations with regard to approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training.

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of radioactive material within a transport vehicle (e.g., in-van use). A second type is transportation of radioactive material to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use).

Licensed activities must be conducted in accordance with the regulations for compliance with 4731.4428, which states that the licensee will obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of radioactive material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for three years after the last provision of service. Additionally, the licensee must survey to ensure compliance with the requirements in 4731.1000 through 4731.2950 (e.g., ensure that all radioactive material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed) before leaving a client's address.

The locations of use for mobile medical services are of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. The following two sections describe the type of information necessary for base locations and temporary job sites.

Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location) for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility, or mobile van. Applicants should specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a non-licensed private practice located within a licensed medical institution (e.g., hospital).

Applicants must submit a description and diagram(s) of the proposed base facility and associated equipment. The description and diagram of the proposed facility should demonstrate that the building (or van) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 4731.2090. Submit a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within a van, the description of the van should address radiation levels in the van driver's compartment to demonstrate compliance with 4731.2020, "Occupational dose limits for adults."

- Multiple base locations may be requested. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile van. When the base facility is in the van, and there is no permanent structure for the radioactive material storage, provide for the following:
    - Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;

    - Secured storage facilities available for storage of radioactive material and radioactive waste if the van is disabled; and
    - Radioactive material delivered (if necessary) directly to the van only if the licensee's staff occupies the van at the time of delivery.
- If a base facility is located in a residential area, provide the following information:
    - Justification of the need for a private residence location rather than for a commercial location.
    - Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service van, etc., on the client property (if necessary) must be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.
    - A description of the program demonstrating compliance with 4731.2090, "Dose limits for individual members of the public."
    - Verification that restricted areas do not contain residential quarters.
- Perform surveys necessary to show that exposure rates do not exceed 2 mrem in any one hour nor 100 mrem per year.

Client Site

For all types of uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed. For self-contained radioactive material services (e.g., in-van), applicants should provide the following additional facility information:

- For mobile services that create radiation areas outside the van, a separate drawing for each client site showing the location of the vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;
- A signed agreement, as delineated in the letter required by 4731.4428, that location of the device/vehicle will be on client-owned or controlled property;
- The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.

If transportable services to the client's site for use within the client's facility by the mobile medical service's employees will be provided, applicants should provide the following client facility information and commitment:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 4731.2090. Applicants should include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.
- A commitment, as delineated in the letter required by 4731.4428, that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.

Supervision

In addition to the requirements in 4731.1020, 4731.4407 requires that applicants will instruct supervised individuals in applicant's written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of radioactive material. Additionally, licensees must require the supervised individual to:

- Follow the instructions of the supervising authorized user for medical uses of radioactive material;
- Follow the instructions of the supervising authorized nuclear pharmacists or supervising authorized user for preparation of radioactive material for medical uses;
- Follow the written radiation protection procedures and written directive procedures established by the licensee; and
- Comply with the applicable provisions of MDH rules and the license conditions with respect to the mobile medical use of radioactive material.

Training for Individuals Working In or Frequenting Restricted Areas

Drivers and technologists will be properly trained in applicable transportation regulations and emergency procedures in addition to the applicable training requirements of 4731.1020, 4731.4407, 4731.4441, 4731.4453, and 4731.4466. The training for these individuals will include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

Instruments must be checked for proper operation before use at each address of use. Dosage measurement instruments must be checked before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Radioactive Material

Radioactive material must be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of radioactive material ordered. Alternatively, applicants may pick up the radioactive material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities. Delivery of radioactive material to a van that is not occupied by the mobile medical service personnel will not be permitted.

Emergency Procedures

Develop, implement, and maintain emergency procedures, in accordance with applicant's radiation protection program required by 4731.2020. Applicants should indicate typical response times of the RSO and Authorized User in the event of an incident and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as, wind, water, or fire that results in damage to exterior or interior portions of the vehicle or the radioactive material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous material-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel;
- The emergency contact numbers for MDH;
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist;
- Procedures for retrieving and securing any radioactive material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers;
- Preplanned decontamination procedures, including ready access to all necessary materials;

- A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys;
- Security of the transport vehicle against unauthorized access, including the driver's compartment; and

Note: The type of response should be consistent with the level of the incident. The response may range from phone contact for minor spills to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 170 – 189. Procedures will include:
    - Use of approved packages;
    - Use of approved labeling;
    - Conduct of proper surveys;
    - Complete and accurate shipping papers;
    - Bracing of packages;
    - Security provisions; and
    - Written emergency instructions.

- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
- Licensed material is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. Applicants must describe the method of storage and final disposal.
- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Radioactive Waste Management

If waste will be stored in vans, the vans will be properly secured and posted as radioactive material storage locations. Applicants will ensure that the van will be secured against unauthorized access and that the waste storage location will be posted as a radioactive material storage area.

Develop, document, and implement final waste disposal procedures.

Excreta from individuals undergoing medical diagnosis with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewerage system, in accordance with 4731.2420. However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewerage system. If restroom facilities are provided in the van for patient use, submit the following information for MDH review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van, and the driver of the van; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any I-131 will be held in the tank.
- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 4731.2020 and 4731.2090, that the external surfaces of the van do not exceed 2 mrem/hour, and that doses to members of the public and workers are

maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.

- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

APPENDIX I
ORDERING AND RECEIVING RADIOACTIVE MATERIAL

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

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

Model Guidance

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

Sample Memorandum

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

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

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

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

at _____.

	Name	Home Telephone
Radiation Safety Officer:	_____	_____
Nuclear Medicine Supervisor:	_____	_____
Chief Nuclear Medicine Technologist:	_____	_____

	Call page operator at extension
Nuclear Medicine Technologist on call:	_____
Nuclear Medicine Physician on call:	_____

APPENDIX J
MODEL SPILL PROCEDURES

You may use the following model procedures as they appear here, stating on your application, "We will establish and implement the Model Spill, Emergency Surgery, and Autopsy Procedures published in Appendix J to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic Procedures."

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

MINOR SPILLS OF LIQUIDS AND SOLIDS

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

MAJOR SPILLS OF LIQUIDS AND SOLIDS

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

DISCUSSION OF MAJOR SPILLS AND MINOR SPILLS

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radio-toxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

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

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

Relative Hazards of Common Radionuclides

RADIONUCLIDE	MILLICURIES	RADIONUCLIDE	MILLICURIES
P-32	1	Tc-99^{m}	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

Assemble a spill kit that may contain the following items:

- Disposable gloves and 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;
- Contamination wipes;
- Instructions for "Emergency Procedures";
- Clipboard with copy of Radioactive Spill Report Form;
- Pencil; and
- Appropriate survey instruments, including batteries.

Spilled Gas Clearance Time
Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, calculations should be made to determine for how long a room must be evacuated in case of an airborne spill. The clearance time should be posted in the room or at a location readily accessible to workers.

Collect the following data:

A The highest activity of gas in a single container, in microcuries.

Q The total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas system.

C The allowable air concentrations for occupational exposure in restricted areas (derived air concentrations-hour [DAC-hour]). The DAC values to determine when a nuclear medicine technologist (NMT) or authorized user may return to a spill in a restricted area are:

Xenon-133 is 1×10^{-4} µCi/ml
Xenon-137 is 4×10^{-5} µCi/ml

V the volume of the room in milliliters. (I ft^3 = 28317 ml –or- 28317ml/ft^3)

2. Make the following calculations for each room:

- The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
- The evacuation time (t)

$$t = -V/Q \times \ln(C \times V/A)$$

Sample Calculation

Evacuation Time	$t = -V/Q \times \ln(C \times V/A)$
Volume of room (in ml)	V = 12 ft x 30 ft x 8 ft = 2,880 ft^3 x 28,317 ml/ft^3 = 81,552,960
Room exhaust (in ml/minute)	Q = 900 cfm x 28,317 ml = 25,485,300
Effluent concentration limit (in µCi/ml)	C = 5×10^{-7} (Xe-133)
Activity (in µCi)	A = 10 mCi = 10,000
Clearance time	$t = -81{,}552{,}960/25{,}485{,}300 \times \ln(5 \times 10^{-7} \times 81{,}552{,}960/10{,}000)$
	$t = -3.2 \times \ln(0.0040776)$
	$t = -3.2 \times -5.50$

t = 17.6 minutes

APPENDIX K
LEAK TESTING SEALED SOURCES

You may use the following model procedures as they appear here, stating on your application, "We will establish and implement the Model Leak Testing Procedures published in Appendix K to the MDH Regulatory Guide for Diagnostic Medical Procedures."

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

Model Leak Test Program

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multi-channel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 µCi) of radioactivity.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5percent of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- Calculate efficiency of the instrument. For example,

$$\textit{Efficiency} = \frac{\textit{[(counts per minute from standard) – (counts per minute from background)]}}{\textit{(activity of standard in microcurie)}}$$

- Analyze each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcurie and record.
- The activity on the wipe sample is given by:
- Leak test records will be retained in accordance with 35.2067 for 3 years. Licensees should include the following in records:
    - The model number and serial number (if assigned) of each source tested;
    - The identity of each source radionuclide and its estimated activity;
    - The measured activity of each test sample expressed in microcurie;
    - A description of the method used to measure each test sample;
    - The date of the test; and
    - The name of the individual who performed the test.

- If the wipe test reveals 185 Bq (0.005 µCi) or greater:
    - Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with MDH requirements.
    - File a report within 5 days of the leak test in accordance with 4731.4527.

APPENDIX L
SAFE USE OF UNSEALED SOURCES

You may use the following model rules as they appear here, stating on your application, "We will establish and implement the model safe use of unsealed sources published in Appendix L to the MDH Regulatory Guide for Diagnostic Medical Procedures."

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

Model Requirements

- Wear long-sleeved laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the restricted area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
- Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins or infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve so syringe shields can still be used).
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
- Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
- If required, wear extremity dosimetry (e.g., a finger dosimeter) while handling radioactive material including during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and while in contact with patients that have been administered radiopharmaceuticals.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test preparation and administration areas, and areas where radioactive materials are stored each week. If necessary, decontaminate or secure the area for decay.
- Survey with a radiation survey meter all areas of licensed material use including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate. Areas used to prepare and administer radiopharmaceuticals should be surveyed daily.
- Store radioactive solutions in shielded containers that are clearly labeled.
- Multi-dose diagnostic vials should be labeled in accordance with 4731.2330 and 4731.4425.
- A log should be used to record additional information such as:
    - The total prepared activity
    - Specific activity (in mCi/cc) at a specified time
    - Total volume prepared
    - The measured activity of each patient dosage
    - Any other appropriate information

- Syringes and unit dosages must be labeled in accordance with 4731.2330 and 4731.4425. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in 4731.2800, the syringe or vial need only be labeled to identify the radioactive drug. To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
- Assay each patient dosage in the dose calibrator before administration.
- Do not use a dosage if it does not fall within the prescribed dosage or if it by more than twenty percent of the prescribed dosage without approval of an authorized user.
- When measuring the dosage, the radioactivity that adheres to the syringe wall or remains in the needle does not need to be considered.
- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (4731.4409).
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the MDH license (or such individual's designee).

APPENDIX M
SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

In addition to 4731.2350

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

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

Model Procedure

All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination in accordance with 4731.2350.

The following procedures for opening each package will be followed:

- Put on gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
- Measure the exposure rate from the package at one (1) meter and at the package surface. If it is more than 10 millirem per hour at three (3) feet (1 meter), stop and notify the RSO. (The transport index noted on packages with Yellow II or Yellow III labels is the approximate dose rate, in millirem per hour, at one (1) meter from the package surface).
- Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with White I labels should be less than 0.5 millirem per hour on the external surface of the package.
- Wipe the external surface of the package in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

  Beta-gamma-emitting radionuclides; all radionuclides with half-lives less than ten days.....22 dpm/cm^2
  All other alpha-emitting radionuclides .....2.2 dpm/cm^2

- Open the package with the following precautionary steps:
  - Remove packing slip.
  - Open outer package following the supplier's instructions, if provided.
  - Verify that the contents match the packing slip.
  - Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
  - If anything is other than expected, stop and notify the RSO.

- If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument [for example, a thin-end-window GM survey meter, a NaI(TI) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter] should be used for these

assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.

- Check the user request to ensure that the material received is the material that was ordered.
- Monitor the packing material and the empty packages for contamination with a survey meter before discarding.
    - If contaminated, treat this material as radioactive waste.
    - If not contaminated, remove or obliterate the radiation labels before discarding it.
- Make a record of the receipt.

For Packages Received under a General License

The following procedure for opening each package will be followed for packages received under a general license:

- Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
- Check to ensure that the material received is the material that was ordered.

APPENDIX N
MODEL PROCEDURES FOR DEVELOPING, MAINTAINING, AND IMPLEMENTING WRITTEN DIRECTIVES

Licensees may either adopt this model procedure or develop your own procedure to meet the requirements of 4731.4408 and 4731.4409. If you may use the following model procedures as they appear here, stating on your application, "We will establish and implement the procedures for administrations that require written directives published in Appendix N to the MDH Regulatory Guide for Diagnostic Medical Procedures."

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

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require written directives. This model does not restrict your use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a written directive. Such procedures are to provide high confidence that the objectives specified in 4731.4409 will be met.

The written directive must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 µCi). The written directive must contain the information described in 4731.4408 and be retained in accordance with 4731.4501.

The administration of radioactive materials can be a complex process for many types of diagnostic procedures in nuclear medicine. A number of individuals may be involved in the delivery process. To help ensure that all personnel involved in the treatment fully understand instructions in the written directive, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the written directive. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of written directives or treatment plans by at least one qualified person, preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve future emerging technologies. For each such modality for which 4731.4408 requires, or would require, a written directive, the licensee should develop, implement, and maintain written procedures for written directives to meet the requirements and/or objectives of 4731.4408, 4731.4409, and 4731.4422, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the patient or human research subject's name;
- Verify the patient's or human research subject's identity prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- Check both manual and computer-generated dose calculations;
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

Review of Administrations Requiring a Written Directive

Conduct periodic reviews of emerging technologies program. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of the treatment modality performed in the institution. If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a written directive are effective.

As required by 4731.4409, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the written directive or treatment plan, as applicable. When deviations from the written directive are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Reports Of Medical Events

Notify MDH by telephone no later than the next calendar day after discovery of a medical event and submit a written report within 15 days after the discovery of the medical event, as required by 4731.4525. Also notify the referring physician and the patient.

APPENDIX O
DEPARTMENT OF TRANSPORTATION REQUIREMENTS

The United Stated Department of Transportation (DOT) has recently updated portions of the regulations pertaining to the transportation of radioactive materials. Several such changes were to the allowable activity limits for the packages used to transport materials being returned to nuclear pharmacies. If you will be returning your radioactive waste to a nuclear pharmacy, your facility will become a shipper of a radioactive material.

MDH is providing you with the following system to ensure you properly prepare packages for return.

Limited Quantity Shipments

Return shipments should be shipped as Limited Quantity Shipments. In accordance with 49 CFR 173.421, package that meet the following requirements can be classified as a Limited Quantity Shipment and are exempt from the specification packaging and labeling requirements:

- The amount of radioactivity in the package does not exceed a specified amount.
- The radiation level at any point on the external surface of the package does not exceed 0.5 mR/hr.
- The non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed 6600 dpm per 300 cm^2 area, as specified in CFR 173-443(a).
- The label and marking cards are attached to the delivery case with the Limited Quantity side facing outwards.

To meet the above requirements, licensees must ensure that the waste being returned does not exceed the specified limits for Limited Quantity Shipments. This can be determined by reviewing the table with activity limits for nuclides. The total quantity of activity being returned cannot exceed the specified Limited Quantity Shipment activity whether returning used dose material or unused doses.

Example of estimating return activity for Tc-99^m products.

Unused Products. If an unused syringe of a 25 mCi dose is held for 24 hours (4 half lives), the remaining activity is:

$$(25\ \text{mCi}) \times (0.5) \times (0.5) \times (0.5) \times (0.5) = 1.56\ \text{mCi}$$

A maximum of seven of these syringes could be returned and remain below the 11 mCi limit for Tc-99^m.

Used Products. Assume 5 percent remains in the syringe after an injection. If the syringe is held for 24 hours (4 half lives), the remaining activity from a 25 mCi dose is:

$$(25\ \text{mCi}) \times (0.05) \times (0.5) \times (0.5) \times (0.5) \times (0.5) = 0.078\ \text{mCi}$$

If ten unit dose syringes were returned, and all ten had been 25 mCi doses, the package would contain only 781 µCi, which is well below the 11 mCi limit in the attached table.

Limited Quantity Activity Limits For Shipments Of Mixed Radionuclides

When shipping more than one radionuclide in the same package, the limit on the radioactivity that may be shipped is the lowest activity assigned for the radionuclide shipped. (See attached table) For example, if Tc-99^{m} and I-131 were being shipped in the same package, only 1.9 mCi of total activity could be shipped.

Limited Quantity Returns	
Radionuclide	LIMITED SHIPMENT QUANTITY (mCi)
Ba-133	8.1
C-14	8.1
Co-57	27
Cr-51	81
Cs-137	1.6
F-18	1.6
Ga-67	8.1
Ho-166	1.1
I-123	8.1
I-125	8.1
I-131	1.9
In-111	8.1
Lu-177	1.9
Mo-99	2
N-13	1.6
Na-22	1.4
Ni-63	81
P-32	1.4
Pd-103	110
Sm-153	1.6
Sr-89	1.6
Sr-90	0.81
Tc-99^{m}	11
Tl-201	11
Xe-133	270 (gas), 27 (liquid)
Y-90	0.81
Note: Multiply values listed above by 10 for solid or sealed sources.	

- Place materials into delivery boxes in the same configuration as received.
- Ensure that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr. Measure all sides of the package. If the radiation levels exceed 0.5 mR/hr at any point on the surface of the package, please call the nuclear pharmacy for further instructions.
- Ensure that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed 6600 dpm when wiped over a 300 cm^2 area. If this limit is exceeded, please call the nuclear pharmacy for further instructions.
- If the package activity, radiation levels and wipe tests are within the limits outlined above, ensure the shipping container is marked as the Limited Quantity Shipment information.

Packages that have not been prepared for shipment back to the nuclear pharmacy in the manner described above should not be accepted for transport.

US Department of Transportation Training Requirements

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>.

APPENDIX P
WASTE DISPOSAL

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for waste disposal that is published in Appendix P to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic Procedures."

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

Overview

There are four commonly used methods of waste disposal:

- Release to the environment through the sanitary sewer or by evaporative release
- Decay-in-storage (DIS)
- Transfer to a burial site or back to the manufacturer
- Release to in-house waste

With the exception of the patient excreta and generally licensed *in-vitro* kit exemptions, nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material.

General Guidance

- All radioactivity labels must be defaced or removed from containers and packages before disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind employees that non-radioactive waste, such as leftover reagents, boxes, and packing material, should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that no unnecessary radioactive waste is created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, and pathogenicity), and expense.

Model Procedure for Disposal of Liquids and Gases

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

- Regulations for disposal in the sanitary sewer appear in 4731.2420. There are specific limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy are exempt from all the above limitations.) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.
- Limits on permissible concentrations in effluents to unrestricted areas are enumerated in 4731.2750. These limits normally apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity and concentration that was released (in millicuries or microcuries), and the vent site at which the material was released.

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

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

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

- Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.
- When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
- Decay the material for at least 10 half-lives.
- Before disposal as in-house waste, monitor each container as follows:
    - Check your radiation detection survey meter for proper operation.
    - Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
    - Remove any shielding from around the container.
    - Monitor all surfaces of each individual container. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages).
    - Discard as in-house waste only those containers that cannot be distinguished from background. Check to be sure that no radiation labels are visible.
    - Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
- If possible, Mo-99/Tc-99^m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, and then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

Model Procedure for Returning Generators to the Manufacturer

Used Mo-99/Tc-99^m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with Department of Transportation (DOT) regulations.

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose rate and removable contamination surveys.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of transfers and receipts in accordance with 4731.3115.

Model Procedure for Return of Licensed Material to Authorized Recipients
Perform the following steps when returning licensed material to authorized recipients:

- Confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's MDH, NRC or other Agreement State license that authorizes the radioactive material);
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with 4731.3115.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION