

MINNESOTA DEPARTMENT OF HEALTH



REGULATORY GUIDE FOR GAMMA STEREOTACTIC RADIOSURGERY

 The logo for the Radiation Control Unit of the Minnesota Department of Health. It features a circular border with the text "Radiation Control Unit - Minnesota" at the top and "Department of Health" at the bottom. In the center is a black silhouette of the state of Minnesota.	<p>Division of Environmental Health Indoor Environments & Radiation Section Radiation Control</p> <p>625 Robert Street North P.O. Box 64975 St. Paul, Minnesota 55164-0975 (651) 201-4545</p>
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REGULATORY GUIDE FOR GAMMA STEREOTACTIC RADIOSURGERY

INTRODUCTION

The Minnesota Department of Health (MDH) regulates the intentional internal or external administration of radioactive material or the radiation from radioactive material to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Chapter 4731 of the Minnesota Department of Health Rules.

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

- gamma stereotactic radiosurgery devices (gamma knives)
- high-, medium-, and low-dose rate afterloaders
- irradiators
- nuclear powered pacemakers
- teletherapy devices

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the rules identified in Chapter 4731 and then complete the application form. The MDH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program.

The purpose of this guide is to assist applicants and licensees in preparing applications for new licenses, license amendments, and renewals that authorize the possession of radioactive material for medical use of gamma stereotactic radiosurgery devices (GSR). This regulatory guide provides specific information on the survey instruments, radiation monitors, performance of required surveys, and operating and emergency procedures associated with a GSR unit.

AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

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

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

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

FILING AN APPLICATION

You should apply for a license by completing the "Application for a Minnesota Radioactive Materials License." Complete Items 1 through 4 on the form itself. For Items 5 through 11, submit the information on supplementary pages. Identify and key each sheet or document with the item number on the application. All typed pages, sketches, and, if possible, drawings should be on 8 1/2 X 11 inch paper to

facilitate handling and review. If larger drawings are necessary, they should be folded to 8 1/2 X 11 inches. You should complete all items in the application in sufficient detail for MDH to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

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

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

Submit one copy of your application to:

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

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

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

Item 1: License Action Type

Check box A for a new license request.

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

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

Item 2: Name and Mailing Address of Applicant

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

Timely Notification of Transfer of Control

Licensees must provide full information and obtain MDH's prior written consent before transferring control of the license, directly or indirectly. Transfers of control may be the results of mergers, contractual agreements, buyouts, or majority stock transfers. Although it is not MDH's intent to interfere with the

business decisions of licensees, it is necessary for licensees to obtain prior MDH written consent. This is to ensure the following:

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

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

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

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

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

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

Item 4: Person to be Contacted About This Application

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

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

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

Item 5: Radioactive Material

Provide the following information for each radionuclide:

1. Radionuclide.
2. Manufacturer's name and model number.
3. Maximum activity per device. The activity may not exceed the activity specified by the manufacturer for the specific device and source combination.
4. Maximum number of sources to be possessed at any one time. You may wish to request authorization for sources used in the device and additional sources for replacement. The replacement sources will be stored in shipping containers until the manufacturer completes the change out. If more than one source model is referenced in item 2, you should indicate the maximum number of sources requested of each model number.
5. Maximum activity of the individual sources.
6. If applicable, you should request authorization for possession of depleted uranium in quantities sufficient to include shielding material in both the devices and source containers used for source exchange. Review and indicate the manufacturer's specifications for each device to determine the total quantity of depleted uranium present in the device in units of kilograms. Indicate whether depleted uranium is used for shielding the source(s) within the device.

Provide the following information for each device:

1. Specify the manufacturer's name, address, and telephone number for each device requested.
2. Indicate the model name and/or number and serial number for each device requested.

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

You should specify the uses or types of treatment planned for the device. Any other intended uses (such as physics calibrations or medical research) should be described so that the intended uses are apparent to the MDH review staff.

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

Responsible individuals include the authorized users and the RSO. An applicant is required by 4731.4411 to be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and property. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience. You should submit a copy of an NRC or Agreement State license to verify qualifications of an authorized user. Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the program.

Authorized Users For Medical Uses

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

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiation dosage or dose and how it is to be administered.

3. Use of the radioactive material or supervising the use by technologists or other paramedical personnel in the use of radioactive material.
4. Interpretation of diagnostic procedures and the evaluation of therapy procedures.

For each proposed Authorized User (AU), submit the user's name; identify types, quantities, and proposed uses of licensed material; and include a copy of the license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials.

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

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

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

All training for users of gamma stereotactic radiosurgery units must comply with the specifications in 4731.4479.

Radiation Safety Officer (RSO)

Radiation Safety Officers must have adequate training and experience. The training and experience requirements for the RSO are described in 4731.4411 and 4731.4479 and allow for the following four training pathways:

- Certification by one of the professional boards recognized by MDH in 4731.4479.
- Didactic training and work experience as described in 4731.4479.
- Didactic training, work experience, and preceptor statement as described in 4731.4411(B).
- Identification on the license as an Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

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

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

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

RSO Responsibilities

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

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

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

Provide the following:

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

Submit one of the following:

- Copy of the certifications for the boards recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.
- Description of the training and experience specified in 10 CFR 35.900(b).
- Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.

In addition, provide both of the following:

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

Authorized Medical Physicist (AMP)

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

Applicants are reminded of recentness of training requirements described in 4731.4415. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required

training and experience. This time provision applies to board certification as well as to other recognized training pathways.

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

- Previous license number or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named as an Authorized Medical Physicist for the units requested.
- Copy of the certification(s) for the board(s) recognized by NRC in 4731.4412 or 4731.4479.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4479 for the units requested.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4412 for the units requested.

In addition, provide both of the following:

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

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

Describe your training program for individuals who work with or near radioactive material.

Item 9: Facilities And Equipment

Facilities

Submit annotated drawings of each dedicated treatment room indicating:

1. Scale, plan and elevation.
2. Identification of the rooms, including room numbers.
3. Type, density and thickness of all shielding materials, including walls, floor and ceiling.
4. The location of the gamma stereotactic unit within the room. Include distances from the isotope center of the device to the walls, doors, etc.
5. Location of doors, windows, and conduit.
6. Distance to and the nature of use for adjacent areas with indication of whether the areas are restricted or unrestricted, as defined in Chapter 4731.

NOTE: The information provided should be sufficient to enable MDH staff to conduct an independent review of the shielding design. To that end, distances from the source center should be referenced.

Treatments must be performed in rooms specially constructed or modified for radiosurgery. The use of gamma stereotactic devices must be restricted to the specific room described in your application. Relocation of a device to another area of use requires prior MDH approval.

Equipment

A. If the gamma stereotactic radiosurgery device is not equipped with viewing and intercom systems, you should equip the treatment room to allow for patient observation during treatment. A description of the systems should be provided with the application and should include:

1. The primary intercom and viewing systems.
2. Backup systems to be used if the primary systems fail. Alternatively, you should commit to suspend treatments until the primary system is repaired.

You should describe the following:

- How the patient and device will be monitored during treatment.
- How to provide for prompt detection of any operational problems with the device during treatment.

B. Provide a description of the security to be provided for the room where a device is to be used or stored. Areas should be secured in accordance with 4731.2290. A description of the following is required:

1. The physical or administrative control of access.
2. The electrical interlock system installed at each entry, including the result of interrupting the interlock when the source is exposed.
3. The actions required following interruption of the interlock before resuming treatment, including confirmation that the interlock must be reset before the device can be activated.
4. The actions required in case of malfunction of the interlock system. You should confirm that if the system malfunctions, the shielding doors will be closed. Verify that the system will not be used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
5. The restricted area controls (e.g., signs, locks, visible and audible alarms, etc.), including descriptions of signs with their locations, sizes and wording. Each suite containing a gamma knife should be equipped with a radiation monitor. The monitor should be permanently mounted and equipped with an emergency power supply separate from the gamma knife unit itself. The monitor must be capable of providing a visible indication (e.g., flashing light, or "Beam On" light) of an exposed or partially exposed source. The indicator must be readily observable by any person entering the treatment room.
6. Provide the methods used to identify the high radiation areas inside the treatment room when the shield doors are open (e.g., colored floor tiles, warning tape, etc.).
7. The method to ensure that whenever the device is not in use or is unattended, the console key(s) will be inaccessible to unauthorized persons.
8. You should confirm that no other radiation-producing devices are located in the treatment room, or provide a description of the mechanisms installed to ensure that only one device can be placed in operation at a time.
9. Verify that the gamma knife, its control console, or any related components are not within close proximity of equipment that produces a high level of electromagnetic

disturbance (i.e., short wave equipment). Those fields have been demonstrated to interfere with the operation of the gamma knife control system.

C. To demonstrate compliance with 4731.2090, submit detailed calculations of maximum radiation levels (and dose rates) that will exist in each area (restricted and unrestricted). The calculations should include the following:

1. The expected radiation levels for each area adjacent to the room housing the device. The radiation levels should consider the most adverse source orientations and maximum source activity used in the device. This includes:
 - maximum source strength
 - combination of sources used for treatment
 - source orientation
 - room size
 - layout
 - treatment time

These calculations should be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s) meet the requirement of 4731.2090.

2. Specify all parameters used to perform the calculations described above. These parameters should include such factors as distance to each area of concern, the type and thickness of materials used in barriers and shields, and the transmission factor of the barriers or shields, and the maximum source strength.
3. The maximum anticipated workload data, such as maximum use time per hour and per week, that will be used in a dedicated room and occupancy factors used for all adjacent areas.
4. Calculations to determine the dose received by individuals present in unrestricted areas should consider continuous occupancy (occupancy factor of one) unless you can make a compelling argument for using a lower value. Calculations to determine the dose received by ancillary staff providing patient care during treatment should include full details of the occupancy factors used.
5. Results of the calculations are to be expressed in units of rem (or millisieverts) in any one hour or year, as appropriate.
6. You should demonstrate that the limits will not be exceeded. If your calculations demonstrate compliance with these limits, outline the steps taken to limit exposure to individual members of the public. Options that may be considered include:
 - a. Adding shielding to the barrier in question with a corresponding modification of the facility description (if necessary).
 - b. Request an exemption and demonstrate how the requirements of 4731.2090 will be met. You should demonstrate the need for and the expected duration of operations that will result in an individual dose exceeding the limits. A program to assess and control dose within the 0.5 rem (five mSv) annual limit and procedures followed maintaining the dose as low as is reasonable achievable should be developed and submitted for review.

D. Confirm the implementation of a survey program to demonstrate compliance with dose limits for members of the public. Submit a description of the program. The program should

include requirements for conducting surveys following source replacement. At a minimum, the survey program should be sufficient to confirm the following:

1. Radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of the occupational dose limits.
2. Radiation levels in unrestricted areas will not result in a dose to any member of the public in excess of the limits specified in 4731.2090.
3. Records of survey results will be maintained for inspection by the MDH for the duration of the license.

Radiation Monitoring Instruments

Describe any other equipment and facilities available for the use and/or storage that is listed in Item 6 of this application. Provide the manufacturer name, model number, and range of the survey instruments being used. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
LGD Scientific, Inc.	MSB-000	1 - 100000 cpm

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide for survey instrument calibration from the MDH.

Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered “servicing.”

Item 10: Radiation Safety Program

The RSO will promptly review all exposure records to look for workers or groups of workers whose exposures are unexpectedly high or low. This procedure does not apply to backup monitor records (for example, pocket ionization chambers) when the monitor of record is a thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

Quality Management Program

Each licensee reviews its operating procedures to ensure that they incorporate the following objectives:

- A. Before administration, a written directive is prepared for any gamma stereotactic radiosurgery radiation dose.
- B. Prior to each administration, the patient’s or human research subject’s identity is verified by more than one method as the individual named in the written directive.
- C. Final plans of treatment and related calculations are in accordance with the respective written directives.
- D. Each administration is in accordance with the written directive.
- E. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

The licensee must retain each written directive and a record of each administered radiation dose for three years after the date of administration.

Operating Procedures

A. Submit a copy of your operating and emergency procedures. Minnesota Department of Health Radioactive Materials Rules, Chapter 4731.4466, provides the safety instructions that are required for operation of this type of device. However, in addition to the rules you may wish to incorporate the following into your operating procedures:

1. The device(s), console, and treatment or storage room will be secured when unattended.
2. During patient treatments, personnel must be immediately available to address radiological concerns and to serve as a resource in case of radiological problems. The appropriate personnel are:
 - The authorized user
 - The medical physicist
 - The Radiation Safety Officer

One or more of these individuals must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech. If the medical physicist is not physically present, that individual must be readily available during patient treatment.

Submit the protocol indicating who will be physically present during patient treatment and any actions that must be implemented to ensure that the medical physicist is readily available. Submit any alternative procedures for MDH review.

B. Chapter 4731.4474 provides the output spot checks and the required frequency. Confirm that as a minimum, the safety checks will be performed and that written, as well as verbal, instruction will be provided to individuals assigned to complete the checks.

A description of the method used to perform the checks and the frequency with which they will be made should be submitted for review. (At a minimum, the checks should be conducted monthly.) The operating procedures should specify when and how the checks are completed, and who completes them.

Emergency Procedures

A. Submit for review the emergency procedures approved by the authorized user(s) and Radiation Safety Officer or medical physicist. You should confirm that copies of the procedures will be provided to device operators, authorized users, and other personnel as necessary. In addition, a copy of the procedures should be posted at the device control console or in a conspicuous location at the treatment area.

B. At a minimum, the procedures should address the following:

1. The procedures to be implemented if the source cannot be fully shielded.
2. The means of controlling radiation exposures to personnel while manually closing the shield doors.
3. The means of physically removing the patient from the unit if the sliding cradle fails to retract as designed.
4. Systematic actions for single or multiple equipment failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios.

5. Requirements to restrict and post the treatment area with appropriate signs to minimize the risk of inadvertent exposure of personnel not directly involved in emergency recovery operations.
 6. The location of the equipment that may be necessary for the various equipment failures described in the procedure.
- C. During patient treatments, a device operator trained in the emergency procedures should be physically present at your facility. The medical physicist or Radiation Safety Officer and the authorized user should be available for prompt assistance in the event that the shielding doors become jammed. The authorized user, medical physicist or Radiation Safety Officer should be immediately notified of any problems encountered during a treatment. Device operators will follow the instructions of the authorized user, medical physicist, or the Radiation Safety Officer and implement emergency procedures as necessary.
- D. Commit to implement immediately applicable emergency procedures if the survey indicates that the source is not fully in a shielded position.

Maintenance

- A. Confirm that only personnel who are licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such services will perform maintenance and repair on the device. Maintenance and repair includes installation, replacement, relocation or removal of the sealed source or the device that contains a sealed source. Maintenance and repair also means any adjustment involving any mechanism on the device, treatment console, or interlocks that could expose the source, reduce the shielding around the source, or affect the shield door drive controls.

Confirm that a record of any maintenance and repair performed on the device will be maintained for the duration that the device is in use. The record should include:

- the date of repair
 - a description of the nature of the maintenance or repair
 - the name of the individual who performed the repair
 - the Agreement State or NRC license number authorizing the individual who performed the repairs
- B. The requirements for full calibration of the device are included in 4731.4471.
- C. In addition to a full calibration, the licensee must ensure that each device will be fully inspected and serviced at a frequency not to exceed five years. The specific requirements associated with inspections are included in 4731.4477.
- D. You may request authorization for an employee trained by the manufacturer to perform maintenance and repair functions. Such authorization should list the employee by name. It should specify the maintenance and repair functions described in a certificate or letter from the manufacturer of the device documenting the training. A copy of the training certification and an outline of the training should be submitted with the request.

Leak Tests

As a licensee, you must perform leak testing of sealed sources. The MDH requires tests to determine whether or not there is any leakage from the radioactive source(s). The leak test should be performed at six-month intervals unless otherwise authorized by your license.

The following options are available for leak testing:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.

2. Take the sample using a commercial leak test kit and send the sample to the kit supplier who will report the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurements.

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

For Option 2, specify the name, address, and license number of the company who will analyze the samples. Commit to the following or submit your own procedures.

1. Identify the sources to be tested. This should include the isotope, the activity on a specified date, and the physical form.
2. Set out a survey meter, preferably with a speaker, so you can monitor your exposure rate. A survey should be done to be sure that sources are adequately shielded during the leak test period.
3. Prepare a cotton swab, injection prep pad, filter paper, or tissue paper. Number each wipe so you will know the location from which it was taken. Samples should be taken as follows:
 - a. Take the wipe with the sources in the shielded position.
 - b. Take the wipe on the shield doors and areas near the radiation port.

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

Annual Audit of the Radiation Safety Program

Annual audits are required by 4731.2010. Currently the MDH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

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

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

Item 11: Waste Management

Submit your procedures for waste disposal. Be sure to include a procedure for each material listed in Item 5.

Item 12: License Fee

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

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

Item 13: Certification

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

AMENDMENTS TO A LICENSE

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

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

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

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

RENEWAL OF A LICENSE

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

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

IMPLEMENTATION

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

INSPECTIONS

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

SUMMARY OF REVISIONS

<u>REVISION</u>	<u>SECTION</u>	<u>DESCRIPTION</u>
5-5-2005	Item 7	Added: For each proposed Authorized User (AU), submit the user's name; identify types, quantities, and proposed uses of licensed material; and include a copy of the license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials.
5-6-2005	Item 10	Removed 'kit model number' from Option 2
9/16/05	Title page and filing an application	Address and section name change.