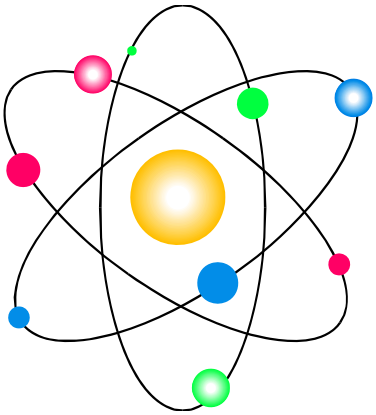
RADIOACTIVE MATERIALS REGULATORY GUIDE



RADIATION THERAPY DEVICES

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TABLE OF CONTENTS

REGULATORY GUIDE FOR THERAPY DEVICES

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 may be obtained for the following therapy applications:

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

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

This guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for use of high dose-rate devices. It describes the regulations for their use as well as specific information on the survey instruments, radiation monitors, performance of required surveys, and operating and emergency procedures associated with a high dose rate afterloader (HDR) or gamma stereotactic radiosurgery (GSR) units. Guidance for medium, low and pulsed dose rate afterloaders may be similar to those for a high dose rate afterloader. However, some conditions may be relaxed based on the hazards of operation.

DEFINITIONS

This guidance defines the following terms as:

- ***High dose rate (HDR)*** -- a dose rate of 20 or more centigray (rads) per minute.
- ***Medium dose rate (MDR)*** -- a dose rate between 200 centigray (rads) per hour and 20 centigray (rads) per minute.
- ***Low dose rate (LDR)*** -- a dose rate of 4 to 200 centigray (rads) per hour.
- ***Pulsed dose rate afterloader (PDR)*** -- a special type of remote afterloading device that uses a single source capable of delivering dose rates in the “high dose rate” range, but is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour. Based solely on their instantaneous exposure rate, these devices are treated the same as high dose-rate devices in this document.

As Low As Reasonably Achievable (ALARA) Philosophy

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. 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 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 Material

For 4731.4463 uses (sealed sources for Afterloaders, Teletherapy Units, and Gamma Stereotactic Units), 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
Cobalt 60 (i.e., specific teletherapy sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 9,000 curies per source and 18,000 curies total
Iridium 192 (i.e., specific afterloader sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 10 curies per source and 20 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total

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

Applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 4731.4423). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by the NRC, or an Agreement State.

The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR Certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that MDH can verify that they have been evaluated in an SSDR Certificate or specifically approved on a license.

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. An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SSDR designations registered with the NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SSDR certificates without obtaining MDH's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the SSDR Registry and registration certificates, applicants may want to obtain copies of the appropriate sections of the Registry certificates and review or discuss them with the manufacturer.

Shielding Material/Depleted Uranium: Applicants receiving large therapy sources and devices also should determine if depleted uranium is used to shield the therapy sources and devices. 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

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

The applicant should define the purpose of use by stating the applicable portion of 4731.4463 (e.g., teletherapy, remote afterloading, GSR) and describing the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (e.g., for use in a Manufacturer's Name and Unit Type, Model xxxx radiation therapy unit for the treatment of humans). The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that an additional source is requested to be stored in its shipping container incident to source replacement. Any other intended uses (such as physics calibrations or medical research) should be described so that the intended uses are apparent to the MDH review staff.

Item 7: Individual Users Responsible for the Radiation Safety Program

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), Authorized Medical Physicists (AMPs), 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, the RSO, and Authorized Medical Physicists.

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 administration of the radiation protection program 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 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 Committee (RSC)

Licensees must establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license if they are authorized more than one of the following:

- 4731.4440 – Unsealed Radioactive Material – Written Directive Required
- 4731.4450 – Manual Brachytherapy
- 4731.4463 – Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

In addition, licensees are required to establish an RSC if they have authorization for more than one type of units under 4731.4463.

Membership of the committee must include:

- an authorized user for each type of use permitted by the license,
- the Radiation Safety Officer,
- a representative of the nursing service,
- a representative of management who is neither an authorized user nor the Radiation Safety Officer, and
- other members the licensee considers appropriate

Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing, as adjunct members, representatives from security, physical plant, housekeeping, and other departments. Adjunct members should abstain from balloting on radiation safety questions.

To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

The Committee shall:

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

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 one 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, Authorized Medical Physicist, or Authorized Nuclear Pharmacist 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

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 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 regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

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 described in 10 CFR Part 35 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 training pathways for meeting requirements for training and experience.

Provide the following:

- Name of the proposed Authorized Medical Physicist.

AND

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

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) 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 individual was specifically named an Authorized Medical Physicist for the uses requested.

For an individual qualifying in accordance with 4731.4412:

- Copy of the certification(s) of the specialty board(s) whose certification process has been recognized6 under 4731.4412 Subpart 1. Item A.

AND

- Written attestation, signed by a preceptor Authorized Medical Physicist, that the required 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.

AND

- Description of the training and experience specified in 4731.4412 Subpart 1. Item A (2) demonstrating that the proposed Authorized Medical Physicist is qualified by training in the types of use for which he or she is requesting Authorized Medical Physicist status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.

OR

- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4412 Subpart 1. Item B. (1) for the uses requested.

AND

- Written attestation, signed by a preceptor Authorized Medical Physicist, that the required 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.

AND

- Description of the training and experience specified in 4731.4412 Subpart 1. Item A. (2) demonstrating that the proposed Authorized Medical Physicist is qualified by training in the types of use for which the licensee seeks approval of an individual as Authorized Medical Physicist,

AND

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

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 (1 millisievert (mSv), the licensee must provide safety instructions as required by 4731.1020. Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in 4731.4441, 4731.4453, and 4731.4466. The licensee's authorized users and authorized nuclear pharmacists are required by 4731.4407 to provide safety instruction to all personnel using radioactive material under their supervision.

Authorized Users, Authorized Medical Physicists, 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 use by an individual under the supervision of an Authorized User, shall instruct supervised individuals in the 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 must describe the proposed facilities and equipment. The facility diagram should include the room or rooms and adjacent areas where radioactive material is used 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 a remote afterloader, teletherapy unit, or gamma knife (4731.4463), the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram. Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy treatment room. 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.

For teletherapy units, it may be necessary to restrict use of the unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit (e.g., electrical or mechanical stops). The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber.

- "For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall."
- "For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95-degree arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall."

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 used or stored.
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 4731.0100.
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations.

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

Radiation Monitoring Instruments

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

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

material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used.

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 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."

Therapy Unit – Calibration and Use

Chapter 4731 provides the MDH requirements, including recordkeeping requirements, for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For LDR remote afterloader sources licensees may use source activity or output determined by the manufacturer, provided that the manufacturer's measurements meet applicable requirements.

Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 4731.4468. The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, ACR, ANSI). In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP.

Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used. The calibration procedures should address, in part, the method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an “in air” measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).

Full calibrations must be performed:

- before first medical use;
- whenever spot-check measurements (if required) indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for decay;
- following replacement of the sources;
- following reinstallation of the unit in a new location not previously described in the license;
- following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly; and
- at intervals as defined in 4731.4469, 4731.4470, and 4731.4471.

Other Equipment and Facilities
For Teletherapy, Gamma Stereotactic Radiosurgery (GSR), and High Dose Rate Afterloader (HDR) facilities, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. One method of meeting the requirements of 4731.4467 Subpart D is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source. Applicants may propose an alternative to a permanently mounted monitor.

4731.4467 Subpart E requires that, except for LDR units, each licensee shall construct or equip each treatment room so as to permit continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system should allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

The regulations require adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. 4731.4467 Subpart C, in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on-off control is reset at the console.

Due to the unique characteristics of **Pulsed Dose Rate (PDR) remote afterloaders** and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;

- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:

    - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;
    - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;
    - The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. This circuit must be manually reset to continue treatment;
    - The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times; and
    - No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of one minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees should prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

For patient rooms where **LDR remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

For teletherapy, remote afterloader, and gamma knife facilities, provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and
- Emergency response equipment.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

Item 10: Radiation Safety 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.

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

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.

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), 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:

- Leak Test;
- 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 survey is of external radiation exposure levels in both restricted and unrestricted areas The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective 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.

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 to determine if monitoring is required. Review of dosimetry histories for workers previously engaged in similar duties may be helpful in assessing potential doses.

If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSD), 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 devices 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.

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.
- 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.

Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices
In accordance with 4731.4465 and 4731.4477, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers’ written recommendations and instructions and according to the SSDR. In addition, teletherapy and gamma stereotactic radiosurgery units must be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to ensure that the source exposure mechanism functions properly. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could

expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

MDH requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by MDH, the NRC or another Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use low dose rate remote afterloaders should review 4731.4465 before responding to this item. An AMP can perform certain service activities with regard to low dose rate remote afterloader units.

If the licensee contracts with personnel who are licensed by MDH or an Agreement State to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the licensee, no additional information is necessary. However, if the applicant requests that an employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the applicant must provide sufficient information to allow the MDH to evaluate and approve such authorization. This should include the following:

Name of the proposed employee and types of activities requested;

AND

Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested;

AND

Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

Note: The applicant should specify only the installation, maintenance, inspection, adjustment, and repair functions described in a certificate or letter from the manufacturer of the device that documents the employee's training in the requested function(s).

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 kit supplier and company who will analyze the samples. Commit to the following or submit your own procedures.

- Identify the sources to be tested. This should include the isotope, the activity on a specified date, and the physical form.
- 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.
- 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:
    - Take the wipe with the sources in the shielded position.
    - 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.

Item 11: Waste Management

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

Item 12: License Fee

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

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

Item 13: Certification

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

AMENDMENTS TO A LICENSE

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

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or

changed, submit a signed application for a license amendment and include the appropriate amendment fee.

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

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

RENEWAL OF A LICENSE

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

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

IMPLEMENTATION

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

INSPECTIONS

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

APPENDIX A
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

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

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

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

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 and Therapeutic Procedures."

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

Model Procedure

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include 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% 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 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 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 or therapy device used. Records of worker training will be maintained for at least 3 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., dosimetrists, technologists, and therapists) may contain the following elements for those who provide or are involved in the care of patients during therapeutic 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;
- 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;
- 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 Therapeutic Treatment Planning

In addition to the topics identified above, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., RSO, Authorized Medical Physicist, Authorized User and Dosimetrist) in the following topics, *commensurate with their duties*:

- Leak testing of sealed sources (4731.4424);
- Emergency procedures (including emergency response drills) (4731.4466);
- Operating instructions (4731.4407, 4731.4466);
- Computerized treatment planning system (4731.4478);
- Dosimetry protocol (4731. 4468);
- Detailed pretreatment quality assurance checks (4731.4407, 4731.4466);
- 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 to ensure that treatment is to the correct site (for Gamma Stereotactic Radiosurgery, correct positioning of the helmet) (4731.4409);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (4731.4466);
- Size and appearance of different types of sources (4731.4466);
- Previous incidents, events, and/or accidents; and

For remote afterloaders, teletherapy units, and GSR units; initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model specific and includes:

- Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;
- Hands-on training in actual operation of the device under the direct supervision of an experienced user including "dry runs" (using dummy sources) of routine patient set-up and treatment and implementation of the licensee's emergency procedures;
- A method of determining each trainee's competency to use the device for each type of proposed use, such as practical examinations.

Additional Training for Authorized Medical Physicists
Applicants for licenses to include Authorized Medical Physicists who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in 4731.4412. Note, for example, that additional training is necessary for an Authorized Medical Physicist planning tasks such as remote afterloader therapy, teletherapy, gamma stereotactic radiosurgery therapy, the use of the treatment planning system that applicants contemplate using, as well as calculation of activity of Sr-90 sources used for ophthalmic treatments (4731.4456). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

Additional Training for Authorized Users of Radioactive Materials Requiring a Written Directive
Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements, attention should be focused on the additional training and experience necessary for treatment planning and quality control system, and clinical procedures. .

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 perform 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

(RESERVED)

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 and Therapeutic Procedures."

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

Contents of Survey Records
Survey records should include the following:

- A diagram of the area surveyed or a list of items and equipment surveyed
- Specific locations on the survey diagram where wipes test were taken
- Radiation or contamination levels with appropriate units
- Date of survey
- Manufacturer's name, model number, and serial number of each instrument used
- Name or initials of the person making the evaluation and recording the results.

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

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. State on your application, "We have developed Model Leak Testing Procedures for your review that are appended as Appendix F," 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 five days of the leak test in accordance with 4731.4527.

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

If you prefer, you may develop your own 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 G," 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 therapeutic dose of radiation from radioactive material. 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 radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an Authorized Medical Physicist, a Dosimetrist, and a Radiation Therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures.

To help ensure that all personnel involved in the treatment fully understand instructions in the written directive or treatment plan, 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 (e.g., an oncology physician, AMP, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities, (e.g., teletherapy, HDR, and gamma stereotactic radiosurgery (GSR). 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 and 4731.4409, 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;
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices; and
- Determine and record the activity of the radiation dose before medical use.

Procedures for Any Therapeutic Dose
Develop, implement, and maintain procedures to meet the objectives of 4731.4408 and 4731.4409. The following is a model procedure:

- An AU must date and sign a written directive prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.
- Prior to administering a dose or dosage, the patient's or human research subject's identity will be positively verified as the individual named in the written directive. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or social security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the written directive or treatment plan. All components of the written directive (total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the written directive.

Additional Procedures for Devices Containing Sealed Therapeutic Sources
Licensees are required to have written directives for certain administrations of doses and to have procedures for administrations for which a written directive is required. Model procedures for meeting these requirements appear below.

- To ensure that the dose is delivered in accordance with the written directive, the Authorized User (and the neurosurgeon for gamma stereotactic radiosurgery therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the written directive.
- Dose calculations will be checked before administering the prescribed therapy dose. An Authorized User or a qualified person under the supervision of an Authorized User (e.g., an Authorized Medical Physicist, Oncology Physician, Dosimetrist, or Radiation Therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:
    - For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).
    - For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
    - For manually-generated dose calculations, verifying:
        - No arithmetic errors;
        - Appropriate transfer of data from the written directive, treatment plan, tables and graphs;
        - Appropriate use of nomograms (when applicable); and
        - Appropriate use of all pertinent data in the calculations.

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using

computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

- Acceptance testing will be performed by a qualified person (e.g., an Authorized Medical Physicist) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.
- Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:
    - An individual who did not perform the full calibration using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 4731.4468); or
    - An Authorized Medical Physicist (or an Oncology Physician, Dosimetrist, or Radiation Therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.
- For gamma stereotactic radiosurgery, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.
- A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes:
    - field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or
    - transmission factors for beam-modifying devices (except non-recastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
- A weekly chart check will be performed by a qualified person under the supervision of an Authorized User (e.g., an AMP, Dosimetrist, Oncology Physician, or Radiation Therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the written directive or treatment plan.
- Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

Conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

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 H
Leksell Gamma Knife® Perfexion™ - Licensing Guidance

Although the Leksell Gamma Knife® Perfexion™ is a gamma stereotactic radiosurgery unit, it includes a number of engineering changes that make its components and operation significantly different from the gamma stereotactic radiosurgery units currently regulated in 4731.4463 as a "Remote Afterloader, Teletherapy or Gamma Stereotactic Radiosurgery Unit." As a result, the US Nuclear Regulatory Commission (NRC) has opted to regulate the Perfexion™ in accordance with 10 CFR 35.1000[1] "Other Medical Uses of Radioactive Material or Radiation from Radioactive Material." Nevertheless, the Minnesota Department of Health (MDH) has chosen to license the Perfexion™ the same as other gamma stereotactic radiosurgery units in accordance with 4731.4463 and to address the unique features and operations of that device by requiring commitments from the licensee and/or imposing license conditions.

Radionuclides, Form, Possession Limits, and Purpose of Use

Identify the radionuclides, chemical/physical form, maximum possession limit, and purpose of use. For example, the following provides the format for an acceptable request:

Item 5 - Radionuclides	Item 6 - Form	Item 7 - Possession Limits
Cobalt -60	Sealed sources (manufacturer and model number, e.g. Elekta model 43685 or General Electric AB ELEKTA model 43047)	192 sources with a mean average not to exceed 34.375 curies and no single source to exceed than 36 curies. Total activity in the device not to exceed 6,600 curies. Total possession during source exchange not to exceed 10,000 curies.

Item 8. Purpose of Use For medical use in the Leksell Gamma Knife® Perfexion gamma stereotactic radiosurgery unit

Facility Address and Description

Provide an address of use and submit a facility diagram and description of the location where the Perfexion gamma stereotactic radiosurgery unit will be used, or stored.

Authorized Individuals

MDH has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the Perfexion gamma stereotactic radiosurgery unit. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by MDH staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individuals are qualified to be authorized individuals.

MDH will not require individuals authorized for use of other gamma stereotactic radiosurgery units to obtain a preceptor statement for use of the Perfexion. For all other individuals, the MDH is postponing requiring a written attestation until July 1, 2009. MDH will continue to review the availability of preceptors and may revise this guidance in this respect at such time as it determines that sufficient preceptors have become available. In addition, all individuals seeking authorization for use of the Perfexion must submit documentation of successful completion of required training.

[1] 4731.4404 in MDH rules.

Authorized Users
Identify each authorized user of the Perfexion gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in the use of the Perfexion unit. MDH Form 313S (AU), "Authorized User Training and Experience and Preceptor Attestation" or other formats may be used to document this training and experience. The physician will be considered qualified for use of the Perfexion gamma stereotactic radiosurgery unit if the individual meets the requirements of 4731.4479.

For all other physicians applying on or after July 1, 2009, a written attestation from a preceptor Authorized User that the individual has satisfactorily completed the above training and has achieved a level of competency sufficient to function independently as an Authorized User for the Perfexion unit. The written attestation must be signed by a preceptor Authorized User who is authorized for the Perfexion unit.

Authorized Medical Physicists
Identify each AMP for the Perfexion gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in the use of the Perfexion unit. MDH Form 313B (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation," or other formats may be used to document this training and experience. The medical physicist shall be considered qualified for use of the Perfexion gamma stereotactic radiosurgery unit, if the individual meets the requirements of 4731.4412

For all other individuals applying on or after July 1, 2009, a written attestation that the individual has satisfactorily completed the above training, and has achieved a level of competency sufficient to function independently as an AMP for the Perfexion unit. The written attestation must be signed by a preceptor AMP authorized for the Perfexion unit.

Radiation Safety Officer
Identify the Radiation Safety Officer (RSO) with responsibility for the Perfexion gamma stereotactic radiosurgery unit and provide documentation of his/her training and experience in radiation safety for the Perfexion unit. MDH Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation," or other formats may be used to document this training and experience. MDH recognizes that some applicants with new installations could have an individual who will have RSO responsibilities for the Perfexion unit but may not have access to an operational Perfexion unit at the time of the radiation safety, regulatory issues, and emergency procedures training. For this reason, the applicant may commit that the individual will complete supplemental hands-on radiation safety and emergency procedure training before first patient treatment. The individual shall be considered qualified to be the RSO for the Perfexion gamma stereotactic radiosurgery unit if the individual meets the requirements of 4731.4411.

For all other individuals applying on or after July 1, 2009, a written attestation, signed by a preceptor (RSO, AMP, or Authorized User authorized for the Perfexion, that the individual has satisfactorily completed the above training and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for the medical use of the Perfexion gamma stereotactic radiosurgery unit.

Written Directives
The Perfexion gamma stereotactic radiosurgery unit delivers a therapeutic dose of radiation from radioactive material and in accordance with 4731.4408 requires a written directive. Unlike earlier gamma stereotactic radiosurgery units, calculation of the dose to the treatment site is now dependent on the shaping of the radiation field at the focal point by selection of different collimators for each of the eight sectors. Therefore, to assure the dose is delivered in accordance with the Authorized User's direction, the written directive for each treatment shot should include the sector positions in addition to the target coordinate settings. The applicant should provide the following commitment:

"For the Perfexion gamma stereotactic radiosurgery unit use, the written directive will contain the patient or human research subject's name; the total dose; the treatment site; and the values for the target coordinate settings and sector settings for each treatment shot within an anatomically distinct treatment site."

When a written directive is needed, licensees are required in accordance with 4731.4409 to have procedures that provide high confidence that each administration is in accordance with the written directive. These procedures are required to address, among other things, verifying that any computer-generated dose calculations are correctly transferred into the consoles of gamma stereotactic radiosurgery medical units. For the Perfexion gamma stereotactic radiosurgery unit, the computer generated dose calculations for each shot (i.e., each set of target coordinates) should also include the sector settings for that shot. For this reason, the applicant should provide the following commitment:

"For the Perfexion™ unit, procedures that provide high confidence that each administration is in accordance with the written directive will address verifying that any computer-generated dose calculations (including target coordinate and sector settings) are correctly transferred into the Perfexion console."

A number of medical events with earlier models of gamma stereotactic radiosurgery units resulted from movement of the head frame or head frame pins during coughing and other patient movement. As part of its program to provide high confidence that the administration is in accordance with the written directive, the applicant should develop written procedures for the following:

- pausing treatment and checking the patient set-up if a patient is observed to move during the course of a treatment shot and
- visually checking the patient set up each time the gamma angle is changed or at the end of the treatment run, which ever comes first.

The applicant should confirm the following:

"Our program to provide high confidence that the administration is in accordance with the written directive will include written procedures for pausing treatment and checking the patient set-up if a patient is observed to move during the course of a treatment shot and visually checking the patient set up each time the gamma angle is changed or at the end of the treatment run, which ever comes first."

Specific Information on Radiation Safety Precautions and Instructions
The applicant must submit the information required by 4731.4403. Because the Perfexion unit is a gamma stereotactic radiosurgery unit, the applicant may simplify its submission by confirming the following:

"For use of the Leksell Gamma Knife® Perfexion™ unit, we will meet the following requirements for a gamma stereotactic radiosurgery unit in Chapter 4731:

- 4731.4463,
- 4731.4465 (and retain records of the information described in 4731.4415 until the licensee no longer possesses the gamma knife),
- 4731.4466 (and retain procedures described in 4731.4466 until the licensee no longer possesses the gamma knife),
- 4731.4467,
- 4731.4468 (and retain a copy of the information described in 4731.4468 until the licensee no longer possesses the gamma knife),

- 4731.4471 (with modifications discussed below and retain a copy of the information described in 4731.4518 with modifications discussed below for three years),
- 4731.4474 (with modifications discussed below and retain a copy of the information described in 4731.4474 with modifications discussed below for the three years), and
- 4731.4478.

Unlike earlier models, the sources in the Perfexion unit are located in the sectors which move. Therefore, radiation surveys required in 4731.4476 will be required following any repairs to the source driving unit or to other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

The applicant should confirm the following:

> "We will follow the survey requirements of 4741.4476 and make the surveys at installation of a new source and following repairs to the source(s) shielding, the sector drive unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). We will retain information for the duration of the use of the unit."

Because the source exposure indicator for the Perfexion unit is on the treatment room wall instead of on the gamma stereotactic radiosurgery unit and the Perfexion unit does not include helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, or a trunnion centricity point, the requirements in 4731.4471 and 4731.4474 to determine these values or test these components cannot be performed and the results of such determinations and tests cannot be recorded.

The applicant should confirm the following:

> "We will follow the full calibration requirements of 4731.4471 and the spot-check requirements in 4731.4474 and retain the information described in 4731.4518 for each full calibration and 4731.4521 for each check except for those involving helmets, helmet factors, helmet microswitches, trunnions, hydraulic backup of the treatment table retraction system, or source exposure indicator lights on the unit. We will keep each record of the full calibration and spot-checks for three years."

The purpose of determining the helmet factors, determining trunnion centricity, testing the helmet switches and testing the trunnions of previous gamma stereotactic radiosurgery models was to assess whether the patient docking systems functioned correctly to place the mechanical center (x = 100 millimeters (mm), y = 100 mm, and z = 100 mm) of the stereotactic frame at the radiation focal point, to know the size of the radiation focal point by confirming the collimator sizes, and to test the precision with which the treatment site could be placed at the radiation focal point and the accuracy of the dose calculations. New tests should be performed as part of the revised spot test and full calibration test to assess these basic properties for the Perfexion unit.

In earlier models, the collimator (i.e., the helmet) was attached to the bed and the patient's head was attached to the helmet by the stereotactic head frame. This configuration resulted in a stationary bed and helmet docked in the gamma knife unit at a fixed and reproducible location. The stereotactic frame was moved small distances to center the treatment site at the radiation focal point. For the Perfexion unit, the patient's head in the stereotactic head frame is attached in an "immovable" position to the bed (by the docking device and frame adapter) and the bed itself is moved over small distances to center the treatment site at the radiation focal point.

The individual removable collimator helmets have been replaced by eight permanently installed independently movable sectors in the Perfexion unit. The eight sectors contain the radiation sources and

are mounted on the collimator body. The collimator body contains three different sets of fixed collimator apertures (4 mm, 8 mm, and 16 mm) as well as two shielded positions (off and home). The angle of each collimator aperture is set so that the focal point remains constant. The location of each sector determines the collimation for that set of sources. The collimator cap isolates the patient from the collimators and blocks the view of the collimator body. While increasing treatment flexibility, this configuration prevents the Authorized User or Authorized Medical Physicist from visually confirming the collimation before initiating a set of treatment shots.

Therefore, location and/or function of the sectors, the patient bed, the docking device, the frame adapter, and source exposure indicator light on the wall of the treatment room are critical to the safe use of and proper functioning of the Perfexion unit, and should be tested as part of the spot-checks and full calibration test. Also, the condition and function of the clearance test tool and "QA" test tool are critical to determining the location of the radiation focal point, table location, and frame adapter function. For these reasons, the applicant should commit to the following actions:

> "Before each patient use, we will confirm that the frame adapter is functioning correctly and can be attached correctly to the coordinate frame. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for three years."
>
> "Before the first use of the Perfexion™ unit each day, we will confirm that the docking device is securely mounted to the table and that the frame adapter can be correctly docked in the docking device. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for three years."
>
> "Before the first use of the Perfexion™ unit each day, we will confirm proper functioning of the source exposure indicator light on the treatment room wall. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for three years."
>
> "On a monthly basis, we will confirm that the location of the radiation focal point, with respect to the table position, is within the specifications provided by the manufacturer. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for three years."[2]
>
> "On a monthly basis, we will confirm that the location of the table at a number of off center positions is within the collision specifications provided by the manufacturer. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for three years."[3]

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[2] Note: At this time, the test can only be performed with the diode centered in the test tool. If, at a later date, a test is developed that uses a diode or other radiation measurement precisely located in an off-centered position, this test should also be performed to verify table position.

[3] At this time the clearance test check tool is used to test for collisions. If, at a later date, this tool or another can be used to test the off center positions of the table, the tool or test should also be used to verify table position accuracy.

"Approximately every six months (with exact date subject to vendor service availability), we will confirm that each sector moves correctly to each position within appropriate tolerance limits. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for three years."[4]

"We confirm that if the frame adapter fails to perform as designed, we will remove it from service until repaired."

"We confirm that if the docking device, sector location, sector movement, or table positioning fail to perform as designed, we will lock the control console in the off position and not use the unit except as necessary to repair, replace, or check the malfunctioning system."

"We confirm that if either the clearance test tool or "Quality Assurance (QA)" test tool fails to function as specified by the manufacturer, we will have the tool repaired or replaced before the next patient treatment requiring the proper function of that tool."

"We confirm that removal or major repair of the components associated with the sector assemblies will be considered a major repair of the source assembly and will require full calibration."

Accepted Published Protocols

Full calibration measurement procedures for gamma stereotactic radiosurgery units are required by 4731.4471 to be in accordance with published protocols accepted by nationally recognized bodies. However, the Leksell Gamma knife® Perfexion™ unit contains components and features that are not addressed in the full calibration procedures accepted and published by nationally recognized bodies. In this case, the applicant may use procedures developed by the manufacturer.

The applicant should confirm the following:

"We will perform full calibration measurement procedures in accordance with published protocols accepted by nationally recognized bodies, except when nationally recognized bodies have not published required full calibration procedures for components and features of the Perfexion™ unit. In the absence of published protocols for the Perfexion™ unit accepted by nationally recognized bodies, we will use procedures developed by the manufacturer."

Procedures Required by 4731.4466 and 4731.4474

For the Perfexion unit radiation safety program only the procedures in 4731.4466 and 4731.4474 are appropriate. It is not necessary for the applicant to provide spot-check procedures for determining proper function of helmet microswitches, trunnion centricity, or source exposure indicator light on the unit because the Perfexion unit does not have components needed for these tests. However, the applicant should provide additional daily spot-check procedures for proper operation of the frame adapter, docking device, and source exposure indicator light on the wall of the treatment room, additional monthly spot-check procedures for the location of the radiation focal point with respect to the table position, and

[4] At this time, the vendor can demonstrate at time of installation or major repair for the licensee's verification that the sector locations and numbers agree with the computer screen display and the vender can perform a physical measurement of each sector rod location at each position during the routine six month service. The licensee may use data from the vendor's measurements to assess sector movement and alignment. If, at a later time, a test is developed that permits the licensee to determine each sector's alignment and proper movement, this test should also be used to verify sector alignment and proper movement.

collision table location, and a six month spot-check procedure (with exact date subject to vendor service availability) for verification of correct sector movement and location.

The applicant must provide a copy of:

- Safety procedures and instruction for the Perfexion unit, and
- Spot-check procedures for the Perfexion unit.

Full Inspection and Service of the Perfexion Unit
Under 4731.4477, MDH requires a five-year inspection for gamma stereotactic radiosurgery units or at source replacement, whichever comes first. While a number of systems external to the radiation vault can be inspected and serviced prior to source replacement, areas inside the vault can only be inspected and serviced in the absence of the sources. Therefore, the full inspection and service of the Perfexion™ unit can only be performed at source exchange.

The applicant should confirm the following:

> "We will commit to have each Perfexion™ gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism.
>
> This inspection and servicing will only be performed by persons specifically licensed to do so by the Commission or an Agreement State.
>
> We will retain records of the information described in 4731.4524 for the duration of the use of the unit."

Suggested Revisions to Existing Perfexion Programs to Conform to this Licensing Guidance[5]
The above licensing guidance may be revised as additional experience is gained regarding medical use of the Perfexion gamma stereotactic radiosurgery unit. A licensee already authorized to use the Perfexion gamma stereotactic radiosurgery unit and committed by license condition to follow the provisions in the guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform to the revised provisions.

An applicant initially applying for authorization for medical use of the Perfexion™ gamma stereotactic radiosurgery unit (or a licensee applying later for an amendment to conform to revisions in this guidance) may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

- The revision is in compliance with the regulations of the NRC or Agreement State;
- The revision is based on the current guidance for the Perfexion gamma stereotactic radiosurgery unit 35.1000 use posted on the NRC website;
- The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;
- The affected individuals are instructed on the revised program before the change is implemented;
- The licensee will retain a record of each change for five years; and
- The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that

[5] Requesting authorization in accordance with the following guidance will permit a licensee to make certain changes in accordance with 4731.4405, Radiation Protection Program Changes to the Perfexion gamma stereotactic radiosurgery unit safety program that might otherwise require a license amendment.

reviewed and approved the change.

If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license.

Licensee Commitments and/or Potential License Conditions for the Leksell Gamma Knife® Perfexion™

1. The licensee shall have written standard operating and emergency procedures. The emergency procedures shall be available and include:

   A. The means of controlling radiation exposures to personnel while manually closing the shield doors and/or removing a patient from the unit if the sliding cradle fails to retract as designed.

   B. A cautionary statement that individuals should not enter the treatment room under normal operating conditions until the radiation unit's shield doors are fully closed.

2. The gamma knife operator and teletherapy physicist must receive training on operating and emergency procedures prior to using the unit. Refresher training in emergency procedures must be performed annually.

3. The written directive for the Perfexion™ must:

   A. Contain the patient or human research subject's name; the total dose; the treatment site; and the values for the target coordinate settings and sector settings for each treatment shot within an anatomically distinct treatment site.

   B. Address verifying that any computer-generated dose calculations (including target coordinate and sector settings) are correctly transferred into the Perfexion console.

   C. Include written procedures for pausing treatment and checking the patient set-up if a patient is observed to move during the course of a treatment shot and visually checking the patient set up each time the gamma angle is changed or at the end of the treatment run, which ever comes first.

4. Before each patient use, the licensee must confirm that the Perfexion™ frame adapter is functioning correctly and can be attached correctly to the coordinate frame. This test and the description of the record of the test must be included in the spot-check procedures. The test must also be performed during the full calibration measurements of the Perfexion™ unit. The licensee must keep each record of the results of these tests for three years.

5. Each day before the first use unit, the licensee must confirm that the Perfexion™ docking device is securely mounted to the table and that the frame adapter can be correctly docked in the docking device. The licensee must also confirm proper functioning of the source exposure indicator light on the treatment room wall. The tests and the description of the record of the test must be included in the spot-check procedures. The tests must also be performed during the full calibration measurements of the Perfexion™ unit. The licensee must keep each record of the results of these tests for three years.

6. On a monthly basis, the licensee must confirm that the location of the radiation focal point with respect to the table position is within the specifications provided by the Perfexion™ manufacturer. The license must also confirm that the location of the table at a number of off center positions is within the collision specifications provided by the manufacturer. The tests and the description of the record of the test must be included in the spot-check procedures. The tests must also be performed during the full calibration measurements of the Perfexion™ unit. The licensee must keep each record of the results of these tests for three years.

7. Every six months (subject to vendor service availability), the licensee must confirm that each sector moves correctly to each position within appropriate tolerance limits. This test and the description of the record of the test must be included in the spot-check procedures. The test must also be performed during the full calibration measurements of the Perfexion™ unit. The licensee must keep each record of the results of these tests for three years.

8. The licensee shall assure that the preventive maintenance checks are performed at intervals prescribed by the gamma knife manufacturer.

9. The licensee is not authorized to perform any maintenance, modifications, or adjustments to any components on the radiation unit, patient positioning system, or control system (except general cleaning and replacement of lamps or microphones). All other maintenance shall be performed only by the manufacturer or by other persons specifically licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such services.

10. The licensee shall make the surveys of the Perfexion™ at installation of a new source and following repairs to the source(s) shielding, the sector drive unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). The information must be retained for the duration of the use of the unit.

11. If the Perfexion™ frame adapter, docking device, sector location, sector movement, or table positioning fail to perform as designed, the licensee must remove it from service until repaired.

12. If either the Perfexion™ clearance test tool or "Quality Assurance (QA)" test tool fails to function as specified by the manufacturer, the licensee must have the tool repaired or replaced before the next patient treatment requiring the proper function of that tool.

13. Removal or major repair of the components associated with the Perfexion™ sector assemblies must be considered a major repair of the source assembly and must require full calibration.

14. The licensee is may not install equipment that produces high levels of electromagnetic disturbance in close proximity to the gamma knife, its console, or related components.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION
02/17/08	Appendix E	Survey records - Added requirements in 4731.2510
02/17/09	Appendix D	Extracted the checklist and incorporated it in separate guidance.