IOWA DEPARTMENT OF PUBLIC HEALTH

GAMMA STEREOTACTIC RADIOSURGERY REGULATORY GUIDE

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Bureau of Radiological Health
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1. INTRODUCTION

1.1 -- GENERAL

The Iowa Department of Public Health (IDPH) regulates the intentional internal or external administration of by-product material or the radiation therefrom, 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 Iowa Radiation Machines and Radioactive Materials Rules, Chapter 641-41.2

The Iowa Department of Public Health usually issues a single by-product material license to cover the radioisotope program. However, separate licenses must be obtained for the following applications:

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

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the regulations identified in Chapter 641-41.2 and should then complete the application form, IDPH Form 299-0514. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program.

1.1.1 -- PURPOSE OF GUIDE

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

1.2 -- APPLICABLE REGULATIONS

In addition to 641-41.2, other regulations pertaining to the medical use of by-product material are found in Chapters 38, 39, and 40 of the Radiation Machines and Radioactive Materials Rules. You may go to www.idph.state.ia.us and click on Health Protection and Environmental Health. Follow the links to the Bureau of Radiological Health. The regulatory guides can be found by further following the links to Radioactive Materials.

1.3 -- AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states "...In addition to complying with the requirements set forth in this Chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA)." As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

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

that commitment with adequate resources. A Radiation Safety Committee (RSC) composed of individuals who have special expertise in the safe use of by-product material is required by 641-41.2(9) to review uses for safety and ALARA considerations.

The Radiation Safety Committee, the Radiation Safety Officer (RSO), and management are required to audit the by-product material program to ensure the continued safe use of by-product material. In addition to being a member of the RSC, the RSO serves as a technical consultant to the committee and is responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing form 229-0514, "Application for Radioactive Materials License." You should complete Items 1 through 5, and 14/15 on the form itself. For Items 6 through 12, submit the required information on supplementary pages. Identify each sheet or document with the item number on the application. All typed papers, 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, fold them to 8 1/2 x 11 inches.

You should complete all items in the application in enough detail for the IDPH to determine that your equipment, facilities, training, 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 public in the IDPH 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 propriety 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 IDPH.

Retain a copy of your application because the license will be issued based on the statements and representations in your application and any supplements to it. The statements and representations you make will bind you as if they were regulations.

3. CONTENT OF APPLICATION

This portion of the guide explains, item by item, the information requested on IDPH Form 229-0514. The appendices to this guide will provide:

- additional information on certain subject areas;
- a model procedure the applicant may adopt in response to an item on the application form;
- an outline the applicant may use to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, or call 515-281-3478.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual applicant, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 1.b.

ITEM 1.b. -- LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. If by-product material is to be used at more than one location, you must give the specific address of each location. In items 6 through 12 of the application, describe the intended use and the facilities and equipment at each location.

ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions only about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only. It would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to the CEO with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee is provided in writing to IDPH.

The IDPH recognizes that licensees may use a consulting service to help prepare the license application and provide support to the radiation safety program. However, if you choose to have the consultant the point of contact for any IDPH questions, we remind you that the licensee management is ultimately responsible for all aspects of the program. This includes any services performed by the consulting service.

ITEM 3. -- LICENSE INFORMATION

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated for amendments or renewals.

ITEM 4. -- INDIVIDUAL USERS -- TRAINING AND EXPERIENCE

Responsible individuals are the authorized users and the RSO. The applicant is required by 641-39.4(25) to be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. The specific criteria for acceptable training and experience for authorized users and the RSO is provided in 41.2(65) through 41.2(77). Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

4.1 -- AUTHORIZED USERS FOR MEDICAL USE

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

1. Examination of patients and medical records to determine if a radiation procedure is appropriate;
2. Prescription of the radiation dosage or dose and how it is to be administered;
3. Actual use or direction of technologists or other paramedical personnel in the use of by-product material;
4. Interpretation of diagnostic procedures and the evaluation of therapy procedures.

Numbers 1 through 4 may be delegated to a physician who is under the direct supervision of an authorized user. Technologists or other personnel may use by-product material under an authorized user's supervision when permitted under Chapter 42. Supervision is defined in 641-41.2(11).

A. If a physician has been previously authorized for medical use and wishes to use material permitted by the previous Iowa Department of Public Health license, you only need to submit the previous license number. You should submit a copy of the license on which the physician was specifically named as an authorized user if the license was issued by any other Agreement State or the US NRC.

B. If a physician is certified by an organization listed in the appropriate section of 641-41.2(65-77), submit Supplement A with Items 1,2, and 3 completed. A physician certified as a British "Fellow of the Faculty of Radiology (FFR) or "Fellow of the Royal College of Radiology" (FRCR) should submit a copy of the certificate and evidence of specialization in radiation therapy.

C. Physicians not previously authorized by NRC or an Agreement State and not certified by an appropriate organization must submit a complete description of their training and experience using Supplements A and B. This documentation will be reviewed on a case-by-case basis.

D. All training and experience shall have been obtained within the five years preceding the date of application or the individual must submit verification of continuing applicable experience since the required training and experience was completed. See 41.2(77).

E. Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users. 641- 41.2(65 through 77) must be used as a guide. The criteria may include a provision that allows the applicant's Radiation Safety Committee to grant case-by-case exceptions.

4.2 -- AUTHORIZED PHYSICIST

A. Submit a copy of the NRC or Agreement State license on which the physicist is authorized as either a teletherapy or a brachytherapy physicist.

B. If the license is of limited scope, you should submit information verifying that the proposed authorized physicist meets the requirements of 641-41.2(74).

C. If license is a broad scope, you should state that the Radiation Safety Committee will approve physicists who meet requirements specified in 641-41.2(74).

4.3 -- SUPERVISION

Authorized user supervision requirements are outlined in 641-41.2(11).

Gamma stereotactic devices are sophisticated in design and capable of delivering an extremely high dose in a relatively short time. Considering this, the IDPH requires that the medical physicist be readily available during patient treatment. This will provide the technical expertise needed in the case of equipment failure.

You must provide a commitment to have the radiation physicist present during patient treatment.

ITEM 5. -- RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using Supplement A. Even if the licensee employs a consultant as RSO, the licensee is still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals and in a safe manner.

ITEM 6. -- RADIOACTIVE MATERIAL

A. SOURCE DESCRIPTION

Provide the following information for each radionuclide:

1. Radionuclide.

2. Manufacturer’s name and model number.

3. Maximum activity per device. The activity may not exceed the activity specified by the manufacturer for the specific device and source combination.

4. Maximum number of sources to be possessed at any one time. You may wish to request authorization for sources used in the device and additional sources for replacement. The replacement sources will be stored in a shipping container(s) until the manufacturer completes the change out. If more than one source model is referenced in item 2, you should indicate the maximum number of sources requested of each model number.

5. Maximum activity of the individual sources(s).

6. If applicable, you should request authorization for possession of depleted uranium in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange. Review and indicate the manufacturer’s specifications for each device to determine the total quantity of depleted uranium present in the device in units of kilograms. Indicate whether depleted uranium is used for shielding the source(s) within the device.

B. DEVICE DESCRIPTION

1. Specify the manufacturer's name, address, and telephone number for each device requested, and

2. Indicate the model name and/or number and serial number for each device requested.

ITEM 7. -- PURPOSE

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

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the program. List the full name of the individual proposed as a medical physicist.

ITEM 9. -- TRAINING FOR INDIVIDUALS

A. Submit outlines of initial training that you give to authorized physician-users and device operators. Include a description of the didactic portion of the training and the minimum hours of "hands on" device operation training that will be provided. Training should be specific to the device model, and include the following:

1. Radiation protection and instrumentation, including the proper use of personnel dosimeters, survey instruments, and radiation monitors.

2. The operating and emergency procedures.

3. Design, use and function of the device, including safety systems.

4. On-the-job training in actual operation of the device under the direct supervision of an experience device user. This aspect of the training should include "dry runs" of routine patient set-up and treatment, as well as implementation of emergency procedures.

5. Method of determining each trainee's competency to use the device.

B. Submit the name, affiliation, and qualifications of the instructor(s) conducting the training. A description of the trainer's experience in use of the specific device(s) for which training will be provided should also be included.

C. An outline of the topics to be covered during periodic retraining of device operators should be submitted and you should confirm that retraining will be conducted at intervals not to exceed 12 months. You should also confirm that retraining will include practice in implementing licensee's emergency procedures (dry run).

D. Submit a description of the orientation training that will be provided to ancillary staff. The training should include nurses, technologists, security staff, and custodians who provide patient care during treatment or who frequent areas where the gamma stereotactic radiosurgery device

is used or stored. This training should meet the requirements of 641.40.111(136C) and 641-41.2(44). You should confirm that the staff will be provided refresher training, as appropriate, at intervals not to exceed 12 months. An outline of the training for ancillary personnel should be submitted for review.

E. Confirm that an individual trained in the use of a survey instrument will be present during periods when patient care is performed.

F. Confirm that records of initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years. Such records should include the names of the instructors, the names of attendees, and an outline of the topics discussed.

ITEM 10. -- FACILITIES AND EQUIPMENT

10.1 -- FACILITIES

A. Submit annotated drawings of each dedicated treatment room indicating:

1. Scale, plan and elevation.

2. Identification of the room(s), including room number(s).

3. Type, density and thickness of all shielding materials, including walls, floor and ceiling.

4. The location of the gamma stereotactic unit within the room. Distances from the isotope center of the device should be included.

5. Location of doors, windows, and conduit.

6. Distance to and the nature of use for adjacent areas with indication of whether the areas are restricted or unrestricted, as defined in Chapter 38 of the Iowa Rules.

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

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

!0.2 -- EQUIPMENT

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

1. The primary intercom and viewing systems.

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

You should describe how:

- the patient and device will be monitored during treatment;

- how to provide for prompt detection of any operational problems with the device during treatment.

B. Provide a description of the security to be provided for the room where a device is to be used or stored. Areas should be secured in accordance with 641-40.55(136C). A description of the following is required:

1. The physical or administrative control of access.

2. The electrical interlock system installed at each entry, including the result of interrupting the interlock when the source is exposed.

3. The actions required following interruption of the interlock before resuming treatment, including confirmation that the interlock must be reset before the device can be activated.

4. The actions required in case of malfunction of the interlock system. You should confirm that if the system malfunctions, the shielding doors will be closed. Verify that the system will not be used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

5. The restricted area controls (e.g., signs, locks, visible and audible alarms, etc.), including descriptions of signs with their locations, sizes and wording. Each suite containing a gamma knife should be equipped with a radiation monitor. The monitor should be permanently mounted and equipped with an emergency power supply separate from the gamma knife unit itself. The monitor must be capable of providing a visible indication (e.g., flashing light, or "Beam On" light) of an exposed or partially exposed source. The indicator must be readily observable by any person entering the treatment room.

6. Provide the method(s) used to identify the high radiation areas inside the treatment room when the shield doors are open (e.g., colored floor tiles, warning tape, etc.).

7. The method to ensure that whenever the device is not in use or is unattended, the console key(s) will be inaccessible to unauthorized persons.

8. You should confirm that no other radiation-producing devices are located in the treatment room, or provide a description of the mechanisms installed to ensure that only one device can be placed in operation at a time.

9. Verify that the gamma knife, its control console, or any related components are not within close proximity of equipment that produces a high level of electromagnetic disturbance (i.e., short wave equipment). Those fields have been demonstrated to interfere with the operation of the gamma knife control system.

C. To demonstrate compliance with 641-40.26(136C), submit detailed calculations of maximum radiation levels (and dose rates) that will exist in each area (restricted and unrestricted). The calculations should include the following:

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

- room size
- layout
- treatment time

These calculations should be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s) meet the requirement of 641-40.15(136C) and 40.26(136C).

2. Specify all parameters used to perform the calculations described above. These parameters should include such factors as distance to each area of concern, the type and thickness of material(s) used in barriers and shields, and the transmission factor of the barriers or shields, and the maximum source strength.

3. The maximum anticipated workload data, such as maximum "on time" per hour and per week that will be used in a dedicated room and occupancy factors used for all adjacent areas.

4. Calculations to determine the dose received by individuals present in unrestricted areas should consider continuous occupancy (occupancy factor of one) unless you can make a compelling argument for using a lower value. Calculations to determine the dose received by ancillary staff providing patient care during should include full details of the occupancy factors used.

5. Results of the calculations are to be expressed in units of rem (or millisieverts) in any one-hour or year, as appropriate.

6. You should demonstrate that the limits specified in 641-40.26(3) will not be exceeded. If your calculations demonstrate compliance with these limits, outline the steps taken to limit exposure to individual members of the public. Options that may be considered include:

   a. Adding shielding to the barrier in question with a corresponding modification of the facility description (if necessary).

   b. Request an exemption and demonstrate how the requirements of 641-40.26(3) will be met. You should demonstrate the need for and the expected duration of operations that will result in an individual dose more than the limits specified in 641-40.26(1). A program to assess and control dose within the 0.5 rem (five mSv) annual limit and procedures followed maintaining the dose as low as is reasonable achievable should be developed and submitted for review.

D. Confirm the implementation of a survey program to demonstrate compliance with 40.26(136C). Submit a description of the program. The program should include requirements for conducting surveys following source replacement. At a minimum, the survey program should be sufficient to confirm the following:

1. Radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure more than the limits of 641-40.15(136C).

2. Radiation levels in unrestricted areas will not result in a dose to any member of the public more than the limits specified in 641-40.26(136C).

3. Records of survey results will be maintained for inspection by the IDPH for the duration of the license.

10.3 -- OTHER EQUIPMENT AND FACILITIES

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

Manufacturer	Model Number	Range
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
LGD Scientific, Inc.	MSB-000	1 - 100000 cpm

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

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

ITEM 11. -- RADIATION SAFETY PROGRAM

11.1 -- PERSONNEL DOSIMETRY

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

B. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, thermoluminescent dosimeter (TLD), optically stimulated dosimeter (OSD), or other approved whole body monitor. The device will be processed by a contract service on a monthly basis if they exceed 500 millirem per quarter. Those licensees whose employees receive exposures of less than 500 millirem a quarter may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:

- supporting documentation that confirms that no employee will exceed 500 millirem/ quarter; and
- proposed frequency of exchange.

Note: The exchange frequency should not be changed without IDPH written approval.

11.2 -- QUALITY MANAGEMENT PROGRAM

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

A. Before administration, a written directive is prepared for any gamma stereotactic radiosurgery radiation dose

B. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive

C. Final plans of treatment and related calculations are in accordance with the respective written directives

D. Each administration is in accordance with the written directive

E. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken

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

11.3 -- OPERATING PROCEDURES

A. Submit a copy of the operating and emergency procedures. Iowa Department of Public Health Radiation Machines and Radioactive Materials Rules 641-41.2(52) provides the safety instructions that are required for operation of this type of device. However, in addition to the rules you may wish to incorporate the following into your operating procedures:

1. The device(s), console, and treatment or storage room will be secured when unattended.

2. During patient treatments, personnel must be immediately available address radiological concerns and to serve as a resource in case of radiological problems. The appropriate personal are:
   - The authorized user
   - The medical physicist
   - The Radiation Safety Officer

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

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

B. Iowa Department of Public Health Radiation Machines and Radioactive Materials Rules 641-41.2(59) provides the output spot checks and the frequency. Confirm that as a minimum, the safety checks will be performed and that written, as well as verbal, instruction will be provided to individuals assigned to complete the checks.

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

11.4 -- EMERGENCY PROCEDURES

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

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

1. The procedures are to be implemented if the source cannot be fully shielded.

2. The means of controlling radiation exposures to personnel while manually closing the shield doors.

3. The means of physically removing the patient from the unit if the sliding cradle fails to retract as designed.

4. Systematic actions for single or multiple equipment failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios.

5. Requirements to restrict and post the treatment area with appropriate signs to minimize the risk of inadvertent exposure of personnel not directly involved in emergency recovery operations.

6. The location the equipment that may be necessary for the various equipment failures described in the procedure.

C. During patient treatments, a device operator trained in the emergency procedures should be physically present at your facility. The medical physicist or Radiation Safety Officer and the authorized user should be available for prompt assistance in the event that the shielding doors become jammed. The authorized user, medical physicist or Radiation Safety Officer should be immediately notified of any problems encountered during a treatment. Device operators will follow the instructions of the authorized user, medical physicist, or the Radiation Safety Officer and implement emergency procedures as necessary.

D. Commit to implement immediately applicable emergency procedures if the survey indicates that the source is not fully in a shielded position.

11.5 -- MAINTENANCE

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

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

- the date of repair
- a description of the nature of the maintenance or repair
- the name of the individual who performed the repair
- the Agreement State or NRC license number authorizing the individual who performed the repairs

B. The requirements for full calibration of the device are included in 641-41.2(58).

C. In addition to a full calibration, the licensee must ensure that each device will be fully inspected and serviced at a frequency not to exceed five years. The specific requirements associated with inspections are included in 641-41.2(64).

D. You may request authorization for an employee trained by the manufacturer to perform maintenance and repair functions. Such authorization should list the employee by name. It should specify the maintenance and repair functions described in a certificate or letter from the manufacturer of the device documenting the training. A copy of the training certification and an outline of the training should be submitted with the request.

11.6 -- LEAK TESTS

As a licensee, you must perform leak testing of sealed sources according to 641-40.32(2). The IDPH 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 options for leak testing are:

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 reports the results to you.

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

For Option 2, specify the kit model number and 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.

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

11.7 -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

40.10(3) requires annual audits. Submit your proposed audit program. Include the following:

- Name of person or group that will perform the radiation safety audit and the auditors qualifications
- Areas that will be audited
- Checklist or guide that the auditor will use in the course of the audit.
- The proposed enforcement program that will ensure deficiencies are corrected

The IDPH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with IDPH rules. Therefore, the consulting service's quality of work and knowledge of IDPH rules should be considered.

ITEM 12. -- WASTE MANAGEMENT

Submit your procedures for waste disposal. Because of the nature of the licensed material contained in the gamma stereotactic radiosurgery device, the only option for disposal is to transfer the material to an authorized recipient. The transfer should be done as soon as practical after there is no further use for the sources.

Authorized recipients are the original suppliers of the sealed sources, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another licensee authorized to possess the licensed material. No one else is authorized to dispose of licensed material.

ITEM 13. -- LICENSE FEES

1. An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at www.idph.state.ia.us. An application received without a fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.

2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.

3. Review 39.4(26) "Financial Assurance and Recordkeeping for Decommissioning." Submit financial assurance as described or provide information that exempts the facility.

ITEM 14, 15 -- CERTIFICATION

The application must be signed by a senior partner, the president, director or chief executive officer. Identify the title of the office held by the individual who signs the application. If the application is for an institution, hospital, or medical center, the director or chief executive officer must sign it.

If the senior partner, president, director, or chief executive officer wishes another person to sign the application, a delegation of authority must be enclosed. The delegation of authority should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later.

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. See 641-41.2(4) for the specific requirements. An application for an amendment must be filed on IDPH Form 299-0514 or as a letter and must be signed by the person delegated in Item 14/15. The appropriate fee must be included.

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

5. RENEWAL OF LICENSE

Licenses are issued for a period of five years. An application for the renewal should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by the IDPH as provided for in 641-39.4(34). The application for 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 IDPH regulations that do not allow you to possess licensable material without a valid license.

6. IMPLEMENTATION

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

7. INSPECTIONS

IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule.

Revision	Section	Description
12/26/00	ALL	Reformat text. Changed address for Bureau of Radiological Health
01/18/01	Section 7	Added information concerning inspections.
03/13/03	Section 1.2	Change address for web access to IDPH rules and publications.
07/01/05	ALL	Changed address for the Bureau of Radiological Health
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.