UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

AUG 0 8 2007

Larry N. Langrill, M.S.
Radiation Safety Officer
MidMichigan Medical Center
4005 Orchard Drive
Midland, MI 48670

Dear Mr. Langrill:

Enclosed is Amendment No. 57 to your NRC Material License No. 21-01549-02 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

This amendment authorizes the new Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions concerning this renewal please contact me at either (630) 829-9841 or (800) 522-3025.

A. **Please note that I could not approve human use of your newly authorized Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit because the information contained in your letter dated July 20, 2007, and facsimile dated August 8, 2007, was insufficient to complete my review.**

In order to pursue this request, please address the information below and submit a written response to my attention, referencing it as "additional information to control number 316424." We will then continue our review.

1. **Please note the following excerpt from the Guidance for licensing the Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit:**

"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 3 years." (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.)"

Please confirm that 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 will also be performed to verify table position.

2. Please note the following excerpt from the Guidance for licensing the Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit:
"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 3 years." (Note: 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.)

   Please confirm that 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 will also be used to verify table position accuracy.

3. Please note the following excerpt from the Guidance for licensing the Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit:

   "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 3 years." (Note: 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.)

   Please confirm that if, at a later time, a test is developed that permits you to determine each sector's alignment and proper movement, this test will also be used to verify sector alignment and proper movement.

4. Please note the following excerpt from the Guidance for licensing the Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit:

"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 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 instructions for the Perfexion™ unit, and Spot-check procedures for the Perfexion™ unit."

I did not find safety procedures and instructions for the Perfexion™ unit, and spot-check procedures for the Perfexion™ unit in your letter dated July 20, 2007. I noted that you submitted data forms for performing these tests but please be reminded that data forms are not an adequate substitute for actual procedures, which describe "how you will perform" each test or check.

Please submit copies of your safety procedures and instructions for the Perfexion™ unit, and spot-check procedures for the Perfexion™ unit.

5. **Please note the following excerpt from the Guidance for licensing the Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit:**

"(Note: Requesting authorization in accordance with the following guidance will permit a licensee to make certain changes under 10 CFR 35.26, "Radiation protection program changes," to the Perfexion™ gamma stereotactic radiosurgery unit safety program that might otherwise require a license amendment).

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 5 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 reviewed and approved the change.

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

Although this authorization is optional, it is recommended that you seriously consider including it, as it could give you the flexibility you need to enhance patient care and safety compliance as you gain experience with the Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit. This authorization may also prevent the need for amending your license in order to incorporate a future guidance enhancement into your licensed program for the Leksell Gamma Knife Perfexion Stereotactic Radiosurgery Unit.

If you wish to include this authorization, please address each item as described above and make an appropriate, explicit commitment.

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025, ext. 9841.

B. NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 21-01549-02
Docket No. 030-02013

Enclosure:

Amendment No. 57