



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

MAR 24 2017

Robert C. Gilliam, M.S.
Radiation Safety Officer
Research Medical Center
Midwest Gamma Knife Center
2316 E. Meyer Blvd.
Kansas City, MO 64132

Dear Mr. Gilliam:

Enclosed is Amendment No. 18 to your NRC Material License No. 24-17998-02 in accordance with your January 3, 2017 request (ML17004A134), with the authorization for the Leksell Gamma Knife® Icon™ unit limited to installation, storage, and pre-operational testing. Please also note that we have deleted Condition No. 14 in accordance with current NRC policy to include the reference to Title 10 of the *Code of Federal Regulations*, Part 71, "Packaging and Transportation of Radioactive Material," in the preamble, on page 1 of the license. Finally, we have added NRC's Agencywide Documents Access and Management System (ADAMS) document accession numbers to the documents referenced in Condition No. 18 to the amended license.

Please review the enclosed license amendment 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) 829-9892 so that we may provide appropriate corrections and answers.

As discussed with your previous Radiation Safety Officer (RSO) Stephen T. Slack, Ph.D., we cannot authorize the Leksell Gamma Knife® Icon™ for medical use until the RSO, at least one Authorized User (AU), one Authorized Medical Physicist (AMP) have completed training and experience as outlined in the 10 CFR 35.1000 guidance document, "Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance," dated May 25, 2016. Based on conversations with Dr. Slack, we understand that such training will be complete on or before May 15, 2017. Once training and experience is complete, you may resubmit your request for a medical use authorization for the new device. Please include documentation of all such training with your request. You may resubmit additional commitments and documentation in accordance with the guidance at that time, or reference your January 3, 2017 letter in your request. We will continue our review of your clinical use application upon receipt of the additional information and renewed request.

Please note that we were unable to add Edward Dickerson, M.S. as an AMP, at this time. Additional documentation – such as via an NRC Form 313 (AMP) – to confirm that his training and experience as related to gamma stereotactic radiosurgery applications, including on the Leksell Model C device listed on your license meets criteria outlined in 10 CFR 35.51. This decision is without prejudice to resubmission.

The enclosure to this letter contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

R. Gilliam

- 2 -

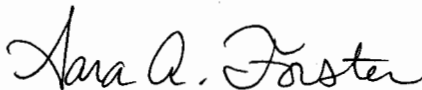
You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of 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.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

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 Title 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>.

In accordance with Title 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's ADAMS, which is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Sara A. Forster, M.S., Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 24-17998-02
Docket No. 030-33507

Enclosure: Amendment No. 18