UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 25, 2016

MEMORANDUM TO: James M. Trapp, Director
Division of Nuclear Materials Safety
Region I

John B. Giessner, Director
Division of Nuclear Materials Safety
Region III

Mark R. Shaffer, Director
Division of Nuclear Materials Safety
Region IV

FROM: Daniel S. Collins, Director ***/RA Pamela Henderson for/***
Division of Materials Safety, States, Tribal
and Rulemaking Programs
Office of Nuclear Materials Safety
and Safeguards

SUBJECT: ISSUANCE OF LEKSELL GAMMA KNIFE® PERFEXION™ AND LEKSELL GAMMA KNIFE® ICON™ LICENSING GUIDANCE

This memorandum is to inform you that on May 25, 2016, the U.S. Nuclear Regulatory Commission (NRC), in conjunction with the Agreement States through a joint working group, issued the enclosed licensing guidance for the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™.

The licensing guidance for the Leksell Gamma Knife® Perfexion™ (hereafter referred to as the Perfexion™) was initially published in July 2007 and can be found in the NRC's Agencywide Documents Access Management System (ML071970335). The NRC issued this licensing guidance under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 due to the engineering changes, which makes the components and operation significantly different from the gamma stereotactic radiosurgery units currently regulated in 10 CFR Part 35, Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units."

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The Leksell Gamma Knife® Icon™ (hereafter referred to as the Icon™) is an image-guided gamma stereotactic radiosurgery device similar to the Perfexion™, but has additional modifications, including on-board cone beam computed tomography and a different immobilization system. The NRC issued the Sealed Source and Device Registration (SSDR) certificate for this system on December 01, 2015.

The working group revised the Perfexion™ licensing guidance in its entirety to incorporate additional licensing conditions and information for the Icon™ unit. This current licensing guidance is now used to support licensing Perfexion™ and Icon™ units under 10 CFR 35.1000.

This current licensing guidance (published in May 2016) supersedes the previous Perfexion™ licensing guidance. As it was amended in its entirety to include the Icon™, it shall be considered revision 0. Notable changes in the guidance include: (1) the compliance with 10 CFR Part 37; (2) the written preceptor attestation requirement for authorized individuals of the Perfexion™ unit, excluding those who hold certification by a recognized specialty board; (3) the delay of the written preceptor attestation requirement for authorized individuals of the Icon™ unit until 2019, excluding those who hold certification by a recognized specialty board; (4) the full inspection and servicing of the Perfexion™ and Icon™ unit during source replacement, but not to exceed seven years; and (5) the grandfathering of individuals authorized for the Perfexion™ unit under the previous licensing guidance.

This licensing guidance may also be found on the NRC Medical Uses Licensee Toolkit at: http://www.nrc.gov/materials/miau/med-use-toolkit.html.

Enclosure:
Leksell Gamma Knife® Perfexion™ and
Leksell Gamma Knife® Icon™ Licensing Guidance

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