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

May 25, 2016

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF ISSUANCE OF LEKSELL GAMMA KNIFE® PERFEXION™ AND LEKSELL GAMMA KNIFE® ICON™ LICENSING GUIDANCE (STC-16-042)

Purpose: To inform the Agreement States that the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance was published in May 2016.

Background: The licensing guidance for the Leksell Gamma Knife® Perfexion™ (hereafter referred to as the Perfexion™) was initially published in July 2007. The U.S. Nuclear Regulatory Commission (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."

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.

A joint Organization of Agreement States and NRC working group was created to: (1) review and evaluate the Icon™ SSDR and relevant documents; (2) determine if the Perfexion™ and Icon™ units were similar enough that they could be addressed in a single 10 CFR 35.1000 licensing guidance document; and (3) develop the 10 CFR 35.1000 licensing guidance document. The working group revised the Perfexion™ licensing guidance in its entirety to incorporate additional licensing conditions and information for the Icon™ unit. The document is intended to be guidance in licensing Perfexion™ and Icon™ units for applicants, licensees and NRC staff and is also available to the Agreement States to use.

Discussion: 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.

If you have any questions regarding this correspondence, please contact me at (301) 415-3340 or the individual named below:

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

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