



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

ALL AGREEMENT STATE RADIATION CONTROL PROGRAM DIRECTORS, WYOMING,
VERMONT

OPPORTUNITY TO COMMENT ON DRAFT LEKSELL GAMMA KNIFE® PERFEXION™ AND
LEKSELL GAMMA KNIFE® ICON™ LICENSING GUIDANCE (RCPD-16-XXX)

Purpose: To provide the Agreement States an opportunity to comment on the draft Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance.

Background: The licensing guidance for the Leksell Gamma Knife® Perfexion™, hereafter referred to as “Perfexion™ licensing guidance,” was initially published in July 2007 and can be found in the NRC’s Agencywide Documents Access Management System ([MLXXXXXXXXXX](#)). The U.S. Nuclear Regulatory Commission (NRC) issued this licensing guidance under Title 10 Code of Federal Regulations (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. NRC issued the Sealed Source and Device Registration (SSDR) certificate for this system on December 01, 2015.

The Organization of Agreement States (OAS) and NRC created a joint working group to review and evaluate the Icon™ SSDR and relevant documents and to determine if the Perfexion™ and Icon™ units were similar enough that they can be addressed in a single 10 CFR 35.1000 licensing guidance document. As such, the working group determined that a single licensing guidance document was appropriate. The existing Perfexion™ licensing guidance has been amended in its entirety to incorporate additional requirements and information for the Icon™ unit.

Discussion: Enclosed for your review and comment is the draft licensing guidance. Comments of an editorial nature will be considered; however, the draft text may undergo additional technical editing and formatting by the NRC prior to publication.

Please provide any comments to the contact person listed below. We would appreciate receiving your comments¹ within 30 days of this letter.

¹ This information request has been approved by OMB 3150-0029 expiration 1/31/2019. The estimated burden per response to comply with this voluntary collection is approximately 3 hours. Send comments regarding the burden estimate to the FOIA, Privacy, and Information Collections Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Additionally, changes for standard language and formatting developed by the NRC's Medical Radiation Safety Team for all emerging technology licensing guidance documents (e.g. cover page; table of contents; document revision date; page numbers; example license language for radionuclide, form, possession limits, and purpose of use) are included in the enclosed draft guidance.

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

POINT OF CONTACT: Sophie Holiday
TELEPHONE: (202) 596-4874

INTERNET: Sophie.Holiday@nrc.gov

Daniel M. Collins, Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Draft Leksell Gamma Knife Perfexion and
Leksell Gamma Knife Icon Licensing Guidance

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Office of Nuclear Material Safety
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