Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee Review and Comments on

Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™
Draft Licensing Guidance, Revision 1

Submitted on: August 31, 2018

Subcommittee Members:
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Background: The subcommittee and its Chair were appointed by ACMUI Chair, Phil Alderson, at the regularly scheduled ACMUI meeting on April 26, 2017. This subcommittee was formed after a presentation on April 26, 2017 by Elekta, Inc. requesting emendation of the Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 licensing guidance for the Leksell Gamma Knife® Icon™ to allow the authorized user (AU) to be physically present in the department during patient treatment and immediately available to come to the treatment room to respond to an emergency based on the very small number of medical events (MEs) that have occurred with modern Gamma Knife® units. The charge to subcommittee: was to propose the appropriate physical presence requirement for the Leksell Gamma Knife® Icon™ (hereafter referred to as Icon™) gamma stereotactic radiosurgery unit.

The initial report was presented on September 12, 2017 at the ACMUI meeting. An updated report was provided on February 1, 2018 based on feedback from the ACMUI meeting in September 2017. The subcommittee provided its recommendations during the February 15, 2018 public teleconference call regarding the physical presence requirements for the Icon™.

The NRC/Agreement State Working Group (WG) reviewed the report and recommendations, the ACMUI meeting transcripts, and submitted comments from Elekta and Michael Sheetz (ACMUI Radiation Safety Officer). The WG's proposed revisions to the guidance was submitted to the subcommittee for review and comment. The WG proposed physical presence requirements similar to that of the high dose rate (HDR) remote afterloader unit where the AU is present at the initiation of the treatment; and an AU or a physician under the supervision of the AU is present during the continuation of the treatment. In addition, the AU will return to the console if there is an interruption of treatment to evaluate the patient, review any information related to an

abnormal situation, and to ensure that treatment is in accordance with the treatment plan and written directive.

The original subcommittee, along with Megan Shober and Zoubir Ouhib who were added to the subcommittee on July 1, 2018, reviewed the draft revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance.

Since the draft revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance is different than the recommendation of the subcommittee report from February 2018, this document will provide a summary of the original subcommittee recommendations, current physical presence requirements, rationale for change, and review and comments of the draft guidance.

Summary of Subcommittee Recommendations for Physical Presence Requirements for the Leksell Gamma Knife® Icon™ (*submitted February 2018*)

1. The AU and authorized medical physicist (AMP) need to be physically present during the initiation of all treatments. This allows independent confirmation that the correct plan is being used for treatment and that the correct site is being treated during the initiation of treatment.

2. The current physical presence requirements for the AU be modified by allowing the AU to be present in the department during treatment, which is defined for the Icon™ as within a two minute walk to the console area, and immediately available to come to the treatment room. An AMP needs to be physically present during the entire treatment. While we recognize the NRC does not have regulations for nursing or auxiliary staff, we recommend as a best practice that appropriately trained nursing or auxiliary staff be present at Gamma Knife treatment to respond to any immediate medical needs. It should be the responsibility of the AU to determine the necessary training and experience required of the nursing staff.

3. If there is an interruption of treatment secondary to medical or mechanical issues, the AU must return to Gamma Knife® Icon™ console to evaluate the patient and/or to review any mechanical issues. The AU must be present to ensure the correct site is being treated prior to re-initiation of treatment.

4. At the conclusion of treatment, the AU must be present at the Icon™ console to discuss and review any treatment or patient issues with the patient, physicist, and nurse.

Current Physical Presence Requirement

In October 2002, the NRC modified the regulations in 10 CFR Part 35 to include a section[1] regarding gamma stereotactic radiosurgery to include the requirement that "For gamma stereotactic radiosurgery unit, require an Authorized User with appropriate training and experience in radiation oncology and Authorized Medical Physicist to be physically present

[1] 10 CFR 35.615(f)(3)

throughout all patient treatments involving the unit." This regulation provided for an appropriate response to an emergency and to ensure that the correct dose of radiation is delivered to the patient. The term[2] "physically present" was defined as "within hearing distance of normal voice".

The NRC issued a Regulatory Issue Summary (RIS) to clarify the definition of "physically present" as a result of an event at one of the Gamma Knife centers. The RIS (RIS-2005-23)[3], "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatment," stated that this meant speaking in a normal conversational tone and not a raised voice. As a result, a distance of 20 feet may not be close enough to adequately hear and respond to an emergent situation. This also ensures the correct dose of radiation was delivered.

Rationale for change

The current definition ensures that an emergent situation will be addressed immediately by the AU and that the correct dose is delivered. The AU has the knowledge and appropriate training to ensure the safe and effective delivery of stereotactic radiosurgery treatment. The current physical presence definition is not ambiguous and ensures the AU is present for the all the critical portions of the procedure, able to address any medical issues that may arise during treatment, and verify the correct dose will be delivered to the target(s). The AU will have the competency to recognize and respond to any aberration of treatment and ensure response times within seconds if needed.

Medical issues during the Gamma Knife® treatment may include pain from the frame, nausea, vomiting, and seizure. Incorrect dose of radiation may result secondary to system failure which could be software, hardware, or combination of both. As serious medical issues and/or significant aberrations in treatment can result in reportable MEs, rules regulating physician presence exist to ensure patient safety.

Over the past ten years of NMED, there are 12 reportable events involving the Leksell Gamma Knife Perfexion™ (hereafter referred to as Perfexion™). Of the 12 Perfexion™ reportable events, only a minority were identified during treatment. The Icon™ unit has significant enhancements over the Perfexion™ unit. Specifically, three features are important: 1) the option of treatment with a thermoplastic frameless mask rather than a frame; 2) ability to perform integrated stereotactic cone-beam computed tomography (CBCT) which provides stereotactic reference for patient setup; and 3) high definition motion management (HDMM) for mask-based treatments. These enhancements re-open the question regarding the physical presence requirements of the AU for the entire treatment. A review of the 12 events for Perfexion™ reveals that none of these events would have escaped detection on an Icon™ unit using the thermoplastic frameless mask and HDMM for mask-based treatments even if the AU was not physically at the console and could have been rapidly and effectively addressed as long as the AU was immediately available.

[2] Section V, Summary of changes of 2002 revised part 35 in *Federal Register* (67 FR 20355)
[3] NRC-issued Regulatory Issues Summary (RIS) 2005-23 – October 2005

Based on the extremely low number of MEs with the Perfexion™ unit coupled with the modifications with the Icon™, the subcommittee recommended modifying the current physical presence requirements for the Icon™ unit.

Working Group's Draft Licensing Guidance for Perfexion™ and Icon™

Physical Presence Requirements Recommended in the Draft Licensing Guidance Document

1. An authorized user and an authorized medical physicist will be physically present during the initiation of all patient treatments involving the Perfexion™ or Icon™ unit;

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the Perfexion™ or Icon™ unit; and

3. An authorized user will return to the Perfexion™ or Icon™ unit console if there is an interruption of treatment to evaluate the patient, to review any information related to an abnormal situation, and to ensure that the treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation of the treatment.

Similarities Between the Working Group and Subcommittee's Recommendations for Physical Presence Requirements

1. An AU and AMP will be physically present during the initiation of all patient treatments. The subcommittee fully agrees with the requirement to have AU and AMP present during initiation of all treatments. If the decision is made to incorporate the Perfexion™ or Icon™ unit under the same licensing guidance, it is important to stipulate that the AU be present for the initiation of every fraction to maximize quality and safety. Since the Icon™ unit allows for multiple treatments (2-5 fractions) during the week, the AU and AMP need to be present at the initiation of every fraction, not just the first fraction of treatment.

2. An AU will return to the console if there is an interruption of treatment.
Since a greater number of patients are being treated with Gamma Knife® radiosurgery, may have longer treatment times secondary to the number of brain lesions being treated, and/or may undergo multiple sessions with the Icon™ unit, the likelihood of an interruption of treatment secondary to a medical issue or patient comfort increases. As a result, it is important that the AU is present to evaluate the patient's condition if needed, to review any information related to an unexpected occurrence, and to ensure the treatment is being delivered in accordance with the written directive and treatment plan prior to the re-initiation of treatment. The AU's presence will maximize quality and safety.

Differences Between the Working Group and Subcommittee's Recommendations About Physical Presence

1. Inclusion of Perfexion™ into the guidance.

   One of the major differences between the WG and subcommittee's recommendation about physical presence is the inclusion of Perfexion™ unit into the guidance. The original subcommittee believed that there were fundamental differences between the Icon™ unit versus the Perfexion™ unit to warrant separate physical presence requirements. These differences include the option to treat with a thermoplastic frameless mask unlike the Perfexion™ unit, CBCT which provides stereotactic reference for patient setup, and HDMM for mask-based treatments. The committee also agrees that many components of the machine are similar, especially the location of the collimator inside the machine, the various positions to turn the beam on and off, and treatment table. Given these engineering similarities, the Perfexion™ unit and Icon™ unit are licensed under 10 CFR 35.1000, unlike the model B and C units which are licensed under 10 CFR 35.600. After discussion about the pros and cons of including both Perfexion™ and Icon™ under similar guidance, the subcommittee supported this recommendation.

2. An AMP and either an AU or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all treatments.

   The subcommittee proposed that physical presence be modified by allowing the AU to be present in the department during treatment, which was defined to be within a 2-minute walk of the console area and immediately available to come to the treatment room after initiation of treatments. The WG and management were not supportive of the 2-minute walk as this was felt to be very ambiguous, which would be difficult to enforce. The WG's proposed physical presence requirement is similar to that of HDR as described in 10 CFR 35.615(f)(2). In addition, the proposed physical presence requirement included both the Perfexion™ and Icon™. Since the guidance proposal includes both Perfexion™ and Icon™, the subcommittee believes similar physical presence requirements to that of HDR is an appropriate alternative to the subcommittee proposal.

3. Our subcommittee also proposed that at the conclusion of treatment, the AU must be present at the Icon™ console to discuss any treatment or patient issues with the patient, AMP and nurse.

   Upon further consideration and deliberation of this recommendation, we conclude that this constitutes a best practice that the NRC should not mandate. In addition, this would be difficult to regulate given the variations in medical practice. The subcommittee does, however, believe that the practice of discussing and reviewing any treatment or patient issue with the patient, physicist, and nurse, does enhance quality, patient experience and outcomes for future patients.

Specific comments

Page 3, section 4.1, 2nd paragraph: Delete "**In accordance with the previously issued licensing guidance for the Perfexion**" and delete "**after July 1, 2009**."

Page 3, section 4.1, 2nd paragraph, last sentence: Replace with "**The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of other gamma stereotactic radiosurgery units**."

Page 4, section 4.1, section 3): last sentence, replace with: "**The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of other gamma stereotactic radiosurgery units**."

Page 5, 1st paragraph: delete "all other" from 2nd sentence. Should read "**For physicians applying**"

Page 5, 1st paragraph, 3rd sentence- should read: a written attestation **is required** from a preceptor

Page 6, 6, 3rd paragraph, 2nd sentence: delete "**all other**"

Page 17, section 6.4: The grandfathering provision should apply to Icon™ authorized users

Summary:

Although the scope and recommendations from the WG are different than the original subcommittee report on Physical Presence Requirements for the Leksell Gamma Gamma Knife® Icon™, we endorse the Leksell Gamma Gamma Knife® Perfexion™ and Leksell Gamma Gamma Knife® Icon™ licensing Guidance with the caveats noted above. Given the proposed guidance, it is imperative that a culture of safety and quality with checks and balances at every level exists to ensure that the safest and most effective care is delivered to patients while simultaneously protecting the workers and public. Licensees are encouraged to continue to audit and monitor their programs and adopt best practices including a high reliability system approach[4] to mitigate MEs. The subcommittee recommends that the ACMUI and NRC review for any negative trends that may occur as a result of this change in guidance.

Respectfully submitted, August 31, 2018
Subcommittee to review the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance, Advisory Committee on the Medical Uses of Isotopes (ACMUI), Nuclear Regulatory Commission (NRC)

[4] Reason J. Human error: models and management. BMJ 32:768-770, 2000