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

Subcommittee on

Physical Presence Requirements for the Leksell Gamma Knife® Icon™

Final Report Submitted On:
February 27, 2018

Subcommittee Members:
Ronald Ennis, M.D.
John Suh, M.D. (Chair)
Laura Weil

NRC Staff Resource: Sophie Holiday

Charge to subcommittee: To propose the appropriate physical presence requirement for the Leksell Gamma Knife® Icon™ radiosurgery unit.

Subcommittee Process

The subcommittee and its Chair were appointed by ACMUI Chairman, Phil Alderson, at the regularly scheduled ACMUI meeting April 26, 2017. This subcommittee was formed after a presentation on April 26, 2017 by Elekta, Inc. requesting emendation of the Title 10 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 initial report was presented on September 12, 2017 at the ACMUI meeting. This is an updated report based on feedback from the last ACMUI meeting in September 2017.

Summary of Subcommittee Recommendations

(for Icon™ unit in either the stereotactic frame or frameless mask mode)

- 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.

- 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.

- 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.

- 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.

Introduction

Gamma stereotactic radiosurgery is a very effective and well established treatment for patients with various benign and malignant brain tumors, vascular malformations and some functional disorders such as trigeminal neuralgia. The shielded unit utilizes 192 or 201 Cobalt-60 (Co-60) sources that simultaneously converge to a central target in the brain by the use of different sized collimator channels that are positioned around the patient's skull. The first Gamma Knife® in the United States was installed at the University of Pittsburgh in 1987 (Model U). Over the next 12 years, the model B and model C units were introduced. These three systems, licensed under 10 CFR 35.600, (Models U, B and C) have tungsten collimators that are external to the Co-60 sources and are placed on the treatment unit manually. All these units required frame-based immobilization and have fixed beam geometry to maximize reliability and minimize quality assurance checks.

In 2006, the Perfexion™ unit was introduced. Unlike the model U, B, and C units, the collimators are inside the treatment unit with sources that can be shielded while the treatment helmet is being switched to another size collimator, which can decrease treatment times and manual intervention by the treatment team. The Perfexion™ also uses five different positions (16 mm, 4 mm, off, 8 mm, and home, which is an off position) to turn the beam on and off. These sectors allow for rapid change (within 1 second) of the collimators of each sector. Along with engineering differences that would not meet the provisions under 10 CFR 35.600, the NRC decided to license the Perfexion™ under 10 CFR 35.1000. In 2016, the Icon™ system was introduced, which allowed for treatment with a thermoplastic frameless mask unlike the Perfexion™ unit. In addition, the Icon™ unit has a cone-beam computed tomography (CT) which provides stereotactic reference for patient setup and high definition motion management for mask-based treatments. Since the introduction of the Gamma Knife® in 1987 in the United States, the use of gamma stereotactic radiosurgery has greatly increased in the United States. Based on information from Elekta, there are 77 Perfexion™ units and 22 Icon™ units. Worldwide, over 1 million patients have been treated with the Gamma Knife®.

Given the many advances in gamma stereotactic radiosurgery, the delivery has become more efficient allowing for treatment of multiple patients each day and treatment of multiple targets in

a single session, which have increased the treatment times for some patients. Given the evolution of the Gamma Knife® over the past decade from the Model C to Perfexion™ and now Icon™, the physical presence requirements were examined by the subcommittee.

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 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. 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 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 (CT) which provides stereotactic reference for patient setup, and 3) high definition motion management 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 high definition motion management 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.

Proposal by Elekta, Inc. on April 26, 2017 for Gamma Knife® Icon™

1. *We will have an Authorized User and Authorized Medical Physicist physically present during the initiation of all treatments involving the unit.*

2. *We will have an Authorized Medical Physicist physically present throughout all patient treatments involving the unit.*

3. *We will have an Authorized User physically present in the department during patient treatment and immediately available to come to the treatment room to respond to an emergency.*

Recommendations

Based on the extremely low number of MEs with the Perfexion™ unit coupled with the modifications with the Icon™, the subcommittee recommends modifying the current physical presence requirements for the Icon™ unit. The major differences between the Icon™ versus the Perfexion™ are: 1) treatment with a thermoplastic frameless mask rather than invasive frame for some patients; 2) ability to perform integrated stereotactic cone-beam computed tomography (CT) which provides stereotactic reference for patient setup; and 3) high definition motion management for mask-based treatments which allows for online adaptation. Although we respect the proposal by Elekta, Inc., we believe their proposal needs to be more stringent to ensure safe and accurate delivery of gamma stereotactic radiosurgery. Physical presence would utilize a similar definition used by Section V, Summary of changes of the 2002 revised 10 CFR part 35 in the *Federal Register*[4]. The following recommendations remain consistent with federal regulations and requirements governing physician supervision from the Centers for Medicare and Medicaid Services and federal regulations. These recommendations are for either the stereotactic frame or frameless mask mode of the Icon™.

1. AU and AMP be physically present during the initiation of all treatments involving the Icon™ unit.

   This will allow independent confirmation that the correct plan is being used for treatment and that the correct site is being treated at the initiation of treatment. This will also allow the authorized user to be part of the universal timeout, which should help prevent the wrong plan from being delivered or the incorrect side from being treated initially.

2. AMP be physically present throughout all patient treatments involving the unit.

   The physical presence of an AMP is essential for the safe and accurate delivery of gamma stereotactic radiosurgery. The addition of a medical physicist would ensure that any software, hardware, or combination of software/hardware failure be recognized immediately and addressed promptly.

   The current physical presence requirements for the AU can be modified by allowing the AU to be close enough to the console to respond quickly to any issue that arises which is defined as within a two minute walking distance to the Icon™ console area, **and** immediately available to come to the treatment room. An AMP needs to be physically present during the entire treatment.

   In addition to the AU and AMP, as a matter of good practice, we recommend that appropriately trained nursing or auxiliary staff be present during Icon™ treatment to respond to any immediate medical needs. It will be the responsibility of the AU to determine the necessary training and experience required of the nursing staff, who will be present throughout the procedure.

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

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

The AU will be physically present close to the console, which is defined in this report as *within 2 minutes from the console area*, during patient treatment **and** immediately available to furnish assistance and direction throughout the performance of the procedure. Specifying time rather than presence in the department mitigates any misinterpretation of the regulations which has happened in the past[5]. This definition would be more stringent than the American Society for Radiation Oncology white paper.[6]

The subcommittee felt that a time, rather than distance, ought to be used to define "physically present in the department." Depending on the configuration of the department, distance may not be easily measured, i.e., the department may be located on multiple floors, not necessarily in close proximity. In addition, the subcommittee believes that 'physically present' in the department can be ambiguous especially if the Gamma Knife® center is distant from the radiation oncology department or if the Gamma Knife® is not present within the radiation oncology department such as a neurosurgery department or free standing center. Since a medical physicist would be physically present for the duration of treatments, medical and software/hardware incidents could be addressed during the 2 minute interval before the AU would arrive.

Summary:

The subcommittee recommends that for the Leksell Gamma Knife® Icon™ (either stereotactic frame or frameless mask mode):

- The AU and AMP need to be physically present during the initiation of all treatments. This allows independent confirmation that the correct site is being treated, confirm that the correct plan is being used for treatment and particularly important for functional cases, all of which are components of the universal time outs. It also provides an opportunity to visualize the movement of the treatment table to the correct position via treatment room cameras.

- The current physical presence requirements for the AU be modified by allowing the AU to be within a 2 minute walking distance of the console area **and** immediately available to come to the treatment room after initiation of treatments. An AMP needs to be physically present by the console area during the entire treatment. (i.e., at the console or within normal hearing voice) of the AU.

- If there is an interruption of treatment secondary to medical or mechanical issues, the AU must return to the 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 during re-initiation of treatment.

- At the conclusion of treatment, the AU must be present at the Gamma Knife® Icon™ console to discuss any treatment or patient issues with the patient, AMP and nurse.

We believe that the recommendations would allow for the safe and effective delivery of gamma stereotactic radiosurgery while allowing the AU more flexibility to be available for other medical issues, other than those requiring personal supervision, in a radiation oncology department if warranted. We also believe that the recommendations will allow the licensee to determine if an ME has occurred, would allow the regulator to inspect and regulate a Gamma Knife® center, would not unfavorably encroach on the practice of medicine, and are consistent with regulations governing physician supervision. As a subcommittee, we believe it is inappropriate for the AU to be more than a 2 minute walking distance from the console under any circumstance as the AU needs to be immediately available and needs to ensure the correct radiation dose is delivered. In addition, we recommend that the AU work with their radiation safety officer to determine how long it will take for the AU to return to the Gamma Knife® Icon™ console area from another location at which he/she wishes to work. The center will need to determine best method to contact the physician as paging a physician can take time. Since any change can be subject to interpretation, it is important that each Gamma Knife® center determine what area would be within 2 minutes walking distance of the console. Ultimately, each AU will need to decide if he or she wishes to adopt the revised physical presence proposal or maintain the current physical presence rules, which is more stringent.

Given the proposed change, 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 public. Licensees are encouraged to continue to audit and monitor their programs and adopt best practices including a high reliability system approach[7] to mitigate MEs.

Respectfully submitted, February 27, 2018
Subcommittee on Physical Presence Requirements for Leksell Gamma Knife® Icon™,
Advisory Committee on the Medical Uses of Isotopes (ACMUI),
Nuclear Regulatory Commission (NRC)

References

1. 10 CFR 35.615(f)(3).

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

4. 42 C.F.R. § 410.32

5. Mastroianni A, McCaffrey JF. Target tumors, not yourself: A review of False Claims Act allegations against radiation oncologists. Appl Radiat Oncol 4(2): 14-21, 2015

6. Solberg TD, Balter JM, Benedict SH, et al. Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy: Executive summary. Pract Radiat Oncol 2:2-9, 2012.

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