



September 23, 2015

Josephine M. Piccone, Director
Division of Materials and Safety, State, Tribal and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission
11545 Rockville Pike, Rockville, MD 20852

Bruce Thomadsen, PhD
Chair, NRC Advisory Committee on the Medical Use of Isotopes
University of Wisconsin, Department of Medical Physics
1005 Wisconsin Institutes for Medical Research
1111 Highland Ave.
Madison, WI 53705

Re: Physical presence requirements for stereotactic radiosurgery and Gamma Knife

Dear Ms. Piccone and Dr. Thomadsen,

On behalf of the American Society for Radiation Oncology (ASTRO), I am writing to present our position on the Nuclear Regulatory Commission's (NRC) physical presence requirements for Leksell Gamma Knife Perfexion ("Perfexion").

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapy. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatment.

NRC staff, as well as the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI), recently heard requests from Elekta, the manufacturer of Perfexion, to relax the current physical presence requirement for Perfexion, such that the authorized user (AU) does not have to be present for the entirety of the procedure. ASTRO believes that the current requirements are reasonable, safeguard patients, and should not be relaxed. Furthermore, ASTRO's members have not indicated that the current physical presence requirements are too strict or limiting in their scope. The most important consideration is patient safety, which we believe would be significantly compromised if this standard is relaxed.

The Perfexion unit uses cobalt-60 (Co-60) sources to deliver a single, high dose of radiation to a specific target in the brain with surgical precision. Standard radiotherapy irradiates targets with a lower dose during thirty or more fractions. The complex nature of the stereotactic treatment process and the higher consequence of errors if high-dose fractions of radiation are not delivered correctly, necessitates strict physical presence requirements. Physician presence during the entirety of the procedure allows the physician to ensure the setup of the patient is correct and remains correct during the procedure. It also

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helps to allay any patient and family concerns regarding the safety of the procedure. Finally, physician presence allows for the physician to make critical decisions, including decisions related to a medical emergency, without delay.

Currently, the use of Perfexion is governed under 10 CFR 35.1000, *Other medical uses of byproduct material or radiation from byproduct material*. In its Licensing Guidance for Perfexion, the NRC requires that users must meet the requirements set forth in 10 CFR 35.615(f)(3), *Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units*, which states: "For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit." In 2005, the NRC clarified this requirement, saying that "as used in this provision, physically present means to be within hearing distance of normal voice" (RIS 2005-23, Clarification of the physical presence requirements during gamma stereotactic radiosurgery treatments).

In its presentations to the NRC and ACMUI, Elekta argued that the AU does not need to be present for the duration of the procedure since the Perfexion is equipped with numerous safety protocols that would shut down the machine should an event occur. ASTRO believes that because the Perfexion uses high doses of radiation, the presence of the AU is essential to ensure patient safety, regardless of any safety protocols contained within the machine itself. A machine's "judgement" should not be substituted for a physician's. Further, we believe NRC's definition of "physically present" allows for sufficient flexibility as to where the AU is positioned during a procedure. Finally, we believe that having the authorized user physically present during the duration of the procedure offers added confidence to patients and their families.

Additionally, Elekta argued that the physical presence requirements for Perfexion should be the same as those for ViewRay, which, like Perfexion, uses Co-60. However, unlike Perfexion, ViewRay uses smaller doses of radiation for shorter periods of time. ViewRay is also appropriately licensed under 10 CFR 35.1000, *Other Medical Uses of Byproduct Material or Radiation From Byproduct Material*, and in its 2013 Licensing Guidance for ViewRay (ViewRay System for Radiation Therapy Licensing Guidance, July 2013), the NRC requires the licensee to confirm that they "will have either an Authorized User or Authorized Medical Physicist physically present in the department during patient treatment and immediately available to come to the treatment room to respond to an emergency." ASTRO believes that the NRC's guidance for ViewRay is appropriate given the technology and use of the machine, and this policy should not be applied to Perfexion. In addition, a variety of other Co-60 units employed for standard radiotherapy schedules historically have used the same requirement for direct supervision. ASTRO also notes that stereotactic radiosurgery (SRS) performed using a ViewRay system would require the same physical presence requirements as is expected for linear accelerator-based or Co-60 treatments.

Finally, the ASTRO White Paper, *Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy* (Practical Radiation Oncology, August 2011), recommends that the radiation oncologist be present for "critical decision making and otherwise immediately available." The paper does not make the distinction between SRS with a linear accelerator and SRS with cobalt. Regardless of the radioactive source, we continue to maintain that the physical presence requirements for the AU using Perfexion are reasonable, ensure the safety of our patients, and should not be relaxed.

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The safety record of Perfexion is excellent because of the required training for physicians, physicists, and therapists; the safety features imbedded within the machine itself; and most importantly because of AU presence during the procedure.

ASTRO appreciates the opportunity to share with the NRC our concerns about relaxing the physical presence requirements for Perfexion. We believe that the current regulations, licensing guidance, and the accompanying clarification are sufficient to ensure patient safety and should not be diminished. Should you have any questions, please do not hesitate to contact Cindy Tomlinson, senior manager for security and safety at 703.839.7366 or cindy@astro.org.

Sincerely,

A handwritten signature in black ink that reads "Laura Thevenot". The signature is written in a cursive, flowing style.

Laura I. Thevenot
Chief Executive Officer