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Statement of Thomas Eichler, MD, FASTRO
On behalf of The American Society for Radiation Oncology
Before the Nuclear Regulatory Commission
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Good morning. Thank you very much for inviting me today. My name is Dr. Thomas Eichler and I am a board-certified radiation oncologist at the Sarah Cannon Cancer Institute in Richmond Virginia. I am also the President of the American Society for Radiation Oncology, or ASTRO for short. ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with a variety of radiation therapy techniques. We thank you for your commitment to stakeholder engagement and appreciate the opportunity to collaborate with the NRC.

Before I move on to suggestions regarding transformation and innovation opportunities from the medical community perspective, I want to take a moment to discuss the staff's recent recommendations regarding training and experience for radiopharmaceuticals. The proposal gives us cause for concern. We continue to believe that there is no need to pursue additional rulemaking, as current regulations are appropriate, protect the safety of patients, the public, and practitioners. However, if the Commission ultimately decides to pursue rulemaking, we believe the board recognition criteria must ensure that existing requirements are maintained, and that any criteria for additional boards is equivalent to existing requirements.

You asked me to speak about transformation and innovation opportunities from the medical community perspective, and I would like to highlight a 2017 ACMUI report entitled "Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture." In its report, the ACMUI made two important observations:

1. First, the NRC's medical event reporting criteria are set at conservative levels – which include events that rarely cause patient harm – when compared to other criteria set by The Joint Commission, the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS). This inconsistency in definitions leads to inconsistent levels of response to a patient safety event and causes confusion in the medical community.
2. Second, despite the recognition that the medical events rarely cause patient harm, a licensee is required to notify the NRC no later than the next calendar day after discovery. After the notification, an inspection occurs looking for violations as the cause of the event.

In other words, the NRC's conservative medical event reporting requirements are inconsistent when compared to other regulatory requirements and current radiation oncology practice, and do not foster a culture of safety.

Based on these observations, as well as the need to consider other ways medical events could be evaluated, the ACMUI made the following recommendations:

- The NRC should establish a program allowing a medical use licensee to evaluate medical events as described in current regulations with an approved patient safety program. The ACMUI describes an approved patient safety program as one or more of the following: a safety program that reports medical events to a Patient Safety Organization (PSO) which has medical expertise in medical use as defined in Part 35; a safety program evaluated by a CMS-approved Accrediting Organization, or; a safety program which is established as part of accreditation by a professional organization for medical use as defined in Part 35.
- NRC licensees with an NRC-approved patient safety program will continue to report medical events as required with certain conditions. These conditions include the NRC not including these events in the Event Notification Report, or, if this is not possible, posting them anonymously. And probably more importantly, the NRC does not conduct a reactive inspection unless the event results in, or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention is required. Additionally, the licensee will write a report describing the event and corrective action taken which will be made available for the next NRC inspection. Finally, the NRC will develop inspection procedures to support a test of this program.
- The NRC should test this program with various medical practice sizes and locations, evaluating the medical event reports with the ACMUI.
- After completion of the test year, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program, and to Agreement States who request to implement the program with their medical licensees.

ASTRO supports the recommendations offered by the ACMUI to promote a culture of safety for medical licensees. The progressive recommendations align with ASTRO's commitment to improving quality and safety in radiation oncology, and support the NRC's Safety Culture Policy Statement, while at the same time maintaining the NRC's regulatory authority to protect patients during the medical use of byproduct materials. We believe that both ASTRO's Accreditation Program for Excellence (APEx®) and RO-ILS: Radiation Oncology Incident Learning System® fulfill the spirit and the requirements set forth by the ACMUI.

First, I would like to discuss APEx. APEx was launched in February 2015 and to date, has accredited more than 150 facilities. The mission of APEx is to recognize facilities by objectively assessing the radiation oncology care team, policies and procedures, and the facility. APEx supports quality improvement and patient safety in radiation therapy practices. Facilities that obtain APEx practice accreditation will have the systems, personnel, policies and procedures that are needed to deliver safe, high-quality patient care.

Obtaining APEx accreditation is a multi-step process beginning with an application and contract, followed by a thorough self-assessment, including a robust medical record review and document upload of relevant processes, procedures and other documents, a facility visit by radiation oncology professionals who are trained as APEx surveyors, and finally a determination made by

ASTRO's APEx committee. The APEx program is constantly evolving with regular quality assurance performed by the APEx committee.

The APEx standards represent the cornerstone of the program and identify systematic quality and safety approaches that build on and reinforce regulatory requirements to add value for practitioners and health care consumers. They are organized around five pillars: The Process of Care in Radiation Oncology; The Radiation Oncology Team; Safety; Quality Management and Assurance in Radiation Oncology; and Patient-centered Care.

Of the 16 APEx standards, the Culture of Safety standard specifically requires that the radiation oncology practice foster a culture in which all team members participate in assuring safety, capitalize on opportunities to improve safety and does not take reprisals upon staff that report safety concerns. This standard ensures that the practice fosters a culture where learning from patient safety events and unsafe conditions is a part of the process of care, and is a mandatory component of the program. We believe that the most effective way for facilities to take action on a safety event or unsafe condition is for them to take ownership of the corrective actions in a non-punitive environment. The facilities are in the best position to make changes and improve safety since they are most familiar with their own processes and procedures. We are pleased that the ACMUI embraced this approach to safety culture, especially when it comes to medical event reporting.

Now I would like to turn your attention to RO-ILS. RO-ILS embodies these same ideals, albeit in a slightly different way. RO-ILS facilitates the collection and reporting of patient safety events from all participating facilities to make suggestions for change. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment. While important legal protections prevent RO-ILS from sharing reported information by a facility, the facility has the ability, and is often required, to share relevant information with the NRC (and other federal and state regulators).

RO-ILS is part of an Agency for Healthcare Quality and Research (AHRQ)-approved PSO. RO-ILS has more than 500 facilities enrolled, and more than 12,000 events have been reported. Approximately 300 of those events involve radioactive materials[1]. Approximately 44% of the reported events are classified by users as "operational/process improvement", which is defined as a non-safety event. This suggests that practices are utilizing the system for more comprehensive quality improvement. An additional 12% of events are classified as therapeutic radiation incidents, where the radiation dose is not delivered as intended, with or without harm, with the majority of those having a less than 5% dose deviation.

The culture of safety in medicine has completely shifted from one of blame to one focused on learning. This has led to an increase in reporting. RO-ILS participants want to identify events and near misses, create interventions to prevent them from happening again, and share safety

[1] Note: this number does not include events using GammaKnife because those are grouped under the broader "stereotactic radiosurgery" events, which include linear accelerators.

risks and solutions with others. Analyzing safety events that were caught before reaching the patient and addressing those error-prone processes is a critical aspect of incident learning in medicine. We believe the current NRC medical event reporting approach does not focus sufficiently on learning, and the ACMUI recommendation holds great promise for improving the process.

To reiterate, ASTRO believes that the NRC could play a greater role in improving safety culture in radiation therapy by implementing the ACMUI's recommendations.

Thank you, and I look forward to answering your questions.