ASTRO
TARGETING CANCER CARE

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February 13, 2020

Kristine L. Svinicki, Chairman
Nuclear Regulatory Commission
Mail Stop O-4F00
Washington, DC 20555-0001

Dear Chairman Svinicki,

I am writing on behalf of the American Society for Radiation Oncology (ASTRO) to express concern over the staff's recommendation to initiate rulemaking for Training and Experience (T&E) requirements for unsealed byproduct material dated January 13, 2020. Given the widespread accessibility of authorized users and strong track record of safety, we disagree with the staff recommendation and do not believe rulemaking is necessary at this time.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. 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 treatments.

The NRC staff recommends rulemaking to change the current T&E requirements so that only physicians certified by an NRC- or Agreement State-recognized medical specialty boards become Authorized Users under 10 CFR 35.300. As part of the rulemaking, NRC would revise current board recognition criteria "so that certification by specialty boards other than the existing nuclear medicine and radiation oncology boards would be an acceptable T&E pathway for the use of radiopharmaceuticals."

The staff further states that:

> *Medical specialty boards seeking NRC or Agreement State recognition would develop radiation safety training programs specific to their medical program objectives and in accordance with the board recognition criteria. Certification by a recognized medical specialty board would credential a physician to be an AU for the medical uses authorized to the specialty board, and ongoing AU status would be tied to the physician's maintenance of board certification.*

This recommendation would phase out the so-called, "alternate pathway," which requires 700 hours of training for those not already board certified. Existing AUs and recognized medical specialty boards would be grandfathered, and physicians awaiting certification would need to work under the supervision of an existing AU.

As we have stated in previous comment letters and statements, ASTRO believes that maintaining the status quo is appropriate, protects the safety of patients, the public, and practitioners. Current NRC regulations ensure that patients have access to safe and effective treatments.

ASTRO is concerned that any revision to the criteria will weaken current training requirements needed to safely administer radiopharmaceuticals. We agree with the ACMUI's October 2019 "Review and Comments on Draft NRC Commission Paper Entitled *Evaluation of Training and Experience Requirements for Administration of Radiopharmaceuticals Requiring a Written Directive,*" which states:

> *Determining AU status by specialty board certification for non-radiation related specialties creates a unique set of challenges. In our view, such a certification must provide the same high level of knowledge of radiation safety and care as the current deemed-status boards. As delineated in 10 CFR 35.390, this requires extensive T&E of appropriate topics which currently requires 700 hours devoted to these topics. This would require other boards to provide and develop the expertise among their membership to develop the curriculum and create training programs for their new trainees, and those already in practice within their specialty.*

The ACMUI continues:

> *There are three boards that have achieved certain NRC recognition (or "deemed-status") for the use of unsealed byproduct material requiring a written directive (the American Boards of Radiology and Nuclear Medicine and the American Osteopathic Board of Radiology). This NRC recognition is conferred on a medical specialty board as a formal acknowledgment of meeting and continuing to meet NRC requirements for AU status for its certified diplomates. That recognition is at least partially based on those boards' requirements for comprehensive training, content, and experiential components in radiobiology, dosimetry, and radiation protection practices. Subcommittee members questioned if, and generally have an expectation that, newly proposed boards would meet the same high level of T&E as current NRC recognized Boards.*

The NRC's focus on patient safety and the safety of the general public, as it develops training and experience requirements, is appropriate. With this in mind, the NRC determined that the level of training required to administer these treatments must include either board certification or 700 hours of training and experience. The classroom and clinical experiences encompassed by radiation oncology and nuclear medicine training programs provide appropriate levels of knowledge and skill for any current and future radioactive agents. ASTRO believes that depth of knowledge and expertise comes with didactic and hands-on experience of the current T&E requirements.

Reducing the current T&E requirements, or changing them in any way, could put patients at risk. The excellent safety record for radiopharmaceuticals can be attributed to the required training and experience for AUs. Between January 2014 and January 2020, only 21 out of 12,829 total

events entered into RO-ILS: Radiation Oncology Incident Learning System®[1] and reported to the PSO were related to radiopharmaceuticals. As indicated in the self-reported data, none of these events have been reported to either the NRC or an Agreement State. Additionally, as noted in a presentation to the ACMUI on April 3, 2019, only 1 event using Ra-223 dichloride was reported during 2018, the same number as in 2017. This is a very small percentage of events when compared to CMS utilization data showing that there were approximately 3,000 radiopharmaceutical infusions performed in 2018.

Further, the alternate pathway offers flexibility and timely certification of new authorized users. Removing this pathway will adversely affect those physicians who have finished a radiation oncology or nuclear medicine training program and are waiting to take board exams, since these physicians would otherwise obtain AU status through the alternate pathway prior to receiving board certification. Any delay in obtaining AU status could potentially reduce the number of available AUs.

We believe that the NRC is the appropriate agency to regulate the T&E of physicians for medical uses, and do not believe that rulemaking is warranted. However, if the Commission decides to pursue rulemaking, the current standards must be maintained.

We appreciate the opportunity to work with the NRC on this important issue. Should you have any questions, please contact Cindy Tomlinson, Senior Patient Safety and Regulatory Affairs Manager at cindy.tomlinson@astro.org or 703.839.7366.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

CC: Commissioner Jeff Baran
Commissioner Annie Caputo
Commissioner David Wright

[1] RO-ILS is the only medical specialty society-sponsored radiation oncology incident learning system. Sponsored by ASTRO and the American Association of Physicists in Medicine (AAPM), 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

CHAIRMAN Resource

From: Cindy Tomlinson <cindy.tomlinson@astro.org>
Sent: Thursday, February 13, 2020 11:03 AM
To: CHAIRMAN Resource
Subject: [External_Sender] Letter from ASTRO re T&E
Attachments: FINAL Commissioner letter 2.13.2020.pdf

Good morning.

Please find attached a letter from the American Society for Radiation Oncology (ASTRO) regarding the staff's recommendations on training and experience for radiopharmaceuticals.

Please let me know if you have any questions.

Cindy Tomlinson, MPP
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