

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

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Siteman Cancer Center, Washington University St. Louis October 28, 2024

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U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

ATTN: Program Management, Announcements and Editing Staff

Re: Draft Interim Staff Guidance: Guidance for the Implementation of Training and Experience Requirements [NRC-2024-0143]

To whom it may concern:

On behalf of the American Society for Radiation Oncology¹ (ASTRO), I am writing to offer our comments on the Draft Interim Staff Guidance: Guidance for the Implementation of Training and Experience Requirements [NRC-2024-0143]. In general, we believe that the Draft Interim Staff Guidance offers clarity to regulations that at times can feel ambiguous. Our comments on specific sections of the Draft Interim Staff Guidance follow.

Board Certification Pathway

Given that the ABR is no longer conferring the "AU Eligible" designation for board certified radiation oncologists, ASTRO recommends adding clarification that this section does not apply to radiation oncologists receiving ABR board certification after December 31, 2023, and that they should refer to section 4.3.1.2 *Alternate Pathway*.

Supervision

To avoid confusion, ASTRO recommends the addition of "200 hours required by the" in the following sentence on page 18, under section 4.3.2.2 *Supervised Work Experience* of the Draft Interim Staff Guidance:

Even though the NRC does not specifically require these clinical activities, this type of supervised clinical experience may be credited toward the "supervised work experience" category to obtain the required total of 700 hours of T&E, but not to the 200 hours required by the classroom and laboratory training category.

¹ ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists, and social workers. They treat more than one million patients with cancer each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

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Recentness of Training

The question that ASTRO receives the most often from members involves the recentness of training requirement. The regulations are ambiguous, and the Draft Interim Staff Guidance lacks significant clarification. In conversations with both NRC staff and Agreement State representatives about what requirements or metrics are needed to satisfy the recentness of training requirements, the answer has consistently been "it depends" or "it is determined on a case-by-case basis." This lack of guidelines and metrics by which to determine what is required is causing confusion and uncertainty.

ASTRO recommends the NRC provide specific guidelines that could satisfy the recentness of training requirements that can be applied uniformly throughout the country. Is merely receiving continuing medical education credits in a specific modality enough? Do you need practical hands-on experience? If so, how much? Do the requirements change based on how long it has been since you completed training? Currently, the answers to these questions vary from state to state, regulator to regulator.

For example: An AU eligible, board-certified radiation oncologist, who received their board certification in 2009 wants to begin administering unsealed sources. What do they need to satisfy the recentness of training requirements? Is practical experience enough (i.e., 3 cases under the supervision of an AU)? Is relevant continuing education received through ASTRO or another accredited body sufficient? At what point, post training, do these requirements change? What are the new requirements? Will there be different requirements now that the ABR no longer conveys AU status to its diplomates and they need to obtain that status through the "alternate pathway"?

If the determination of what is needed really is up to the regulator, on a case-by-case basis, without specific requirements or metrics, we recommend including an explicit statement in the Draft Interim Staff Guidance that each individual must consult with either the NRC or their agreement state for a determination.

Case Scenarios

ASTRO appreciates the inclusion of specific case scenarios, including examples of completed NRC forms. We recommend that a statement be added acknowledging that some agreement states have their own forms and that they may or may not accept the NRC forms.

ASTRO thanks the NRC for the opportunity to provide comments on the Draft Interim Staff Guidance for the Implementation of Training and Experience Requirements. We look forward to continuing to work with the Commission on this and other important issues. Should you have any questions, please do not hesitate to contact Cindy Tomlinson, ASTRO's Senior Manager for Patient Safety and Regulatory Affairs at cindy.tomlinson@astro.org or 703.839.7366.

Sincerely,

Laura I. Thevenot

Chief Executive Officer

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