SUNSI Review Complete
Template = ADM-013
E-RIDS=ADM-03
ADD=Sarah Lopas, Carrie Crawford

COMMENT (45)
PUBLICATION DATE:
5/2/2019
CITATION: 84 FR 18874

# PUBLIC SUBMISSION

**As of:** 7/2/19 1:23 PM
**Received:** July 02, 2019
**Status:** Pending_Post
**Tracking No.** 1k3-9at2-8i84
**Comments Due:** July 03, 2019
**Submission Type:** Web

**Docket:** NRC-2018-0230
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

**Comment On:** NRC-2018-0230-0162
Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

**Document:** NRC-2018-0230-DRAFT-0196
Comment on FR Doc # 2019-10760

## Submitter Information

**Name:** Lisa Langenderfer

## General Comment

Please see attached comments from The US Oncology Network.

## Attachments

The US Oncology Network_NRC T&E Comments

The US Oncology Network

July 3, 2019

VIA ELECTRONIC SUBMISSION

Office of Administration
Attn: Program Management, Announcements and Editing Staff
Mail Stop: TWFN-7-A60M
US Nuclear Regulatory Commission
Washington, DC 20555-0001

**Re: Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive [NRC-2018-0230]**

**To whom it may concern:**

On behalf of the physicians of The US Oncology Network (The Network), I thank you for the opportunity to comment on *Draft Approaches for Addressing Training and Experience (T&E) Requirements for Radiopharmaceuticals Requiring a Written Directive* (NRC-2018-0230) published in the Federal Register on May 2, 2019.

The Network is the nation's largest and most innovative network of community-based oncology physicians, including 210 radiation oncologists, treating over one million cancer patients annually in over 470 locations across 25 states. The Network unites physicians around a common vision of expanding patient access to the highest quality state-of-the-art care close to home, and at lower costs for patients and the health care system.

The Nuclear Regulatory Commission (NRC) seeks comment on whether changes to the T&E requirements for authorized users (AUs) administering radiopharmaceuticals are necessary and outlines several draft approaches to do so. Overall, The Network believes the existing T&E requirements to become an AU are appropriate and provide sufficient access to high-quality care; therefore, they should not be revised.

The NRC seeks feedback from the medical community on whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals. The Network shares the American Society for Radiation Oncology's (ASTRO) opposition to this approach and agrees that any changes to the current regulations would put patients and the public at risk. Additionally, we agree with ASTRO that the current requirements for those seeking AU status outside of the board certification pathway is sufficient and should not be reduced or changed.

The NRC also proposes to remove prescriptive T&E requirements from the regulations and instead focus oversight on the performance-based aspects of a licensee's medical program for the administration of radiopharmaceuticals. Specifically, the NRC proposes to allow licensees to develop and use their own policies and procedures to make self-determinations of whether their credentialed physicians have the appropriate T&E to be an AU for one or more radiopharmaceuticals under 10 CFR 35.300, and asks how to credential physicians in small practices under this framework. The Network shares ASTRO's concerns that this proposal could result in inconsistent requirements among licensees, which could harm patient care and lead to disparate patient

outcomes. Given the need to review and monitor the new performance-based aspects of this approach, we are not convinced this would increase access for larger facilities, and it could be costlier and even dangerous for smaller practices who would need to keep track of varying T&E requirements.

The NRC also seeks feedback on a team-based approach, which could remove prescriptive T&E requirements for AUs, focus training requirements on the competency of the entire team, or revise the current 700-hour T&E requirement for AUs by pairing the AU with another individual with expertise in administering radiopharmaceuticals. The Network opposes this approach. Again, we share ASTRO's view that advanced practice providers play an integral role as physician-extenders; however, a board-certified/ board-eligible radiation oncologist is the clinically appropriate physician to supervise and administer radiation treatments. This approach could create confusion in both the NRC's regulatory framework as well Medicare's supervision and billing requirements, as Authorized Nuclear Pharmacists (ANPs) do not have scope of practice privileges to perform therapeutic administration of radiopharmaceuticals in any state. Partnering an AU with an ANP would also not increase access because ANPs do not have the breadth or depth of knowledge necessary to relieve the AU of his/her responsibilities and could potentially put patients at risk if this recommendation allowed an AU to not be present for the administration of the radiopharmaceutical.

In summary, **The Network believes maintaining the status quo is the safest and most effective way to regulate future radiopharmaceuticals**, especially given there is no identified shortage of AUs.

On behalf of The US Oncology Network and our more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide our comments on *Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive* (NRC-2018-0230). We welcome the opportunity to discuss the issues outlined above and other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncology.com.

Sincerely,

Ben Jones
Vice President, Government Relations and Public Policy
The US Oncology Network