

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

# PUBLIC SUBMISSION

COMMENT (39)  
 PUBLICATION DATE:  
 5/2/2019  
 CITATION: 84 FR 18874

<b>As of:</b> 7/2/19 9:04 AM <b>Received:</b> July 01, 2019 <b>Status:</b> Pending_Post <b>Tracking No.</b> 1k3-9asc-f9yl <b>Comments Due:</b> July 03, 2019 <b>Submission Type:</b> 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-0190

Comment on FR Doc # 2019-10760

## Submitter Information

**Name:** Caitlin Kubler

**Address:** United States,

**Submitter's Representative:** Satoshi Minoshima

**Organization:** Society of Nuclear Medicine and Molecular Imaging

## General Comment

See attached file(s)

## Attachments

SNMMI\_ACNM\_NRC\_training\_experience\_FINAL\_072019

July 1, 2019

Daniel S. Collins  
Director, Division of Materials Safety, Security, State, and Tribal Programs  
Office of Nuclear Materials Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

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

Dear Mr. Collins:

The leadership of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), together with representatives from the American College of Nuclear Medicine (ACNM) offer the following collective comments on the Nuclear Regulatory Commission (NRC) Federal Register Notice “Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive.”

By way of background, the SNMMI has more than 17,000 members, including physicians, technologists, scientists, physicists, chemists and pharmacists, all participating in the field of nuclear medicine and molecular imaging. These members set the standard for nuclear medicine practice by creating clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging, therapy, research and the practice of Nuclear Medicine. For more than 50 years, SNMMI members have developed—and continue to explore—innovations in medical imaging and radionuclide therapy leading to improved noninvasive diagnosis, patient management, and treatment of diseases, with benefit to numerous generations of patients.

The Society includes a Technologist Section, which has a membership of 11,000 professional nuclear medicine technologists. Under the supervision of an Authorized User (AU), nuclear medicine technologists mix, prepare and administer imaging and therapeutic radiopharmaceuticals and operate and monitor the equipment used to image the movement and distribution of these radiopharmaceuticals within the body. Nuclear Medicine technologists are integral in delivering high quality patient care in hospitals, universities, medical clinics and research centers across the United States and abroad. They are particularly essential in the delivery of radiopharmaceutical therapy by providing radiation safety education and protection to the patient and the public during and after the therapy administration. They administer the therapy dose under the personalized supervision of the AU. Technologists’ unique training and education provide a necessary component in the safe treatment of patients and helps assure a successful clinical outcome.

The ACNM is a professional organization that directly represents the interests of Nuclear Medicine physicians before legislative and regulatory bodies, other medical organizations, the media and public. The College comprises physicians and scientists dedicated to enhancing the practice of Nuclear Medicine through the study, education and improvement of clinical practice. The goal of ACNM is to assure a legislative, legal, regulatory and economic framework that encourages and makes practicable the safe,

appropriate use of nuclear medicine procedures to improve the quality of health care service available to patients. ACNM, alongside SNMMI, is pleased to offer comments on specific topics detailed below. As previously stated in our January 2019 comments, the Society and the College ad-hoc group cast a wide net in inviting all relevant stakeholders to this group. Our discussions have included physicians, most, but not all, of whom are authorized users, as well as technologists, medical physicists, radiopharmacists, and radiochemists. We also engage patients, both as individuals and as members of patient advocacy groups. **We would like to stress that our main objective is to emphasize patient and public safety, while ensuring access to quality care.**

Many of the inquiries in the May 2<sup>nd</sup> Federal Register Notice the SNMMI and ACNM have already been addressed in our prior January 2019 SNMMI-ACNM comments as well as our July 2018 SNMMI-ACNM-ASTRO comments. For these questions, we will reference our previous comments and note the section. We continue to strongly believe that maintaining the current level of training is the best option for both patients and the public. We do not believe the other options listed will benefit patients or the public. Lowering any requirements could put patients and the public at risk or lower the quality of care. If the NRC cannot fully ensure that won't happen, then the status quo should not be changed. It is certainly counterintuitive to expect increased patient safety by lowering minimum training requirements.

**Question 1: If the “Status Quo” is maintained, how should the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals?**

The current system is fully able to handle the expected increase in number and complexity of future radiopharmaceutical therapy, and this needs to be done in the context of appropriate training. As stated in section A of our January 2019 comments, SNMMI and ACNM advocate that the current T&E pathway is critical to be able to provide high-quality care to patients and to ensure their safety as well as that of their families and the general public. Parenteral radionuclide therapy can be administered appropriately only by personnel with an extensive understanding of radiation physics, radiopharmacy, pharmacokinetics, dosimetry, and radiation biology, as well as the principles and practices of radiation safety. In addition, the safety of pediatric radionuclide therapy is a special concern due to the higher radiosensitivity of children, their longer anticipated lifespan after therapy, and the special care that children need. For example, pediatric patients frequently require close contact with caregivers and may not have the developmental maturity to cooperate with instructions. Reducing the training requirements for parenteral administration of unsealed radionuclide therapy will compromise the safety of patients, their caregivers, and family members.

**Together with the fact that there is no identified shortage of AUs, there is no clear need to develop a new tailored T&E pathway.** Equally, we believe that the creation of a new tailored T&E pathway for physicians seeking limited AU status could open the possibility that these therapies will be administered in clinical settings that do not have the systems infrastructure to support the safe use of parenteral radionuclide therapy and to manage the potential radiation safety issues and medical complications that may arise.

**Question 2: Is there a challenge with the current T&E requirements—such as concerns regarding patient access to radiopharmaceuticals—that should be addressed through a rulemaking?**

No, there is no challenge with the current T&E requirements that need to be addressed through rulemaking. As previously stated in section C of our January 2019 comments, there are inherent disparities in access to medical care due to geographic, economic, or social factors. For example, patients in rural areas may have to travel to receive advanced medical care. However, these factors affect access to medical care in general and are not specific to procedures involving radiopharmaceuticals. The safe use of radionuclide therapy requires an integrated system of medical

care involving a team of medical professionals. Changing NRC regulations with the intent of expanding access to radionuclide therapy in the absence of improving access to all types of advanced medical care could result in the administration of radionuclide therapy at facilities without adequate medical expertise for all facets of a patient's medical care and without the ability to ensure the same high-level delivery of radioisotope therapy and radiation safety. Thus, the proposed changes to the AU T&E requirement could lead to decreased safety for patients, caregivers, and families.

Currently, there are three different pathways for obtaining AU status:

- (1) Certification by a medical specialty board whose certificate is recognized by the NRC or an agreement state;
- (2) Completion of T&E including 200 hours of classroom training and 500 hours of supervised work experience; finally,
- (3) Previous identification as an AU on an NRC or agreement state license or permit.

Radiopharmaceuticals are unique drugs with unique risks to patients and the public. Specific training, including didactic training and experiential clinical training, is required to ensure the safe use of radiopharmaceuticals. As the field of nuclear medicine and molecular imaging expands and new parenteral radionuclide therapies become available, it is essential that robust training be maintained to ensure the safety of patients, caregivers, and families. Of the three pathways, certification by one of the currently recognized medical subspecialty boards demonstrates that authorized user has been trained within the parameters of the AU T&E and in an environment that focuses on the medical use of radiation and provides a culture of radiation safety. As new drugs with different potential risks become available, the medical specialty boards will be best situated to revise training guidelines and curricula.

**Question 10: What are the advantages and disadvantages of the draft approaches?**

The merit of draft approach A is in maintaining the bare minimum of training and experience requirements (700 hours) that is currently required by the US NRC. However, this bare minimum does not withstand the far more comprehensive international comparison. The International Atomic Energy Agency which provides guidance pertaining to training and experience in nuclear medicine at an international level delineates the need for four years of training (6700 hours) in order to practice nuclear medicine responsibly at a high standard.<sup>i</sup>

We do not see any advantages of the draft approaches B, C, or D since the original argument to create these approaches, namely the assumed shortage of authorized users limiting patient access to care, does not exist as has been stated previously in our January 2019 comments as well as by the NRC Advisory Committee on the Medical Use of Isotopes February 2019 report. Furthermore, statements from patient advocate organizations, for example comments provided to NRC by NorCal CarciNet, a community advocating for patients with neuroendocrine tumors, demonstrate patients' strong opposition to diminishing training and experience requirements. A copy of this statement is attached to this document. Thereby, draft approaches B, C, and D lack a reasonable justification to be pursued.

**Question 11: Are there significant costs or benefits associated with any of the approaches?**

Draft approaches B-D will result in a significant promulgation of rulemaking and associated costs without any expected benefit. The increased costs will naturally translate into rising licensing fees with the potential counterproductive consequence of limiting availability of and access to specialized care. SNMMI and ACNM strongly recommend an independent outside review of NRC's medical use program before any changes in training and experience requirements with unknown consequences are

implemented. A similar outside review commissioned by NRC was carried out by the National Academy of Sciences Institute of Medicine (NAS-IOM) in 1994.<sup>ii</sup>

**Question 12: Would any of the draft approaches impact patient access to radiopharmaceuticals or address stakeholder concerns of overly burdensome (regulatory) requirements?**

Please refer to our January 2019 comments Section A, Question 1 on Reasonable and necessary pathways and Section C, Question 3 on Patient Access.

**Question 17: Are there any unintended consequences of the draft approaches?**

The unintended consequences of the draft approaches are in the fact that while attempting to increase patient access to radioisotope therapies, there will be a real increased risk of inferior delivery of these therapies and radiation safety concerns to the patient and the public. The inferior delivery concerns including the gamut of care from inappropriate selection of patients for the therapy, sequencing of therapy, preparation of the patient for therapy, dose selection, managing side effects, radiation safety precautions, handling radiation spills, and proper handling of residual radioactivity, decay products, and waste. Increasing access to care by these draft approaches should not come at the risk of these serious unintended consequences. Equally, the only way to avoid them is to maintain the high standards of T&E currently required by the NRC.

**Question 19: Should the NRC continue to play a role in the review and approval of AUs?**

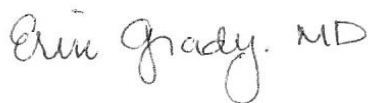
Yes. We feel that NRC plays an important role in the review and approval of AUs. It not only helps to protect the public, but also to promote the safe use of radiation which is the charge of the NRC. We believe that the NRC should collaborate more closely with the ABNM and ABR given that the targeted radionuclide therapies will be applied in diverse disease processes and with increasing complexities. If the NRC does not have this role, we believe it would cause confusion and decrease safety to patients and public. We have grave concern that industry could thus potentially have an unchecked means of increasing delivery of their products by individuals who do not have the appropriate knowledge or training and experience related to radiation and safe handling of radiopharmaceuticals. The role of the NRC in this regard is perhaps more important than ever.

The Society and College appreciate the opportunity to provide feedback to the NRC on training and experience requirements. Additional feedback can be found in our July 10, 2018 Joint Statement from SNMMI, ACNM, and ASTRO as well as our SNMMI-ACNM Statement from January 2019. SNMMI and ACNM are ready to discuss any of its comments with the NRC. In this regard, please contact Caitlin Kubler, Associate Director, Health Policy and Regulatory Affairs, by email at [ckubler@snmmi.org](mailto:ckubler@snmmi.org) or by phone at 703-326-1190.

Sincerely,



Satoshi Minoshima, MD, PhD  
SNMMI President 2018-2019



Erin Grady, MD, CCD, FACNM  
ACNM President 2019-2020

---

<sup>i</sup> IAEA Nuclear Medicine Resources Manual. (pp 10-36 Training of Medical Doctors). Accessed on June 16th, 2019 from <https://www.iaea.org/publications/7038/nuclear-medicine-resources-manual>

<sup>ii</sup> Gottfried KD, Penn G: Radiation in medicine. A need for regulatory reform. National Academy Press. Washington DC. 1996.