January 28, 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-2018-0230-0001, Training and Experience Requirements for Different Categories of Radiopharmaceuticals**

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) formed an ad-hoc committee to offer their collective comments on the Nuclear Regulatory Commission (NRC) Federal Register Notice "Training and Experience Requirements for Different Categories of Radiopharmaceuticals."

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 and nuclear medicine therapy research and practice.

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, 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, 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 during and after the therapy administration. They administer the therapy dose under the personalized supervision of the AU. Their 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.

The Society and the College 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 have engaged patients, both as individuals and as members of patient advocacy groups. The questions posed are not easy, but we want the Commission to understand that our main objective is to emphasize patient and public safety, while ensuring access to quality care.

Where should radionuclide therapy be administered: Patient care in Wyoming

Radionuclide therapy is best performed within an integrated system of medical care with a team of clinicians and caregivers who bring together the wide-ranging expertise needed to care for patients with complex medical conditions. For example, one of the members of this writing committee has a family member who required radionuclide therapy and lives in a small town (under 3,500 residents) in Wyoming. This family member did not receive care in their hometown, but instead drove a few hours away to receive specialized medical care. This is the expected and usual practice for receiving advanced medical care throughout the United States and allows high quality care to be provided within a system that is prepared to offer all aspects of integrated advanced medical care. As in most rural areas, residents of the area have come to expect that travel will be necessary for *any* specialty medical care. Trying to expand access to radionuclide therapy by using clinicians with limited authorized user training may result in its use at medical facilities that cannot provide the needed medical care and do not have the systems to ensure radiation safety. We suggest that the best practice is to have radionuclide therapy performed at medical facilities that have a team of medical professionals, including authorized users who have the training and experience to perform radionuclide therapy safely, as well as physicians with expertise in the medical care of complex patients, radiologists and nuclear medicine physicians to oversee and interpret advanced medical imaging, and medical experts readily available to manage potential complications.

Specific Questions

A. Tailored Training & Experience Requirements

1. Are the current pathways for obtaining authorized user (AU) status reasonable and accessible?

Yes. When looking at Part 35 of the 10 CFR, the training and experience requirements are clearly outlined in subparts D-H. The applicant list is broad, encompassing physicians, dentists and podiatrists. Requirements are clearly listed. While the actual number of physicians, dentists and podiatrists completing this training is not known to us, we do know of individuals who have completed this training, particularly in the specialty of endocrinology, where the appropriate training is embedded within the subspecialty training program. It is also noted that there is a dedicated certification board in nuclear endocrinology, which serves this group. Similar practices are noted in cardiology.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety?

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.

3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements?

No. 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 safely 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.

4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?

Yes, the training expectations should remain the same. It would seem counterintuitive to expect increased patient safety by lowering minimum training requirements.

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?

As indicated above, we believe the current T&E pathway is appropriate and that the resulting AUs are adequately trained. Additionally, we believe there are a sufficient number of AUs who are able to meet current and future radioisotope therapy needs in the US. As such, there is no need for a new limited AU category for administration of parenteral radionuclide therapy.

i. Classroom and laboratory training - The classroom and laboratory training should remain the same. Understanding the scientific principles underlying radionuclide therapy is essential to the safe use and administration of these drugs.

ii. Work experience - The work experience should remain the same. The expectation should be that an authorized user has training and experience in the practical and applied aspects of the parenteral administration of radionuclides.

iii. Competency - The competency should remain the same and consist of a written exam at a minimum. A practical examination by an independent examining committee can be considered in addition.

a. The preceptor attestation should be required. If anything, it should be *more stringent* to ensure that the trainee has had meaningful participation in multiple therapies and has not been just a passive observer.

b. The radiopharmaceutical manufacturer definitely should not be the entity to provide preceptor attestation. Their employees are not trained in nor practice medicine and would be heavily biased in approving additional AUs who could prescribe and administer their product.

c. The curriculum ideally could be established and administered by the medical specialty boards, either alone or in conjunction with a medical professional society or independent educational group. The organizations involved in these activities should be dedicated to the mission of training AUs.

B. NRC's Recognition of Medical Specialty Boards

1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?

There are no additional specialty boards that the NRC could consider for recognition under 10 CFR 35.390.

2. Are the current NRC medical specialty board recognition criteria enough? If not, what additional criteria should the NRC use?

This appears to be the same as asking if the criteria for "deemed" status for medical specialty boards are sufficient.

The NRC recognition criteria should require a medical specialty board to demonstrate an ability to develop training guidelines, certify authorized users, and facilitate continued training and competency in radiation safety. Ideally, a recognized medical specialty board should certify physicians whose primary medical practice involves the medical use of radiation. Only these boards will have a sufficient depth and breadth of professional expertise to develop appropriate curricular guidelines and adequately assess physicians at the end of formal training.

C. Patient Access

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical?

No. Data from the American Board of Nuclear Medicine (ABNM) is readily available online. Based on this data, there have been on average 67 new Nuclear Medicine diplomates per year in the last ten years (2008-2017). This number appears to plateau at about 50 diplomates per year in most recent years (63 in 2015, 43 in 2016, and 49 in 2017). Additionally, in the last 5 years, 568 diplomates have taken the ABNM maintenance of certification examination. Based on conservative estimates, a work force of at least more than 1,200 board-certified nuclear medicine physicians across the US are available.

Furthermore, based on broad licensing by NRC graduates from other programs like diagnostic radiology and radiation oncology are eligible to become authorized users. Given the robust number of AUs both in the workplace currently and those in training, we do not believe that there is a shortage of AUs.

2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.

The answer to this is unclear, and we feel that the NRC would be best suited to provide accurate statistics on number and location of authorized users. What is clear is that all tertiary level and most secondary level medical care centers/facilities have a nuclear medicine service/division or a radiation oncology department and hence do have physicians who have been trained as authorized users. Thereby, a wide net of authorized users is already in existence across the country. Smaller medical facilities are less likely to have an authorized user on staff, but also are unlikely to have other members of the team: medical specialists with expertise in treating complex medical conditions, imaging professionals to perform the advanced imaging needed to manage the care of patients requiring radionuclide therapy, or medical experts with familiarity in treating the possible complications of radionuclide therapy. These smaller medical facilities are unlikely to have the staff of nuclear medicine technologists, medical physicists, and radiopharmacists who are needed to ensure patient safety. Therefore, the provision of radionuclide therapy appropriately will follow the typical model for providing other forms of advanced medical care in the United States and should be performed only in medical facilities who have the systems infrastructure and team of medical professionals to provide integrated advanced medical care.

3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals?

No. Unfortunately, there are disparities in access to medical care due to geographic, economic, or social factors. For example, as described above, patients in rural areas may have to travel to receive advanced medical care. However, these factors affect access to medical care in general, and do not specifically limit access 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 systems to ensure radiation safety. Thus, the proposed changes to the AU T&E requirement could lead to decreased safety for patients, caregivers, and families.

4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine?

The current NRC regulations and AU T&E appropriately aim to protect human research subjects and workers. Research and development are essential to the continued development of novel diagnostic and therapeutic radiopharmaceuticals. There are currently many innovative and active researchers who have obtained AU status through one of the traditional pathways. Also, research training is a key requirement of many nuclear medicine training programs. Research and development in nuclear medicine in U.S. lag behind international competitors, and this likely is due to many factors. However, there is no clear evidence that current NRC regulations or, specifically, that the regulations on AU T&E requirements contribute to this lag or directly impact nuclear medicine research and development in the U.S.

D. Other Suggested Changes to the T&E Regulations

1. Should the NRC regulate the T&E of physicians for medical uses?

Yes. The Society and College appreciate the NRC wanting to provide a construct for patient safety. Our primary concern is ensuring patient safety. The role of the NRC should be to establish the general parameters of AU T&E to ensure that authorized users receive sufficient didactic and experiential training for the safe use of medical radionuclides, while ensuring the safety of the patient, caregivers, and family. Within these regulations, the currently recognized medical specialty boards have developed specific curricula to provide robust training in the principles, practice, and safety of the medical use of radionuclides. Ideally, this training is provided in a clinical environment where the use of medical radiation is routine, where experts in radiopharmaceutical use can serve as preceptors and role models, and where there is a culture of radiation safety.

As an example, the training regulations set forth in Subpart F pertaining to manual brachytherapy sources as defined in 35.490 and in Subpart H pertaining to teletherapy and stereotactic radiotherapy units as defined in 35.690 can be illustrated. In this instance the training requirements clearly outline a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the ACGME and passing of an examination, administered by diplomates of the specialty board (Board certification). In this

example, NRC rightfully relies on the knowledge and skills obtained during a specialty board certified residency training without providing highly prescriptive requirements for training.

2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

No. The training requirements in 10 CFR parts 35.390, 35.392, 35.394 and 35.396 are all safety related. No non-safety training requirements are currently listed.

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the public, patients, and human research subjects?

Any transformation of the regulatory approach for AU T&E should involve the currently recognized medical specialty boards. For the members and diplomates of these specialty boards, the focus their professional medical practice is on the safe medical use of radiation. These boards have many years of experience in developing training guidelines and certifying trainees within the framework of the NRC regulations. Much as agreement states work with the NRC to implement NRC regulations, the recognized medical specialty boards work with the NRC to implement AU T&E regulations. Only specialty boards whose practice of medicine is focused primarily on the medical use of radiation have the breadth and depth of professional expertise to develop adequate training guidelines, certify trainees, and ensure up-to-date maintenance of competency for the safe medical use of radionuclides.

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. 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 or by phone at 703-326-1190.

Sincerely,

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