CHAIRMAN Resource

From:	Carol Marcus <csmarcus@ucla.edu>
Sent:	Monday, January 28, 2019 12:13 PM
To:	CMRBurns Resource; CMRBARAN Resource; CHAIRMAN Resource; CMRCaputo Resource; CMRWright Resource
Subject:	[External_Sender] SNMMI-ACNM T&E comment letter
Attachments:	NRC SNMMI T&E comments 01-28-19.pdf

Jan. 28, 2019

Dear Commissioners:

Attached is the comment letter from the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and the American College of Nuclear Medicine
(ACNM) regarding the NRC staff's plan to create alternate training and experience requirements for nuclear medicine therapy. As you can see, SNMMI and ACNM are firmly against any such action, and for good reasons.

Sincerely,

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SNMMI Value Initiative
SOCIETY OF NUCLEAR MEDICINE & MOLECULAR IMAGING

ACNM

January 18, 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's more than 17,000 members include physicians, technologists, scientists, physicists, chemists and nuclear pharmacists who set the standard for molecular imaging and nuclear medicine practice through the creation of clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice.

For more than 50 years, SNMMI members have developed—and continue to explore—innovations in medical imaging to allow noninvasive diagnosis, management and treatment of diseases, benefiting countless generations of patients.

The Society includes a Technologist Section, comprised of 11,000 professional nuclear medicine technologists. Under the supervision of the Authorized User technologists mix, prepare and administer imaging and therapeutic radiopharmaceuticals and operate and monitor equipment to trace the movement and concentration of these radiopharmaceuticals in 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 provides a necessary component in treating patients and assuring 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 is comprised of physicians and other nuclear medicine professionals 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. SNMMI, alongside ACNM, is pleased to offer comments on specific topics detailed below.

We want to assure NRC that the society and College cast a wide net in inviting all relevant stakeholders to this group. As such we engaged with not only physicians, but also technologists, physicists, and radiochemists. 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.

Patient care in Wyoming

One of the members of this writing committee has a family member who has had differentiated thyroid cancer in a relatively isolated town in Wyoming with under 3,500 people. This family member did not receive care in their home town, instead drove a few hours away to receive care. This was not overly onerous for the family member, and the practice is actually quite common. Residents of the area come to expect that travel of a few hours, for *any* specialty visit is necessary. Rather than potentially degrading the quality of care to increase access (or pharmaceutical sales), we would suggest that radionuclide therapies be performed in locations that not only have knowledge and experience on how to perform such therapies safely, but also have experts readily available to cope with potential complications, some of which can be severe.

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 people who have completed this training, particularly in the specialty of endocrinology, often the training is embedded in their fellowship. 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 comprised of 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 is thus required and as the field of nuclear medicine and molecular imaging is expanding, it is necessary that training be maintained to mitigate the associated risks. The certification by the boards and the T&E appear to be sufficient, however, as new drugs with different risks come onboard new training should be expected.

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. Additionally, the safety of pediatric radionuclide therapy is a special concern due to the higher radiosensitivity of children, the longer anticipated lifespan after therapy, and the special care that children need. Radionuclide therapy in children can be safely administered only by personnel with extensive understanding of physics, radiopharmacy, pharmacokinetics, dosimetry, and radiation biology, as well as principles and practices of radiation safety in children. Pediatric patients frequently require close contact with caregivers and may not have the developmental maturity to cooperate with instructions. Reducing the training requirements for administration of unsealed radionuclide therapy will compromise the safety of pediatric 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 therapies to practice in suboptimal centers and by physicians who are not appropriately trained to handle radioactivity, assess their utility in the proper context of radionuclide therapies, and to deal with any 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 the resultant 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 limited AU category.

i. **Classroom and laboratory training** - The classroom and laboratory training should remain the same.

ii. **Work experience** - The work experience should remain the same.

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.

b. The preceptor attestation should be required. If anything, it should be *more stringent* to ensure that the trainee has truly participated in multiple therapies; not just observed them.

c. The radiopharmaceutical manufacturer should definitely not provide preceptor attestation. They are not trained in nor practice medicine and are heavily biased in approving additional AUs to prescribe and give their product.

d. The curriculum could ideally be established and administered by the medical specialty boards, either alone or in conjunction with a medical professional society or independent educational group. The latter would require proper development of an educational group dedicated to this 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?

The current training and experience requirements specified under 10 CFR 35.390 are inadequate for new and emerging medical technologies, as suggested by NRC licensing decision announcements for specific, recently FDA approved products of radium-223 dichloride and lutetium-177 DOTA-TATE. Indeed, even the licensing guidance first issued in 2002 for yttrium-90 labeled microspheres is undergoing its 10th revision and remains without a more definitive statement. A comprehensive revision of training requirements is required in anticipation of forthcoming beta- and alpha-emitting radionuclides, including those with alpha-emitting daughter products such as actinium-225.

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 though, is that all tertiary level and many secondary level medical care centers/facilities have a nuclear medicine service or division, or a radiation oncology department and hence presence of authorized users. Thereby a wide net of authorized users across the country is already in existence. As it is well known, medical service in general is scarce in some mainly rural regions of the country and availability of specialty care is not limited to those who can administer radiopharmaceutical therapies. As we noted above, patients in rural areas are ready to travel longer distances to the nearest specialized centers to receive both complex and non-complex procedures or evaluations. An appreciation for specialty training is common as these patients know that they will receive greater expertise at these centers. These specialized centers are also more adept at dealing with complications, some of which can be serious. Radioligand therapies are highly specialized treatments requiring several years of training and experience that guarantees in-depth knowledge and expertise in all aspects of these therapies. Many of these new therapeutic agents are part of clinical trials and can only be offered at specialized centers.

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

No. As indicated above, patients in rural areas or underserved regions are accustomed to traveling to gain access to greater expertise and higher levels of care. If we consider this a limitation for radionuclide therapies in isolation, it would be inappropriate. Referrals to all specialties to advanced, tertiary centers are often made from rural or underserved areas.

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

There are currently many innovative researchers in practice who have obtained AU status through one of the traditional pathways. Research is a fundamental requirement of training in several institutions in the U.S., and comprehensive research training prepares these trainees to conduct valuable research projects during their training and beyond. While research and development in nuclear medicine in U.S. lag behind international comparison there is no clear evidence that current NRC regulations on AU T&E requirements directly impact research and development in nuclear medicine in U.S.

D. Other Suggested Changes to the T&E Regulations

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

The society and College appreciate the NRC wanting to provide a construct for patient safety. Our primary concern is ensuring patient safety. It is best left in the hands of the specialty boards to confirm training and experience as is already occurring in parallel with the NRC.

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 too prescriptive requirements in training.

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

The training requirements in 10 CFR part 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?

By ensuring AUs maintain the minimum required training during the transformation or transferring this responsibility to medical specialty boards.

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,

Satoshi Minoshima, MD, PhD
SNMMI President 2018-2919

ACNM President 2018-2019