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

COMMENT (79)
PUBLICATION DATE:
10/29/2018
CITATION: 83 FR 54380

PUBLIC SUBMISSION

As of: 1/29/19 10:02 AM
Received: January 28, 2019
Status: Pending_Post
Tracking No. 1k3-97xv-ztkg
Comments Due: January 29, 2019
Submission Type: Web

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

Comment On: NRC-2018-0230-0001
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Document: NRC-2018-0230-DRAFT-0085
Comment on FR Doc # 2018-23521

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General Comment

Please see that attached comment from the Nuclear Medicine Residents Organization (NMRO), re Docket ID NRC-2018-0230-0001.

Attachments

NMRO to NRC, Training and Experience Requirements for Different Categories of Radiopharmaceuticals

January 24, 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 Nuclear Medicine Residents/Fellows Organization (NMRO), representing more than 1000 trainees in nuclear medicine, is the trainee branch of the American College of Nuclear Medicine (ACNM). The NMRO has been following the recent considerations of the NRC to reduce training and experience requirements related to 10 CFR 35 Medical Use of Byproduct Material Subpart E Unsealed Byproduct Material Written Directive Required with a great deal of concern for the safety of our patients, health care workers, and general public.

The NMRO strongly opposes any attempts at minimizing training requirements for physicians and the creation of fragmented pathways to authorized user (AU) status. The NRC, in close collaboration with approved medical specialty boards, has created rigorous standards and training guidelines. We feel that any deviation from these established standards will jeopardize patient safety, healthcare worker safety, the quality of patient care, and excellence in the practice of nuclear medicine.

The NMRO wishes to submit below comments about “Training and Experience Requirements for Different Categories of Radiopharmaceuticals,” published in the Federal Register on Oct. 29, 2018.

Please note that the contents of this statement represent the opinion of the NMRO members. The ACNM will submit their separate comments in conjunction with the Society of Nuclear Medicine and Molecular Imaging (SNMMI).Thank you for your attention and consideration.

Sincerely,

Samuel Mahgerefteh, MD

President, Nuclear Medicine Residents Organization 2018-2019

A. Tailored Training & Experience Requirements

1. Are the current pathways for obtaining AU status reasonable and accessible?

Nuclear medicine is, as with any area of medicine, a highly specialized field requiring equally specialized training. Safe and valuable practice of nuclear medicine necessitates broad and deep knowledge in a wide variety of disciplines, not only in the direct clinical care of patients, but also in radiation physics and radiation biology. Moreover, application of the principles of nuclear medicine in practice requires ample experience in the clinic; much of the know-how of nuclear medicine can only be acquired by hands-on experience.

The current pathways through the American Board of Nuclear Medicine (ABNM) and the American Board of Radiology (ABR) are both reasonable and accessible. The relatively newly accessible training tracks provided to diagnostic radiology residents open this career pathway to thousands of new residents across the US each year, in addition to trainees who successfully complete a nuclear medicine residency training. Each year, we are seeing more and more interest from both medical students and diagnostic radiology residents, which demonstrates that these pathways are both reasonable and attractive to a multitude of trainees.

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

Over the past 50 years, the Nuclear Regulatory Commission (NRC) has been entrusted to protect the public and patients through their training standards for physicians and professionals that work with radioactive materials. Through partnership with nuclear medicine physicians and physician organizations such as the ACNM, these standards have protected millions of people. We assert that less rigorous or less prolonged training would be inadequate to ensure quality and safety in nuclear medicine.

Public health and safety can be divided in this context into radiation safety and safety in terms of quality of medical care: Is the patient receiving the correct radiopharmaceutical, and at the correct dose? Has the patient been educated regarding radiation safety precautions? Have the patient's close contacts been taken into consideration? Has the general public been protected?

Other questions are related to quality and expertise in medical care in nuclear medicine: What dose of radionuclide needs to be administered to achieve the therapeutic effect? What internal dosimetry calculations need to be carried out? How can the side effects of the therapy be reduced (e.g. renal toxicity, risk of carcinoid crisis in Lu-177-DOTATATE [Lutathera ™] treatments, bone marrow suppression in I-131 therapy, or hypertensive crisis in I-131 Iobenguane therapy, protection of thyroid gland prior to MIBG therapy, etc.)? What sequence of

therapies should be applied based on interdisciplinary conferences? This expertise can only be acquired in prolonged training in nuclear medicine.

As we enter an age of increasing applications for advanced nuclear and molecular medicine, we must correspondingly increase our vigilance to protect patients. In nuclear medicine, there is increasing use of not just diagnostic tests, but therapeutic procedures, which have potential to significantly harm patients. The increased use of radiopharmaceuticals for treatment necessitates rigorous guidelines established by the NRC together with nuclear medicine physicians. Therefore, we strongly caution against relaxing the NRC's training standards.

3. Should the NRC develop a new tailored T&E pathway for these physicians?

We believe that creating new "tailored T&E pathways" would be akin to having non-surgeon physicians take quick courses in order to perform cholecystectomies, appendectomies, or hernia repairs, with none of these individuals having comprehensive knowledge of surgery or its potential complications. As with surgery, knowledge of nuclear medicine must be comprehensive, not fragmented. For example, if one is to treat thyroid cancer, it is not enough to simply administer I-131. One must consider findings from imaging studies such as thyroid ultrasound and an I-123 whole body scan, monitor serum thyroglobulin levels, and decide the best patient preparation for optimal I-131 efficacy. The patient must then be thoroughly educated regarding the procedure, potential complications, and radiation safety. Often, very high doses of therapeutic I-131 may be needed, and dosimetry becomes necessary. It also sometimes becomes necessary to administer high doses in an inpatient setting, a situation that comes with its own clinical, radiation safety, and logistical challenges. Even after a patient is treated, further clinical/laboratory and imaging manifestations can trigger the need for retreatment, often leading to an even more complex strategy than the initial treatment.

We are strongly concerned that the proposed tailored pathways would lead to diminished competence in dealing with such challenges, thereby jeopardizing the safety of patients, healthcare workers, and the public.

The T&E requirements outlined in 10 CFR part 35.490 and 35.690 pertaining to manual brachytherapy sources and teletherapy or stereotactic radiation therapy units used in radiation oncology are illustrative of this point. Here, the T&E unambiguously requires at minimum 3 years of training in an ACGME-accredited radiation oncology training program and board certification. There are no provisions for alternate pathways or limited authorized users in this regulation. The regulatory standards must be at least as stringent in the case of radiopharmaceutical therapies which are distributed throughout the body.

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. As with the example of I-131 for thyroid disease given above, oral administration of radiopharmaceuticals can pose deep challenges in terms of clinical outcome, radiation safety, interdisciplinary collaboration, and logistical efficiency. The challenges are certainly greater with parenteral administration. The parenteral radiopharmaceuticals of today, and those being developed, often have more numerous and more severe side effects, and can pose greater danger to the patient and the general public than orally administered therapies. For instance, parenteral administration of Ra-223 requires regular monitoring of blood cells given its potential for serious marrow toxicity. Those with NRC-approved rigorous training have a clear understanding of the radioactive decay, which is essential to ensuring that sufficient doses are administered with controlled toxicity, that scheduling is done properly, and that patients receive the most benefit from each administration, with the lowest risk and minimal waste.

High quality care in all aspects of nuclear medicine is only guaranteed by a comprehensive educational curriculum, including radiation safety and all clinical aspects of nuclear medicine. These goals for clinical excellence and safety as outlined by the ABNM and ABR ensure patient safety and the highest quality of patient care.

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

Dividing the rigorous training developed by the NRC and nuclear medicine physicians by category of radiopharmaceutical does not reflect the standard of care. This would significantly compromise the quality of patient care. The partnership of the NRC and nuclear medicine specialty physician groups in establishing rigorous guidelines of training and experience have ensured patient and public safety, and the NRC and these nuclear medicine boards should continue to collaborate on these guidelines as new radiopharmaceuticals and technologies are introduced into the market.

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?

Sufficient training and experience in administration of systemic radionuclide therapies can only be guaranteed by dedicated training in a nuclear medicine program with board certification in nuclear medicine or training in a combined nuclear medicine and radiology program with dual board certification in nuclear medicine and radiology.

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

In determining the safe and appropriate criteria for a medical specialty board, we again look to the long record of safety established by the NRC and the specialty boards over approximately 50 years. These guidelines regarding training and specialty board recognition have protected patients from the dangers of radiation exposure, and we urge that these criteria not be loosened, partitioned, or diminished. Additional, more stringent criteria may potentially become necessary over time as advanced radiotherapies are developed.

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?

There is no evidence or data indicating a shortage of AU's in US. Based on recent estimates* there is an existing workforce of board-certified nuclear medicine physicians (AUs) across the US amounting to at least 1200 with addition of 50-60 new-graduates every year. We believe that these thoroughly trained nuclear medicine specialists will be able to meet the projected needs in radiopharmaceutical therapies in the upcoming years. Furthermore, for reasons described above, any future increase in demand for nuclear medicine specialists must be filled by physicians who have been properly trained through existing educational channels via the ABNM or ABR, in accordance with proven and established curricula. As detailed in the response to A.1., we also believe that through newly approved dual boarding pathways created by the ABNM and ABR, the number of AUs will increase rapidly over the next few years.

*Razmaria A, Calais J, Czernin J. Delivering Radionuclide Therapies Requires Extensive Training and Competence. J Nucl Med January 1, 2019 vol. 60 no. 1 1-2

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

The NRC as a licensing agency for non-agreement states and in its supervising function for agreement states ensures that patients have access to accurate numbers of licensees in different geographic areas. In general, patients who live in rural areas may not have access to most medical subspecialties and may need to travel to larger cities for non-emergency specialist care. However, this ensures that the complex treatments are performed by physicians who are well trained and that any complications will be adequately, efficiently, and swiftly ameliorated. Additionally, nuclear medicine diagnostic and therapeutic procedures require the cooperation of large and highly specialized interdisciplinary medical teams to coordinate appropriate care for the patient, which can only be found in larger medical centers.

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

Based on information presented by the radiopharmaceutical industry (Advanced Accelerator Applications) at the most recent SNMMI annual meeting in Philadelphia in June of 2018, after the recent FDA approval of Lu-177-DOTATATE (Lutathera ™), approximately 60 therapy centers across the US have been established. This quick implementation occurred within a time frame of only six months after FDA approval of Lu-177-DOTATATE (Lutathera ™) in January 2018. This fact demonstrates that the current existing network of authorized users is able to quickly respond to patient needs and new therapeutic radiopharmaceutical FDA approvals.

Moreover, it must be noted that the administration of such highly expensive and advanced therapies must occur as part of the decision and oversight of a collaborative interdisciplinary team in larger medical centers. Indeed, the potential for misuse of advanced radiopharmaceuticals--including the loss of dose radioactivity secondary to inefficiencies in clinical practice--must weigh heavily on questions of access and training, as such misuse may translate to significant financial losses for the healthcare system.

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

The NRC regulations for research ensure patient, healthcare worker, and general public safety. We are seeing a resurgence in research funding to nuclear medicine specialists, spearheaded by the medical and scientific advances in both theranostics and molecular imaging, which is not hampered by the NRC regulations.

D. Other Suggested Changes to the T&E Regulations

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

As previously noted, the collaboration of the NRC with medical specialty boards has resulted in consistent patient safety. We strongly urge continued collaboration between the NRC and medical specialty boards when defining training requirements.

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

No, we feel that the requirements are appropriately defined within the NRCs purview of radiation safety.

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?

As mentioned above, the collaboration of the NRC with medical specialty boards has resulted in a strong record of patient safety. As the field of nuclear medicine advances, we urge continued collaboration with nuclear medicine physicians on specialty boards. This collaboration will lead to continued safety for workers, the public, patients, and human research subjects.