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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

See attached file(s)

Attachments

NRC Radiopharm T&Ecategories-RPLIETO

January 29, 2019

May Ma, Office of Administration
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: (Docket ID NRC-2018-0230, 83 FR 54380); "*Training and Experience Requirements for Different Categories of Radiopharmaceuticals*"

I appreciate the opportunity to comment to the U.S. Nuclear Regulatory Commission (NRC) regarding authorized user (AU) "training and experience (T&E) requirements for different categories of radiopharmaceuticals" (NRC-2018-0230, 83 FR 54380). My comments are based on experience as a medical physicist in nuclear medicine and Radiation Safety Officer with NRC licensees for forty years.

General Comments and Concerns

I support the need for periodic review of the appropriateness of all regulations in 10 CFR Part 35 by the NRC with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the medical stakeholder community. Radiopharmaceutical therapy is a critically important tool in the clinical treatment armamentarium when used appropriately according to medical standards and guidelines. Professional nuclear medicine literature indicates its use will continue to be a strong need by clinicians. **However, I strongly oppose the NRC consideration to create "limited scope" authorized user (AU) with decreased training and experience (T&E) and without NRC-recognized board for any radionuclide therapy uses under 10 CFR Part 35, Subpart E.**

If implemented, this "limited scope" pathway would become the de facto "alternate pathway" because of its reduced T&E focus. This concept would create regulatory complexities and additional burdens for NRC, Agreement States, and medical licensees without proof of benefits or assurance of maintaining adequate radiation safety. Also radiopharmaceutical medical events by AUs in the current regulatory paradigm are very uncommon. No credible evidence for an inadequate number of AUs to provide written directives and this limit AU concept has been frequently unsupported by the NRC Advisory Committee on Medical Uses of Isotopes (ACMUI). There are no data for the number of AUs and their geographical distribution to support that rural areas are underserved. **NRC resources, the interests of patients and families, medical licensees, and the general public will be best served by avoiding further pursuit to create a radionuclide specific limited-scope AU pathway**.

Specific Comments in Response to NRC Questions

A. Tailored Training & Experience Requirements

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.

Yes, current pathways for obtaining AU status under 10 CFR 35, Subpart E are reasonable and accessible. There is evidence of increasing numbers of 35.300 AU-eligible physicians entering the workplace from the traditional nuclear medicine, radiation oncology, and diagnostic/nuclear radiology pipelines. Current AU eligibility prerequisites were implemented during the major Part 35 reform in 2002 and have become permanently ingrained elements of the related ACGME-approved physician training programs. NRC's regulations combined with existing NRC recognized board certification and maintenance of

continuing education requirements have show to be effective for ensuring health and safety of patients, personnel, and caregivers.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.

Yes, the current AU T&E requirements defined in 10 CFR 35.390 provide definite assurance of adequate protection of public safety. This as evidenced by the rare occurrence of reportable medical events in the Nuclear Materials Events Database (NMED) involving unsealed radioactive materials requiring a written directive. Even in those uncommon occurrences, which are annually reviewed by the NRC ACMUI, inadequate AU T&E has never been documented as a contributing or causative factor.

There is no evidence in medical education that reducing T&E standards results in maintaining safety and patient quality of care. A real concern of weakening alternate pathways for these higher risk therapeutic radiopharmaceuticals in an effort to expand numbers of non-expert AUs will result in failures to identify medical events due to the lack of comprehensive T&E and infrequent clinical experiences of limited-scope AUs in handling radionuclides.

In the preamble of the major Part 35 reform final rule published in 2002, NRC explained how the minimum 700 hours T&E covering the broad topics listed in 35.390 was an abstraction of the T&E necessary for a physician to function independently as an AU for unsealed byproduct material requiring a written directive. NRC noted that the 700 hours together with broad references to the covered topic areas provided flexibility to programs and negated the need for the agency to require an extra examination and/or further breakdown of the training regimen.[1] The ABR and ABNM study guides/assessment-preparation requirements have become the de facto curricula for ACGME-approved 4-year residency programs and their boards. These programs currently have the agility to add topics relatively quickly, which is important for new agents.[2] Time has proven that this approach met the intended effect. The NRC should continue its current risk-based approach with the AU T&E prerequisites in 35.390, which provide relevant boards and programs with appropriate flexibility while maintaining reasonable assurance of adequate protection of public health and safety.

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? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and

[1] Nuclear Regulatory Commission. Final rule: medical use of byproduct material. 2002 April 24;67 FR 20249;RIN 3150-AF74. https://www.federalregister.gov/documents/2002/04/24/02-9663/medical-use-of-byproduct-material#p-243

[2] American Board of Radiology. Study guide for medical physics for radiation oncology. Accessed 2019 Jan 15. https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/medical-physics-radiation-oncology

American Board of Radiology. Study guide for radiation and cancer biology. Accessed 2019 Jan 15. https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/radiation-cancer-biology

American Board of Nuclear Medicine. Content manual. Accessed 2019 Jan 15. https://abnm_wordpress_uploads.s3.amazonaws.com/wordpress/wp-content/uploads/Content_Manual.pdf

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beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]

No, the NRC should not initiate a rulemaking to establish lesser, tailored T&E pathways for physicians without NRC-recognized board certification. There is no evidence to support that changes to AU T&E will result in an increase of AUs into rural areas.

Any significant regulatory paradigm changes would be costly and severely disruptive to existing training programs, as well as to the NRC and Agreement States. NRC pursuit of this questionable limited AU concept will encompass a major revision of the regulations. Current history shows that this could take well over 10 years to finalize. The rate of change in medical advancements most likely will make any such revision obsolete creating an endless cycle of updating with no improvement in patient or public safety.

The suggested new categorizations are only a reshuffling of existing radiopharmaceuticals into overly specific categories based on false premise that current T&E is too much! They are not risk-based. All radiation has the potential for mishandling and untoward events that requires special knowledge, skills and tools for handling. Pre-packaged, unit dose delivery systems do not obviate these concerns. Many isotopes have multiple emissions, often including a gamma component. For example, Lutetium Lu-177 dotatate, which is often cited by vendors as a "safe" because of its 490 keV beta-emission, also has a 208 keV gamma-emission which is suitable for imaging for localization and dosimetry, but also of concern for safety and security; it is administered in hundreds of millicuries and requires administration of special amino acids for patient preparation.

The current categorization paradigm of low risk radiopharmaceuticals (do not require a written directive) and high risk (requiring a written directive) has served well and should be maintained with their current T&E requirements. Additionally, there is a clear lack of a supportable technical basis to justify the creation of an limited scope AU. **No trustworthy and comprehensive data from NRC and Agreement States demonstrates an AU shortage exists at all.** ACMUI and stakeholders have previously requested that NRC collect comprehensive AU data from all states over an extended period of time to explore AU trends. An ongoing, multi-year AU data collection mechanism would provide very beneficial information for a variety of medical use issues under current and future NRC consideration.

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?

For reasons previously mentioned, the concept of a new limited-scope AU status for physicians should not be pursued by the NRC. Physicians who do not meet the NRC-recognized board certification standard must meet the current the 700 hour alternate pathway. It is strongly recommended that NRC not initiate a rulemaking to implement such a concept. Otherwise, such rulemaking totally undermines the existing requirements of the existing "alternate pathway".

Commenters during the public webinars give the impression that because these therapeutic dosages can be received as unit dosages and/or that they are "only" alpha/beta emitting agents, they have minimal risk and require limited training and experience. This demonstrates a lack of adequate radiation safety knowledge necessary in management of these agents. Issues such as spills, residual activity in tubing and syringes, radioactive waste material handling, etc., require knowledge and skills acquired through years of training and experience and a culture of safety among primary providers and staff.

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

a. Describe what the requirements should include:

i. Classroom and laboratory training—What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]

The current levels of AU T&E for radiopharmaceutical therapy are appropriate and should not be reduced. As mentioned previously, the ABR and ABNM study guides and assessment preparation requirements have become the de facto curricula for 4-year residency programs. The NRC's current AU T&E in 10 CFR 35.390 allows these ACGME approved and programs to evolve to address new agents and radiation safety topics of additional interest in a manner far more rapid than rulemaking.[3]

ii. Work experience—What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?

This is a very difficult experience to quantitate. The work experience of relevant ACGME-approved residency programs in nuclear medicine, radiation oncology, and nuclear radiology is integrated with classroom work for the total training and experience. This education is not easily separated as in many years past. The current 700-hour total T&E of the alternate pathway is believed an appropriate minimum for other AUs-in-training.

Patient quality of care is improved by those physicians performing a high number of procedures. Thus, more is better. While the current minimums should definitely not be reduced, there has not been any current assessment if they are adequate or not. Should it be 3, 5, 10, or more? Recent history seems to rely on manufacturers input, which has a vested interest, but realistically must consider that some of these newer procedures are not done in significant volumes outside major cancer centers and often require a team approach. The NRC may need to make specific effort in concert with the professional physician organizations to assess what specific number is an appropriate minimum.

iii. Competency—How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.

The NRC recognized during its public webinars that competency is an inappropriate term in this issue and inconsistent with the revised Part 35 that became effective in January 2019. The issue is assessing that a requisite body of knowledge has been achieved by the AU to function independently. Any type of exam, whether written or oral, demonstrates a level of knowledge only at that time. Observation and performing several cases does not necessarily demonstrate competency. The true measure of competency is to perform independently as an AU over time and the ability to manage problematic situations that arise. This level of skills and knowledge is gained through certification-based training and continuous management of radiopharmaceutical therapy administrations.

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[3] American Board of Radiology. Study guide for medical physics for radiation oncology. Accessed 2019 Jan 15. https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/medical-physics-radiation-oncology
American Board of Radiology. Study guide for radiation and cancer biology. Accessed 2019 Jan 15. https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/radiation-cancer-biology
American Board of Nuclear Medicine. Content manual. Accessed 2019 Jan 15. https://abnm_wordpress_uploads.s3.amazonaws.com/wordpress/wp-content/uploads/Content_Manual.pdf

b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.

No change to the current requirements are recommended, which were amended by the recent Part 35 update rule published on July 16, 2018. Preceptor attestations in NRC Form 313 are appropriate for individuals submitting their T&E via the alternate pathway. Because the alternate pathway provides the means for a physician to become an AU without having an NRC-recognized board certification, the preceptor attestation provides a formal method for AU preceptors to document trainees' completion of NRC's regulatory prerequisites.

c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rationale for your answer.

No. Radiopharmaceutical manufacturers do not provide programs with the 700 hours of T&E needed to meet the alternate pathway for prospective AUs for 35.300 uses. Accordingly they can not serve as preceptors for the written attestation required on NRC Form 313A. More importantly, the NRC must maintain that the preceptor be a physician as is currently required for the alternate pathway.

d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]

While a national "medical radiation safety" exam has merit, there has been not interest by any professional organizations including the NRC because of the cost and resource burden to initiate and maintain. Board diplomates already incur significant expense in their board examination and maintenance. Such effort would be effective and resource efficient if spent on working with the ACGME training guidelines and their assessment for the NRC recognized boards.

The current curriculum and certification process have served the professions and public well. In addition to the NRC regulations, the current maintenance of certification (MOC), continuing education, and facility accreditation requirements as sponsored the relevant radiological professional organizations and CMS-approved accrediting groups assure continuation of knowledge and skills for providers and continuous levels of excellence in facilities.

e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

With utilization of radioactive substances, competency is determined by years of training and ongoing clinical experience, including management of adverse circumstances such as spills, extravasations, and disposal of unused material. This competency is developed only by 4-year residency-based training program followed by board certification, and then ongoing maintenance of certification or continuing education activities by the relevant radiological professional organizations.

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?

The currently recognized boards provide eligibility for those diplomates that intensively train and obtain the necessary knowledge and skills as indicated by previously referenced study guides/assessment preparation materials. No other physician boards have applied or indicated interest in becoming

recognized because they do not meet the criteria of the alternate pathway nor have any indicated such interest at ACMUI meetings or during the webinar presentations.

During the NRC webinars on this Federal Register request for information, two non-physician professional groups, commercial nuclear pharmacists and nuclear medicine advanced associates, advocated their credentials to be a limited scope AU in support of the limited AU pathway creation. Any serious consideration of such an extreme would open a Pandora's box of regulatory and rulemaking issues. Beyond the obvious financial reasons, this radical proposal is very problematic because:

- Current NRC regulations require the AU to be a physician. To create non-physician AUs in Subpart E will open the T&E requirements of entire Part 35 for petition by non-physicians to be AUs. If an AU can be an RSO, couldn't a non-physician RSO be an AU? Ever since the NRC regulated the medical use of radioactive materials, it has recognized the importance of specialized physician AUs for patient safety and supervision. This would be totally undermined in all areas of Part 35.
- The clinical application of uses requiring a written directive are beyond the expertise of nuclear pharmacists and extender professionals training.
- Hospital scope of practice and state licensure standards may present accreditation and legal issues to be overcome that are beyond the scope of NRC.
- Most importantly, the AU is responsible for supervision of the use from receipt to administration to disposal. There are real practical problems of either distance or scope of practice that would prevent such supervision on-site.

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

The current NRC medical specialty board recognition criteria for 35.300 uses appear to be sufficient. However, the specific criteria and process to approve a board is not clear nor where this information is available. Accordingly, further comment cannot be made.

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? Explain how.

This is the crux of the whole motivation for this limited scope AU issue. It has been recognized for years in the ACMUI meetings and re-emphasized during the NRC webinars that there is no verifiable or reliable information as to the number of AUs and/or their geographical distribution. Concerns have been raised by a few industry stakeholders regarding limited access to AUs but these have been anecdotal, often have financial interests involved, and have not been substantiated by other physician professional organizations.

ONLY the NRC has access or can obtain the information because it has the licensee data needed to produce this information. During the webinars, NRC staff indicated that it was attempting assess in NRC states and voluntary request to Agreement States. While laudable, the NRC must make a serious, statistically valid determination geographically of its medical therapy AUs before any further consideration to this limited AU pathway can proceed.

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

As stated above, the NRC must provide a reliable assessment of the AUs in number and location. This assessment needs to address not only AUs for 35.300 but should also encompass the sealed source therapy uses in 35.400, 35.600, and diagnostic human use in 35.200. This should be part of an annual or biennial update of the licensing information that is created in NRC reports. It reflects very poorly on the

NRC and its Agreement States that they do not have any reliable assessment of the number of active AUs they have approved.
it is unlikely that modifying AU eligibility prerequisites in 10 CFR Part 35, Subpart E would result in a large increase of NRC/Agreement State license applications from previously-unlicensed rural facilities. There are more consequential factors beyond AU T&E prerequisites, including a myriad of variables some of which are outside of NRC's jurisdiction, such as the extremely high cost of therapy radiopharmaceuticals and high annual NRC license fees.

3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
At this time there is no evidence to support that current NRC regulations have a detrimental impact on patient access to the use of diagnostic or therapeutic medical radionuclides.
As NRC ACMUI indicated in previously cited reports, utilization of radipharmaceutical therapies are multifactorial and involve many considerations outside of NRC's control.
Many factors influence the clinical decision to use radionuclide therapy that are outside the scope of NRC: equivalent alternative treatments not involving radiation, inappropriate reluctance by referring physicians to refer their patients out for subspecialized care regardless of the proximity of an AU outside their own practices, practice guidelines and technical standards, insurance coverage and reimbursement issues, expensive nature of many therapy radiopharmaceuticals and cost of missed appointments, state-mandated health professional licensure or certification requirements, state-based scope of practice regulations, self-referral rules, facility accreditation requirements, and patient's fear of radiation. Another unknown factor affecting the number of AUs are those physicians who satisfy the NRC AU T&E requirements but choose not to become authorized.

4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.
No comment.

D. Other Suggested Changes to the T&E Regulations
1. Should the NRC regulate the T&E of physicians for medical uses?
The NRC provides a necessary national regulatory framework for the safe use of therapy amounts of medical radionuclides. The therapeutic use of radionuclides must maintain the AU is an appropriately specialized physician. The current AU T&E prerequisites appropriately establish vetted criteria based on NRC-recognized specialty boards and associated training programs and decades old reviews. Thus, the regulations for radionuclides requiring a written directive should not be revised at this time.

2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?
No comment.

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?
I assume this question is general in nature seeking comments on any subject affecting T&E.

1. The Radiology and Nuclear Medicine board certification study guides/assessment-preparation requirements have become the de facto curricula for ACGME-approved 4-year residency programs and their boards. These programs currently have the agility to add topics relatively quickly, which is important for emphasizing changes in radiation safety topics. The NRC should

develop a coordination with those groups providing input into those guidance documents to address T&E improvements. This avoids rulemaking within the current regulatory paradigm. This possibly could be effected through the ACMUI.

2. The NRC could effect a tremendous improvement by establishing T&E for the workers (technologists) actually administering the radiopharmaceuticals. While some Agreement States have done this already, NRC would establish national radiation safety standards for all licensees. This has only positive benefits to patient safety.
3. It is indefensible that NMED medical events reports done under Part 35 are not made available to the licensees. These reports are purged of any patient identification and should be available. They can educate licensees of problems and circumstances causing these unfortunate events. The ACMUI has recommended this for over ten years. Recognizing that these reports need improvements of documentation and causitive factors as repeatedly identified by the ACMUI, they can provide beneficial training and education to licensees, AUs, and radiation workers.

Thank you again for the opportunity and consideration to comment.

Sincerely,

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