Required Training and Experience for Authorized Users for Radionuclide Therapy

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This letter responds to the request from the U.S. Nuclear Regulatory Commission for comments on training and experience requirements for different categories of radiopharmaceutical, published in the Federal Register, Vol. 83, No. 209, Monday, October 29, 2018 in Notices, pages 54380-54382. The recommendations given herein resulted from a panel including participants from several professional societies:

The American Association of Physicists in Medicine (AAPM),
The American Brachytherapy Society (ABS),
The American College of Radiology (ACR),
The American Society for Radiation Oncology (ASTRO),
The Health Physics Society (HPS), and
The Society for Nuclear Medicine and Molecular Imaging (SNMMI).

This letter has been endorsed by each of these organizations.

Summary
We recommend not reducing the current Training and Experience requirements. Radiopharmaceutical therapy has been a safe treatment modality for decades. Very few events have been reported for these therapies. Lessening the training and experience requirements could jeopardize the safety and effectiveness for these treatments.

Previous Comments in Response to this Request
The ACR in a letter dated 2018/08/27, and the SNMMI, ASTRO and the American College of Nuclear Medicine (ACNM) in a letter dated 2018/07/10, have sent separate responses to the call for comments referenced above. Highlights of the recommendations from the ACR response include the following:

- The current training and experience regulations are an integral part of current American Board of Radiology (ABR), American Board of Nuclear Medicine (ABNM) and American Osteopathic Board of Radiology (AOBR) certification requirements for Authorized User (AU)-eligibility, are essential for patient, personnel and care-giver safety, and are not burdensome for training programs, the Nuclear Regulatory Commission (NRC), or Agreement States.
- Any dilution of the existing training and experience requirements would place an undue burden on the NRC and Agreement States for oversight and would require a degree of inflexibility that could potentially hamper introduction of new agents into the research and clinical armamentaria.
- Current training and experience regulations are such that AUs and their staff are trained to deal with any routine or unusual occurrence or adverse radiation event. It is unlikely the limited-category AUs and their staff, often handling limited quantities of radioactive materials, would possess such capability.

- As identified in the September 2018 meeting of the Advisory Committee on Medical Uses of Isotopes (ACMUI), the March 2018 ACMUI subcommittee draft report grossly underestimated the number of radionuclide therapy AUs in the pipeline because the content was exclusively based on a decline in ABNM-awarded certificates, ignoring the greater numbers of AU-eligible certificates awarded by the ABR in radiation oncology and nuclear radiology, as well as a relative stabilization of the ABNM certificate award numbers.
- No reliable, actionable, NRC-curated data exists on total number of AUs, AU geographic distribution, or availability and willingness of current and future AUs to administer current or future agents. No changes in the training and experience requirements should be considered until comprehensive data — encompassing all NRC states and Agreement States — is available. **The NRC is encouraged to generate data to assist in evaluating the access situation.**
- Current AUs work with trained teams of staff with an ingrained culture of safety regardless of the physical properties of the isotopic agents employed, and whose daily activities involve exposure to radioactive sources. A similar culture could not be duplicated in facilities providing only limited radiation-related services.
- The myriad factors related to utilization of specific radiation-emitting agents other than AU-availability have been inadequately considered and are likely significant determinants of ultimate utilization. As is the case with the agents indicated for relapsed lymphomas, a significant factor in underutilization is disruption of their potential use by replacement, non-radioactive agents. As these replacement therapies become available, utilization among a group of limited category AUs would of necessity decline. Furthermore, the decline would be greater because of their narrow scope of practice.
- All radioactive materials, regardless of the specific radiation type emitted, energy or half-life, have the potential for untoward events when mishandled, which leads to an underlying public fear. Avoiding events requires experience and special knowledge, skills and tools for risk containment and reduction. Widespread availability of the agents for use by personnel with limited training raises the potential for local, regional and national security concerns. Pre-packaged, unitized dose delivery systems do not obviate these concerns. Many isotopes have multiple emissions, often including a gamma component. Lutetium-177 dotatate, which is often cited by vendors as "safe" because of its 490 keV β emission, also has a 208 keV γ emission, which is suitable for imaging for localization and dosimetry, but also raises concerns for safety and security.
- The ACMUI subcommittee and NRC commissioners have raised the potential for competency-based category-specific AU classifications. With utilization of radioactive substances, competency is established by years of training and experience, including management of adverse circumstances such as spills, extravasations, disposal of unused material and treatment toxicities. This competency is developed *only* by 4-year residency-based training followed by initial certification, and then career-long maintenance of training and skills. This continuous provider assessment is in parallel to continuous assessment of facilities by the accreditation programs of the ACR, ASTRO, and others.

Answers to the specific questions asked in the Federal Register Notice:

A. Tailored Training and Experience Requirements

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

   Yes. The current requirements are reasonable and accessible, and they have provided decades of safe radiopharmaceutical therapy.

   Safe and effective use of radiopharmaceuticals requires a thorough knowledge and understanding of the modality and experience with the various facets and potential toxicities and dangers to patients, staff and the public. Like any specialization in medicine, gaining the necessary training and experience takes time. The large number of Board certified physicians who could be AUs for radiopharmaceutical therapies demonstrates that access to such therapy is not limited by the training and experience requirements.

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 pathways for obtaining AU status through a residency and certification or via completion of the alternate pathway are adequate and considered a minimum requirement. While the didactic parts of the training are essential, they yield little understanding without a considerable experience in clinical applications. Safe and effective use requires more than just walking through a few cases; it requires performing enough cases under the supervision of an experienced AU so that each step in the process becomes routine and familiar, and that situations outside of the routine have been encountered and managed successfully. The development of such expertise requires hands-on experience in many clinical cases under a variety of contexts and considerations over a period of years. The skills necessary must be honed, evaluated and corrected by a mentor and allowed to become second nature. *An abbreviated training cannot provide these skills*. Processes that involve medical credentialing organizations are better prepared to specify and monitor criteria for who should administer radioactive materials to a patient.

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

   Most definitely NO. NRC should retain its current AU training and experience requirements and not institute a limited AU program. The skills and understanding for radiopharmaceutical therapy are similar for various radionuclides and pharmaceutics, thus limiting a practice to even one would not reduce the required minimum training. Shortening the training and experience requirements could lead to unsafe practices where unrecognized or unfamiliar situations arise. The comprehensive training requirement provides a wider knowledge. The implied use of this limited AU is in a smaller facility where the person would, more likely than at an academic medical center, be the perceived 'expert'. However, they would not have the experience or breadth of knowledge to address questions or concerns.

4. *Should the fundamental T&E be required of physicians seeking limited AU status?*

Yes. Fundamental training is necessary for all AUs. As in question 3, there should be no limited AU status based on abridged training and experience because it could lead to hazardous situations and compromise patient care.

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

The training and experience requirements should remain the same for all categories of radiopharmaceutical therapy, because the training and experience requirements *are* the same for all categories of radiopharmaceutical therapy.

a. Describe what the requirements should include:

i. *For classroom and laboratory training.*

The NRC's current regulations should not be changed. The appropriate training and experience to qualify for the practice of radiopharmaceutical therapy is addressed in the study guides of the specialty certification boards:

- https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/medical-physics-radiation-oncology
- https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/radiation-cancer-biology
- https://abnm_wordpress_uploads.s3.amazonaws.com/wordpress/wp-content/uploads/Content_Manual.pdf

ii. *Describe what the requirements should include: Work experience.*

NRC's current T&E requirements reflect the appropriate minimum training and experience for radiopharmaceutical therapy.

iii. *Competency. How should competency should be evaluated?*

The current method of assessing a proposed AU's ability to independently fulfill radiation safety-related duties is adequate and should not be changed.

iv. Should the fundamental T&E be required of physicians seeking limited AU status?

Yes, fundamental training should be required for all AUs.

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

The preceptor requirements—amended by the July 16, 2018 final rule--for radiopharmaceutical therapy should be the same as for any other Part 35 medical use. A preceptor statement should only be required for a physician seeking AU eligibility via the alternate pathway to document the candidate has achieved the ability to independently fulfill radiation safety-related duties.

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

No. While manufacturers can be useful participating in familiarizing practitioners with the performance of new therapy options as the technologies are being included into residency training, such participation cannot be a substitution for the training received in a residency because there is much more to treating patients than just the mechanistics of

radionuclide administration. Only an AU should be allowed to provide the preceptor attestation.

d. *Who should establish and administer the curriculum and examination?*

The curriculum should be developed by the relevant radiological professional organizations. The examination should be administered by a medical specialty certification board recognized by the NRC.

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

We recommend retaining the current regulatory paradigm.

B. NRC's Recognition of Medical Specialty Boards

1. *What boards other than those already recognized by the NRC could be considered for recognition for medical uses under 10 CFR 35.300?*

The currently recognized boards are those relevant to radiopharmaceutical therapy.

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

The Board Certification pathway to AU status already provides a more comprehensive preparation for 35.300 uses than does the alternate pathway for physicians whose training does not focus on radiological science. NRC should not revise its regulations to impose additional prescriptive mandates on these Boards.

C. Patient access

1. *Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300?*

As noted above, there is no data relevant to this question. Also as noted above, **the NRC is encouraged to generate data to assist in evaluating the access situation.**

2. *Are there certain geographical areas with an inadequate number of AUs?*

Again, there is no data on this. There likely are geographical regions within which patients must travel greater distances to access an AU, but there is no reason to believe that such issues would be ameliorated by lowering AU T&E standards. The answer to access of care for any of these examples is not lowering the training and experience required to provide specialized procedures.

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

Limited patient access to care is a complicated issue with myriad causes. As in the question above, the solution to any access issues should not be lowering of the quality and safety of the care provided.

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

No. Research in nuclear medicine, and in radiopharmaceutical therapy in particular, is very active and developing new therapies rapidly at this time.

D. Other Suggested Changes to the T&E Regulations

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

   Yes, using the current regulatory framework.

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

   In the long run, patient care is a matter of safety, and thus requirements on experience in patient care is safety related. The training necessary for safe use of radiopharmaceuticals also leads to effective treatments.

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?*

   The current regulation requirements are performing well for protection of the general public, patients and human subjects.

Contact information for further information or discussion, please e-mail NRCTrainingReq@aapm.org