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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0162
Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

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Submitter Information

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Organization: American Association of Physicists in Medicine

General Comment

See attached file(s)

Attachments

AAPM Letter NRC Radiopharma T&E Final

AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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VIA email: www.regulations.gov

RE: Request for Comment: Draft Approaches for Training and Experience Requirements, Docket Number: NRC-2018-0230

Dear Ms. Lopas:

The American Association of Physicists in Medicine (AAPM)[1], is pleased to submit comments to the Nuclear Regulatory Commission (NRC) regarding its request for comment on draft

[1] The AAPM is the premier organization in medical physics, both in the U.S. and abroad. Medical physics is a scientific and professional discipline that uses physics principles to address a wide range of biological and medical needs. The mission of the AAPM is to advance medicine through excellence in the science, education and professional practice of medical physics. Currently, the AAPM represents over 9,000 medical physicists.

Medical physicists contribute to the effectiveness of medical imaging by ensuring the safe and effective use of radiant energy (e.g., optical, ionizing, ultrasonic, or radiofrequency) to obtain detailed information about the form and function of the human body. Medical physicists continue to play a leading role in the development of novel imaging technologies, as well as in guiding the optimization of existing imaging modalities. In addition, medical physicists contribute to development of new therapeutic technologies in radiation oncology, as well as in other disciplines, such as in thermal ablation or high intensity focused ultrasound. Clinically, medical physicists work side by side with radiation oncologists to design treatment plans and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation at the correct location.

approaches for training and experience (T&E) requirements, including potential advantages, disadvantages, and other considerations associated with each approach.

General Comments

The AAPM commends the NRC on its work on the T&E issue and in crafting the numerous potential scenarios identified in its request for comment. The AAPM strongly urges the NRC to maintain the current T&E pathway for these physicians and to avoid development of a new tailored T&E pathway.

We believe that the current T&E requirements ensure that AUs and their staff are trained to deal with any routine or unusual occurrence or adverse radiation event. In contrast, we are concerned whether the limited-category AUs and their staff, who may handle only limited quantities of radioactive materials, would have that capability. Accordingly, we believe that shortening the T&E requirements could lead to unsafe practices, particularly where unrecognized or unfamiliar situations arise.

We note that radiopharmaceutical therapy has been a safe treatment modality for decades. Very few events have been reported for these therapies. We caution that lessening the T&E requirements could jeopardize the safety and effectiveness for these treatments.

The AAPM's position on the T&E issue is summarized as follows:

1. There is no shortage of AUs who could perform the treatments.
2. The decrease in utilization of some particular agents is due to other treatments being available and selected by the oncology community.
3. The training for a single agent is mostly the same as that required for the use of any and all agents.
4. Abbreviating the T&E required for AU status creates a potentially dangerous situation for patient, staff and the general public.
5. The current requirements have provided safe and high-quality care and should not be changed.

Comments Addressing Specific NRC Questions

Question 1: If the "*Status Quo*" is maintained, how should the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals?

The AAPM recommends that the NRC look for guidance from the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The ACMUI represents a considerable body of expertise and the committee is there for sharing that expertise with regulators. In addition, we believe professional societies, like AAPM, offer considerable expertise in research, clinical practice and safety issues, and the NRC should look to those professional societies for assistance.

The AAPM recognizes as well that manufacturers can be useful participating in familiarizing practitioners with the performance of new or emerging therapy options as the technologies are being included into residency training. The AAPM, however, cautions that manufacturer 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.

Research in nuclear medicine, and in radiopharmaceutical therapy, is very active and we can anticipate introduction of new therapies. Accordingly, the AAPM recommends greater collaboration between the Food and Drug Administration (FDA) and the NRC as new radiopharmaceuticals are advancing in the pipeline. Currently, there seems to be a gap between FDA approval of a pharmaceutical and NRC guidance on how the new item will be categorized, how its use should be regulated and how guidance or other regulatory oversight should be implemented. The AAPM suggests that it would be helpful if there was concurrent review by the NRC and FDA once a drug reaches a certain stage in the development/approval process so that the NRC can release its guidance in close proximity to the FDA approval date. Moreover, we believe that relaxing T&E requirements will not solve the issue of rapid release of new radiopharmaceuticals.

Question 2: Is there a challenge with the current T&E requirements—such as concerns regarding patient access to radiopharmaceuticals—that should be addressed through a rulemaking?

The AAPM believes that there is adequate access to radiopharmaceutical therapies through nuclear medicine and radiation oncology departments. The current requirements are reasonable and accessible, and they have provided decades of safe radiopharmaceutical therapy. We note that 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. We believe, however, that 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 T&E requirements. We note as well that as with other specialty care, patients may need to travel to specific centers for treatment. It is critically important that a patient's safety not be compromised merely to accommodate a patient's convenience with administrations at nearby facilities. We believe that limited patient access to care is a complicated issue with myriad causes, and the solution to any access issues should not be lowering of the quality and safety of the care provided.

We note there is no data to indicate a shortage of AUs and the ability to provide access to patients for 35.300 therapies. In addition, 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. We believe a significant factor in underutilization is disruption of some radiopharmaceutical therapies' potential use by replacement, non-radioactive agents.

We do not believe that rulemaking would improve patient access to radiopharmaceuticals. Accordingly, the AAPM recommends that no changes in the T&E requirements be considered until comprehensive data is available, and we urge the NRC to generate appropriate data to assist in evaluating the access situation.

Question 3: How should the complexity of the radiopharmaceutical administration protocol be considered in establishing the T&E requirements for the limited approaches described in Sections B.1 and B.2 below?

The AAPM believes that neither the proposal in B1 nor that in B2 should be implemented. The T&E as currently required is necessary to understand the subtleties of the practice. For particular applications, additional training for a specific application may be necessary if the delivery modality, the biological nature of the carrier, or the particulate of the emission is different from the user's previous T&E.

We note that the use of unit doses does not reduce the necessary training for the AU, nor does it take from the AU the responsibility to ensure the material given to patient is correct in its makeup and quantity. The complexity of planning administration is not significantly impacted by a dosage being patient-ready or not.

Physician training is one aspect of assuring safety for the patient, staff, physicians and the general public. The proposed option to train physicians specific to 'nuclide type' will not address the fundamentals of a radiation protection program as is addressed in the current and required hours within residency training for physicians intending to administer radioactive materials (RAM). Accordingly, the AAPM urges the NRC not to consider limited AU status.

Question 4: How should the NRC categorize radiopharmaceuticals with mixed emissions?

The AAPM recommends that NRC categorize radiopharmaceuticals with mixed emissions under part 35.300 or subsections within 35.00. We believe that single emissions and mixed emissions should have the same level of training and could be categorized together for simplification. We note that the training for a single agent is mostly the same as required for the use of any and all agents.

When the ACMUI considered whether radium dichloride should be included in part 35.1000 (new and novel uses) or included in part 35.300 with all the rest of the radionuclide therapy, the committee expressed the view that even for alpha emitters, the basic principles were the same for all radionuclide therapies.

Question 5: Under what conditions should a radiopharmaceutical be considered "patient ready" such that the T&E requirements could be tailored?

We believe that radiopharmaceuticals should never be considered "patient ready" other than as discussed in our response to Question 2. Therapeutic radiopharmaceuticals prepared as patient-ready doses must require assay before administration, and we note that significant risk affecting patient outcome could be an unintended result. The characterization "patient ready" suggests a unit dose that does not require parsing a bulk dose or compounding of a kit with a unit or bulk dose.

Moreover, each therapy presently available may have a special administration device and is not less complex if delivered to the user facility in unit dose form. For example, Zevalin uses a pump infusion; Ra-223 uses hand pushed IV; Lu-177 uses the gravity drip method or a pump infusion; and Y-90 spheres uses a whole circuit system with interventional radiology (IR). Each agent has its own radiation safety issues. We believe that although a lot of the training can be categorized together, the complexities of each of these administrations cannot be. We note that the delivery mechanism for each radiopharmaceutical may be unique--and for some radionuclides there may be planning imaging performed-- but these are details and variations in delivery that someone well-versed in radionuclide therapy would understand. Moreover, that well-versed person would understand the ramifications of the peculiarities of the particular delivery.

We strongly believe that a reduction in 300 hours of classroom training is unlikely to provide more access for lesser-trained individuals. 200 hours is basically equivalent to 12-credit hours of college courses.

Question 6: How could a competency-based evaluation ensure appropriate training and experience for AUs administering radiopharmaceuticals?

Under this approach, proposed AUs would be required to demonstrate competency in radiation safety topics and radiation safety-related job duties through a formal competency evaluation (e.g., an examination or preceptor attestation). The AAPM believes that such an evaluation begins with the certification exams already recognized by the NRC. The AAPM notes that competency is established by years of T&E that includes management of adverse circumstances. We believe this competency can be achieved only by the current 4-year

residency-based training followed by initial certification, and then career-long maintenance of training and skills.

Question 7: How could physicians in small practices be credentialed (e.g., physicians not associated with hospitals or other large institutions and their credentialing boards)?

Assuming that the question refers to physicians who have not trained in the radiological specialties, the AAPM believes such physicians should complete a residency that covers radionuclide therapy. We believe that relaxing the requirement would place patients, staff and the general public in jeopardy. As noted in our response to Question 2, such relaxation is not necessary. There are regions of the country that have limited access to healthcare, including access for cancer surgery. Yet it is not considered prudent to establish major cancer surgery in a small clinic. Use of this limited AU in a smaller facility, where the person would, more likely than at an academic medical center, be the perceived 'expert' raises concerns because these limited AUs would not have the experience or breadth of knowledge to address many of the questions or concerns that would arise.

Clinic size and facility location should not indicate a difference in patient care offered. Allowing patients to receive care by physicians with limited training, meeting lower competency standards, is not appropriate, quality healthcare. Physicians should have consistent training and certification regardless of treatment location. The medical staff credentialing office relies on national boarding organizations (T&E requirement, etc.) to credential all physician groups in the facility, why would therapeutic-RAM-use physicians differ?

We believe that physicians in small practices could continue to be approved through the *status-quo* method with their radioactive materials license (RML) and the current process.

Question 8: How should the AU's radiation safety responsibilities be clearly distinguished from other members of the team?

The AAPM notes that the preparation of the radioactive material should be the responsibility of the authorized nuclear pharmacist (ANP), who also should perform the official assay of

the activity. Dose calculations, when possible, and establishing safety procedures, along with performing checks on assays, should be the responsibility of the AU physician or delegated to the authorized medical physicist (AMP).

We note that either the ANP or AMP or RSO should be responsible for radiation surveys, while the actual measurements could be performed by staff supervised by either of these. This requirement, however, does not relieve the AU from understanding any of the safety procedures. The AU has responsibility for the entire process and should be trained in all aspects of the process, as is done in residency training.

The AAPM believes that team-based approaches add unnecessary complexity. Presently, there is a preceptor pathway for members of a team to be supervised during initial training.

Question 9: How should the radiation safety responsibilities be divided between the AU and ANP?

See our response to Question 8.

The AAPM believes that ANPs should be responsible for radiation safety responsibilities in the preparation of doses. The AU should be responsible for quality control (QC) checks of ANP products and all radiation safety responsibilities at their facility.

Question 10: What are the advantages and disadvantages of the draft approaches?

While nuclear medicine technologists are trained in delivering radionuclide therapy treatments, they do so under the supervision of an AU. The training of the technological staff is not appropriate for the functions in the proposal.

Scope of practice is routinely written within state regulation to indicate appropriateness of practice within a specialty. The scope of practice language for technologists requires physician supervision for administration of radiopharmaceuticals.

Overall, the proposed approaches do not simplify the process. Again, we note there is no evidence to suggest that there are access limitations for patients.

Question 11: Are there significant costs or benefits associated with any of the approaches?

The AAPM asserts that any lessening of the training and experience of the physicians performing radionuclide therapy, while possibly reducing costs, does so at the expense of safety and quality for the procedures.

In addition, we believe that adding complexity to the AU pathway increases costs for time to review and approve credentials by regulators and RSOs of RMLs with internal approval authorization of AUs.

Question 12: Would any of the draft approaches impact patient access to radiopharmaceuticals or address stakeholder concerns of overly burdensome (regulatory) requirements?

The AAPM notes that this question appears to be based on the mistaken premise that the regulations are overly burdensome. As with other specialty care, patients may need to travel to specific centers for treatment. This is not uncommon in many aspects of medical care. The AAPM believes that patient safety should not be compromised or to assure a patient the convenience of therapeutic administrations at a nearby facility. It is critical to maintain safety.

The AAPM believes the *status quo* process is straightforward and not overly burdensome. Moreover, we assert that there is no evidence of limitations to patient access.

Question 13: For the draft approaches that consider tailored hours of T&E, what are the appropriate numbers of hours and what radiation safety topics should comprise the limited T&E?

We believe the current number of hours is appropriate. The NRC's current regulations should not be changed. The appropriate T&E 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

The AAPM notes that current pathways for obtaining AU status through a residency and certification or via completion of the alternate pathway are adequate and we consider these pathways a minimum requirement for protecting public health and safety. We believe that the didactic parts of the training are essential, but the AU must also have considerable experience in clinical applications. We believe that safe and effective use 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." Accordingly, training must include hands-on experience in many clinical cases under a variety of contexts and considerations over a period of years. We believe that an abbreviated training cannot provide these skills.

Question 14: Should the NRC consider inclusion of a formal radiation safety competency assessment and periodic reassessments for any of the draft approaches above? If so, who should establish and administer these assessments?

We support periodic reassessment of AUs and recommend requiring maintenance of certification in order to maintain AU status, as most AUs are on time-limited certifications. We recommend retaining the current regulatory paradigm for periodically assessing AU competence.

Question 15: How would the draft approaches impact the medical organizations that use the NRC's T&E requirements as a basis for establishing their training programs?

The AAPM cautions that implementing the proposed reduction on T&E for practitioners of radionuclide therapy would undercut the organizations that have maintained the safety and quality of such treatment. We believe physician societies should identify appropriate training for physicians, not the NRC. Appropriately trained physicians understand potential challenges and potential negative patient outcomes. Diminishing the T&E for physicians removes that layer of patient protection.

We believe that 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. We believe that the NRC should not revise its regulations to impose additional prescriptive mandates on these Boards.

Question 16: Are there concerns regarding implementation and/or viability for any of the approaches discussed above?

The AAPM has significant concerns. The concerns are real because such reduction in T&E, and the expansion into facilities that are not equipped to handle the quality and safety procedures necessary for such treatments will have detrimental results in treatments and safety to the staff and public.

The AAPM believes that the current process is effective and cautions against adding limited status. We believe adding limited AU status, which would allow lesser trained individuals to administer therapies, will increase complexity and increase danger to the public.

Question 17: Are there any unintended consequences of the draft approaches?

We believe that there would be unintended consequences of the draft approaches. The AAPM notes that all radioactive materials have the potential for untoward events when mishandled. We believe that avoiding those events requires experience, knowledge, and skills for risk containment and reduction. We are concerned that widespread availability of the radioactive agents for use by personnel with limited training would raise the potential for both safety and security incidents.

There is considerable literature related to developing safety culture and improving safety. Currently, AUs work with trained teams of staff whose routine activities involve exposure to radioactive sources. These trained teams have an ingrained culture of safety that we believe would be difficult, if not impossible, to duplicate in facilities providing only limited radiation-related services.

Training is often cited as a recommendation for improving patient care (see Webb, 2011; World Health Organization, Global Health Workforce Alliance, 2008). Accordingly, we believe a review of the literature studying the effectiveness of training on patient safety may be valuable. In addition, the AAPM believes that reports of medical incidents can be revealing and urges the NRC to review the annual reports to the ACMUI as well as the NRC reports to Congress for abnormal events. While the number of events is small, clearly, there is a lot at stake and bad things can happen--even in the current system. We ask, why put patients at risk by modifying the T&E *status quo* that has a long-term history for safety.

Question 18: Which of the draft approaches best positions the NRC to effectively regulate future radiopharmaceuticals?

The AAPM believes the current approach, with the addition of our recommendations in answers to Questions 1 and 6, serves patients and the community well. We assert that the *status quo* of keeping the current training requirements in place assures best practices and best patient outcome.

We believe that the current process is straightforward. Adding limited status adds unnecessary complexity and potential danger to the public if lesser trained individuals administer therapies.

Question 19: Should the NRC continue to play a role in the review and approval of AUs?

The AAPM believes the NRC should continue to play its current role in the review and training of AUs, although certification by the appropriate radiological certification board should provide *prima facie* evidence of qualification to be an AU. We believe that the NRC's

regulatory oversight of physician training provides the framework for licensees to restrict radioactive material (RAM) use per regulatory requirement and removes the burden from the RSO to restrict physician access. Moreover, we assert that without the strength of regulation behind RAM use, patient safety would be compromised.

In summary, the AAPM believes that the NRC should retain its current AU T&E requirements and not institute a limited AU program. We believe shortening the T&E requirements could lead to unsafe practices where unrecognized or unfamiliar situations arise. The comprehensive training requirement currently required provides a wider knowledge that ensures the best patient care and safety.

The AAPM hopes that the NRC will consider the AAPM's comments and adopt the AAPM's recommendations when crafting its final policy. We would be happy to provide additional expertise or resources to you during that process. Thank you again for the opportunity to comment on this important document. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Project Manager, at 571-298-1227 or Richard@aapm.org

Sincerely,

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