HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

June 25, 2019

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

Nolan Hertel, Ph.D., P.E.
President

Subject: Docket ID NRC-2018-0230: Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

The Health Physics Society[1] (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments, in the attached document, as a response to the May 2, 2019 request.

If you have any questions regarding these comments, please contact the HPS Agency Liaison, Craig Little, at 970-260-2810 or by email to agencyliaison@hps.org.

Sincerely,

Nolan Hertel, Ph.D., P.E.
President

Attachment: multi-societal letter dated January 28, 2019

cc: Eric Golden, Ph.D., CHP, HPS President
Craig Little, Ph.D., HPS Agency Liaison
Brett Burk, HPS Executive Director

[1] The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

Health Physics Society Comments on

Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

Position Details

As a scientific organization of professionals who specialize in radiation safety, the HPS recommends that NRC not create a limited scope Authorized User (AU) pathway or decrease training and experience requirements. The goal of this limited scope AU pathway is to increase the availability of nuclear medicine procedures for which a written directive is required (10 CFR 35.300). However, the medical community has raised concerns about the adequacy of existing alternate pathway training and experience requirements for newer therapies and expressed concern that further reductions could compromise patient care and public safety.[2] Radiopharmaceutical therapy has been a safe and effective medical procedure for decades with very few reported events. We are concerned that lessening requirements could adversely impact the safety and effectiveness of radiopharmaceutical therapies.

The goal of AU training and experience (T&E) requirements should be to ensure a physician is adequately trained to address the radiation safety needs of patients, families and the public while focusing on patient care. It is possible that lower T&E requirements would not adequately prepare a physician for these challenges. The impact would be higher in rural areas that are likely to have a less robust radiation safety infrastructure. Such changes would increase the burden on medical institutions and radiation safety staff that may not be prepared for the medical and radiation safety complexities of radiopharmaceutical therapy. This combination would likely increase the possibility that medical events may be underreported, increase public health and safety risks and further complicate the already tentative public position on radiation exposures.

This letter continues the comment submitted January 28, 2019, attached, in response to the Federal Register, Vol. 83, No. 209, on Monday, October 29, 2018 submitted on behalf of the following 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).

[2] SNMMI Position, Training for Radionuclide Therapy 2018, Theranostics Consensus Conference National Cancer Institute Bethesda, Maryland November 9, 2018 Daniel J, Lee, MD. http://snmmi.files.cms-plus.com/Theranostics%20Consensus%20Conference_Nov%209.pdf

***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 NRC should maintain the current training and experience requirements for authorized users (T&E). To address changes in medicine, the NRC should define the required radiation safety T&E requirements and work with the medical specialty boards to establish T&E requirements for the clinical aspects of radiopharmaceutical medicine. These medical specialty boards already assess and certify doctors against training and education requirements for clinical practice and continually adapt to changes in medicine. These organizations are experienced in adapting to changes in clinical practice and can more readily adjust requirements to changes in the practices of medicine.

Working with Accreditation Council for Graduate Medical Education (ACGME) will transform the above-established criteria into practical training and education programs that will produce physicians who understand the clinical complexities of the anticipated future radiopharmaceuticals.

We note that the current T&E requirement is compatible with the International Atomic Energy Agency (IAEA) Nuclear Medicine Resource Manual[3].

***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?*

No, there are no challenges with the current T&E requirement that should be addressed. As exemplified in the NRC's Nuclear Materials Events Database there is a very low incidence of abnormal occurrences or medical events related to radiopharmaceuticals.

However, we are concerned that weakening the T&E requirements for alternate pathways for comparatively higher risk therapies could lead to an increased risk of less experienced clinicians performing procedures with complex radiopharmaceuticals who would not fully understand the radiation safety issues with such radioactive materials. This could lead to an under reporting of events and erode confidence in our nation's radiation safety programs.

***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 of the Federal Register Notice?*

> *B1. Limited AU for Alpha- or Beta Emitting Radiopharmaceuticals Under this approach, any physician could complete at least 400 hours of T&E to be authorized to administer any alpha- or beta-emitting radiopharmaceutical. The T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to alpha- and beta emitting radiopharmaceuticals. Preceptor attestation would be required.*
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> *B2. Limited AU for Unit-Dose, Patient Ready Radiopharmaceuticals Under this approach, any physician could complete at least 400 hours of T&E to be authorized to administer any unit-dose, patient-ready radiopharmaceutical. The T&E would consist of 200 hours of classroom*

[3] https://www-pub.iaea.org/MTCD/publications/PDF/Pub1198_web.pdf, accessed June 5, 2019.

and laboratory training and a minimum of 200 hours of supervised work experience tailored to unit-dose, patient-ready radiopharmaceuticals. Preceptor attestation would be required.

The administration of a radiopharmaceutical is more complicated than simply injecting an amount of radioactivity following the recommendations of a manufacturer's package insert. The process requires the thoughtful decisions of the patient's care team with consideration of the radiopharmaceutical impact on the patient, care providers and others. The team requires the involvement of many medical specialties including diagnostic radiologists, radiation oncologists, oncologists, nuclear medicine physicians, nuclear medicine technologists, nurses and radiation safety staff working in concert with referring physicians to manage the patient's overall health. As patient acuity increases, the patient's care becomes more complicated and has a greater impact on those who support the patient at home.

The proposal to decrease the T&E requirements creating a limited scope AU to address access issues is contrary to sound patient and radiation safety practices. The concept that such an approach could be applied to newer targeted therapies that often involve higher acuity patients who are treated with larger amounts of radioactivity further exacerbates the deviation from best practices.

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

We do not support a proposal to create categories for different type emission radiopharmaceuticals. A mixed emission radiopharmaceutical, for example one with beta and gamma emissions, provides many of the same clinical and radiation safety issues as alpha or beta radioactive materials. It is important that an AU understand the radiological properties of the pharmaceutical and appropriate radiation safety practices. However, the clinical aspects of an administration require a therapy specific knowledge that is gained by clinical experience. The introduction of newer therapeutic radiopharmaceuticals adds radiation safety issues that may very well be missed by physicians with reduced training and education.

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

B3. Limited AU for Any One Parenteral Radiopharmaceutical Under this approach any physician could complete at least 400 hours of T&E to be authorized to administer any one parenteral radiopharmaceutical. The T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to the radiopharmaceutical they wish to administer. Preceptor attestation would be required. Limited AUs who have initially completed at least 400 hours of T&E and then wish to administer a different radiopharmaceutical would be required to complete, minimally, an additional 80 hours of tailored, supervised work experience for each additional radiopharmaceutical.

We do not believe a T&E program based on "patient ready doses" is appropriate. With changes in pharmacy regulations, contract radiopharmacies deliver many radiopharmaceuticals as unit (or custom) doses for a single patient. While unit doses are convenient, they may not simplify procedural requirements and do not address clinical or radiation safety issues. Downgrading the T&E requirements is likely to lead to a less well prepared AU who could be ill prepared for the patient's needs or not understand radiation safety considerations. This would lead to increased exposures or regulatory risk only further frustrating the public's acceptance of radiation.

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

A competency-based T&E program that is framed around a minimum set of tasks that a candidate AU must be able to reproducibly complete could be an improvement to the current T&E program. Such a program would require a didactic component that explains the basis of the required task (regulatory, clinical, operational, etc.) and a demonstration component where the candidate first watches the task completion and then independently completes the task a number of times (e.g., more than five) while explaining the reason the task is performed as shown. For this to be successful, the competency needs to be very well defined with success criteria that a preceptor can evaluate against.

***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)?*

The administration of radiopharmaceuticals, especially those for therapy, requires a team of medical and support professionals who understand the clinical and radiation safety implications of the therapy on the patient, care providers and the public. All physicians who provide such services should meet the current T&E requirements and practice in an environment that fully supports the therapy.

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

We support the International Atomic Energy Agency[4] position that the nuclear medicine physician should have the 'primary responsibility for ensuring overall radiological protection of patient'. As a result, radiation safety training and experience requirements should not be decreased or shared across multiple roles.

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

Decades of experience have shown that clear, unambiguous and well-understood radiation responsibilities sharply reduce the number and extent of radiation safety issues. A review of NRC's Nuclear Materials Evens Database[5] and Medical Event Reports[6] shows that training[7] and lines of responsibility are frequently cited as root causes. Radiation safety responsibilities should not be divided between the AU and ANP.

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[4] International Atomic Energy Agency, Safety in nuclear medicine: Responsibilities of health professionals, https://www.iaea.org/resources/rpop/health-professionals/nuclear-medicine/responsibilities-of-health-professionals, Accessed June 6, 2019.
[5] Nuclear Regulatory Commission's Nuclear Materials Evens Database, https://nmed.inl.gov/
[6] Nuclear Regulatory Commission's Medical Use Tool Kit listing Medical Events, https://www.nrc.gov/materials/miau/med-use-toolkit.html#mep
[7] Nuclear Regulatory Commission's ACUMI Medical Events Subcommittee Report, September 20, 2018 https://www.nrc.gov/docs/ML1903/ML19038A495.pdf.

A decrease in T&E requirements or distributing responsibilities over multiple people could increase radiation risks for patients and the general public. These changes are of greater concern in rural and other locations where technical resources, such as those in medical physics, radiation safety, and radiopharmacy, may not be immediately available. In these situations, the AU needs to have competencies to independently address dosimetry, measurement, emergency response and radiation safety issues related to patient release and waste.

In addition to concerns about distributing responsibilities across clinical staff, it is possible that obtaining limited AU status could enable such an AU to meet the regulatory obligations for a radiation safety officer[8]. This could jeopardize the safety of patients, staff and the public.

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

Decreasing the T&E requirements or sharing those requirements over multiple people will place increased responsibilities on the institution and radiation safety staff to qualify an individual as an AU. This is likely to have an uneven implementation resulting in qualification of AUs who may not fully understand radiation safety requirements. This is likely to result in an increase in and under reporting of Medical Events[9] or other radiation safety issues due to lower training and experience requirements. Any such outcomes will further erode the public's already skeptical perception of radiation and tarnish nuclear medicine's otherwise excellent record.

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

We are concerned that the decreased T&E requirements could result in decreased patient and radiation safety while increasing the burden on the local institution and its radiation safety officer to address the diminished capabilities of a limited AU. These could lead to reputational losses for the facility, regulators and the field of nuclear medicine.

***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?*

T&E requirements should include a radiation safety competency assessment and periodic reassessments. The NRC should determine radiation safety competency requirements and work with professional medical organizations to develop and implement these assessments.

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

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[8] 10 CFR 35.3045, US Nuclear Regulatory Commission, Training for Radiation Safety Officer and Associate Radiation Safety Officer.

[9] 10 CFR 35.3045, US Nuclear Regulatory Commission regulation on Report and notification of a medical event.

As stated in the response to other questions, we are concerned about the impact of this proposal on radiation safety as it relates to the patient, caregivers, medical staff and the public as well as the potential to tarnish the excellent safety record of nuclear medicine.

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

We do not believe the draft approaches are in the best interest of the patient's medical care or patient or public radiation safety.

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

The NRC should continue involvement in the approval of AUs. The NRC focus should be on radiation safety aspects while working with professional medical organizations to develop acceptable training and experience requirements.

January 28, 2019 Multi-societal Comment to Docket ID NRC – 2018 – 230

Required Training and Experience for Authorized Users for Radionuclide Therapy

January 28, 2019

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Office of Nuclear Material Safety and Safeguards

Rockville, Maryland

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