

CHAIRMAN Resource

From: Carol Marcus <csmarcus@ucla.edu>
Sent: Saturday, February 02, 2019 12:21 AM
To: CMRBurns Resource; CMRBARAN Resource; CHAIRMAN Resource; CMRCaputo Resource; CMRWright Resource
Subject: [External_Sender] Comment Letter from the American College of Radiology regarding therapy T&E
Attachments: NRC ACR T&E comments 01-29-19.pdf

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Feb. 1, 2019

COMMENT (144)
PUBLICATION DATE: 10/29/2018
CITATION: 83 FR 54380

Dear Commissioners:

Attached is an extremely strong comment letter from the American College of Radiology (ACR) against your possible rulemaking concerning decreased training and experience requirements for Authorized Users to administer individual radiopharmaceuticals. The ACR represents both Radiation Oncology and Diagnostic Radiology.

It occurs to me that none of the comment letters, including my own, mentioned the fact that virtually every therapy radiopharmaceutical requires imaging studies to determine the patient's appropriateness for administration of a therapy radiopharmaceutical and/or effectiveness of that therapy. Imaging equipment is expensive, and T&E requirements for imaging are extensive. Patients will have to go to imaging centers outside rural areas in any case, so they might as well have their therapies there as well, with qualified professionals.

Given the very strong comments by the Society of Nuclear Medicine and Medical Imaging (SNMMI) and the American College of Nuclear Medicine (ACNM) which I sent you a couple of days ago, and this even stronger worded opposition by the ACR, I think that you should strongly consider (1) aborting this expensive and dysfunctional rulemaking adventure by your medically incompetent staff and management, and (2) removing the NRC individual responsible for pushing this dangerous and grossly dishonest rulemaking and making the NRC Commissioners look seriously incompetent in the medical area.

Thank you for your attention and consideration.

Sincerely,

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January 29, 2019

Submitted via regulations.gov

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;” comments of the American College of Radiology

The American College of Radiology (ACR)—a professional organization representing more than 38,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to provide feedback 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). The following comments were compiled under the leadership of a multi-specialty workgroup within the ACR Commission on Government Relations-Federal Regulatory Committee.

General ACR Comments and Concerns

The ACR supports periodic review by the NRC, together with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the medical stakeholder community, of the appropriateness of all regulations in 10 CFR Part 35. However, reviews of the agency’s regulations should prioritize compliance issues and other problems identified by medical use licensees in support of NRC’s mission of providing patients and other members of the public with reasonable assurance of adequate protection of public safety.

The controversial concept under NRC consideration of a tailored, radionuclide-specific, “limited-scope AU” pathway for uses under 10 CFR Part 35, Subpart E featuring less comprehensive T&E requirements for clinicians without NRC-recognized board certification is generally opposed by the pertinent stakeholder community and has been frequently called into question by ACMUI. If implemented, the concept would introduce regulatory complexities and additional burdens for NRC, Agreement States, and medical licensees without demonstrable offsetting benefits, as well as provide a potentially problematic and inappropriate pathway. Non-expert providers and inexperienced staff handling unsealed therapeutic radiopharmaceuticals when there are already appropriately trained experts to

provide these uncommonly used therapies would introduce unacceptably higher levels of risk and significantly decrease public trust in NRC's ability to adequately oversee these materials. More important to U.S. patients and their families, the limited-scope AU concept could foster an environment of financially-motivated utilization, conflicting with the broadly accepted standard of cancer care of a multidisciplinary team of subspecialized experts working collaboratively to provide the right treatment, at the right dose, at the right time.

Radiopharmaceutical therapy is a critically important tool in the clinical cancer care armamentarium when used appropriately and in accordance with medical standards and guidelines. Patients in need of radiopharmaceutical therapy are typically referred for subspecialized care by a generalist or disease specialist responsible for the overall management of the patient's care. Practice guidelines, clinical decision support tools, peer-reviewed literature, patient education, and other resources can help inform decisions by patients and their care teams, but there are varying levels of awareness within the referring physician community regarding the appropriate use of radiopharmaceutical therapy options. In certain cases, alternative treatments not involving radiation are available with similar appropriateness ratings and measurable outcomes.¹ In other situations, there could be an inappropriate reluctance by referring physicians to refer their patients out for subspecialized care regardless of the proximity, expertise, or quality of care performed by providers of cancer therapies outside their own practices—a scenario which would be exacerbated by the concepts under NRC's current consideration. Additionally, practice guidelines and technical standards, insurance coverage and reimbursement issues, cost of the agents, cost of missed appointments, state-mandated health professional licensure or certification requirements, state-based scope of practice regulations, self-referral/anti-kickback rules, facility accreditation requirements, and patients' general fear of radiation can influence treatment and referral decisions.

Due to the wide variety of factors influencing radionuclide therapy utilization, the rarity of medical events by AUs in the current regulatory paradigm, the lack of trustworthy evidence demonstrating that NRC regulations cause patient access problems, and the strong possibility that any hypothetical modification of the 35.390 AU T&E requirements would fail to improve access to therapeutic radiopharmaceuticals in rural areas, **the ACR believes it would be in the best interests of patients and families, medical licensees, regulators, and the general public if NRC were to decline to proceed with a rulemaking to create tailored/limited-scope AU pathways.** The unintended negative consequences, disruptions to licensees and programs, and increased public health and safety risks of controversial and complex regulatory changes would outweigh any theoretical benefits of proceeding with less comprehensive AU T&E pathways in 10 CFR Part 35, Subpart E.

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. This is evidenced by the increasing numbers of 35.300 AU-eligible physicians entering the workplace

¹ American Radium Society. Appropriate use criteria, radiation oncology documents by panel. Accessed 2019 Jan 15. <https://www.americanradiumsociety.org/page/docsbypanel>

from the traditional nuclear medicine, radiation oncology, and diagnostic/nuclear radiology pipelines. Current AU eligibility prerequisites—implemented during the major Part 35 reform in 2002 and revised in 2005—have become permanently engrained elements of the related ACGME-approved training programs. NRC’s regulations, in combination with existing ABR, ABNM, and AOBR certification and maintenance of certification requirements, are essential for ensuring health and safety of patients, personnel, and care-giver safety in the U.S.

Any significant regulatory paradigm changes would be costly and severely disruptive to existing training programs, as well as to the NRC and Agreement States. Changes to AU T&E are unlikely to result in a significant surge of new NRC and Agreement State licenses. It would be a more efficacious allocation of NRC’s limited resources to continue with the current AU T&E requirements in 10 CFR 35.390, refocus on more impactful priorities of NRC’s medical team and the licensee community, and avoid any controversial rulemaking activities designed to effectively reduce the comprehensiveness of AU T&E requirements for those without NRC-recognized board certification.

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 reasonable assurance of adequate protection of public safety, as evidenced by the low numbers of abnormal occurrences and other medical events involving unsealed radioactive materials requiring a written directive. There is no reason to believe the exemplary safety record of Subpart E would be maintained if NRC were to reduce AU T&E requirements.

NRC’s publicly accessible annual reports from the Nuclear Materials Events Database (NMED) do not specify if reported medical events occurred under the supervision of NRC-recognized board certified AUs or under the supervision of alternate pathway/grandfathered AUs. However, we are concerned that weakening alternate pathways for the comparatively higher risk therapeutic radiopharmaceuticals in an effort to expand numbers of non-expert AUs could easily introduce problems and issues where, in the hands of subspecialized physician experts and experienced staff accustomed to using radiological materials for a wide array of diagnostic and therapeutic applications, the associated risks have historically been minimal. Moreover, there could be systemic failures to identify medical events or general underreporting 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.² Indeed, the ABR and ABNM study guides/assessment-preparation requirements have become the de facto curricula for 4-year residency programs, and the ACGME, boards, and programs currently have the agility to add topics relatively

² 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>

quickly, which is important for new agents.³ Time has proven that this approach had the intended effect of allowing 10 CFR 35.390 to persist reasonably well as the boards and programs have had ample flexibility to tailor educational foci to remain current. The alternatives of additional curriculum specification and/or a mandatory AU examination, which were considered and rightly rejected in the 2002 rule, would have necessitated periodic updates by NRC. We believe the NRC should continue its current risk-informed approach exemplified by the AU T&E prerequisites in 35.390, which have provided 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 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. The perceived benefits of less comprehensive T&E requirements for non-specialized clinicians are entirely theoretical and severely outweighed by health and safety risks, regulatory burdens, and other negatives.

First, the concept of limited-scope AU pathways fundamentally conflicts with accepted patient care standards and practice guidelines.⁴ The predominant medical paradigm for treating patients who may require radiopharmaceutical therapy utilizes a multidisciplinary team approach so patients benefit from the unique expertise of many medical specialties. Within that framework, public health and safety are optimally protected when unsealed radiopharmaceutical therapies are supervised and performed by appropriately trained and licensed physicians. Typically these are nuclear medicine physicians, radiation oncologists, nuclear radiologists, and certain other diagnostic radiologists in close cooperation and communication with referring physicians responsible for overall clinical management of the patients, and supported by staff trained and experienced in handling of radioactive materials, imbued with a culture of safety for patients and personnel.⁵

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>

⁴ American College of Radiology. ACR practice parameter for the performance of therapy with unsealed radiopharmaceutical sources. Revised 2015(res 49). <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/UnsealedSources.pdf>

⁵ American College of Radiology, American Association of Physicists in Medicine, and Society of Pediatric Radiology. Technical standard for therapeutic procedures using radiopharmaceuticals. Adopted 2017(res 39). <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RadioPharm.pdf>

Regardless of specific radiation-related physical factors such as nature of the emission, energy level(s) of the emission(s), or half-life, there is an underlying public fear of radiation. All radiation has the potential for mishandling and untoward events that may require special knowledge, skills and tools for handling, and widespread availability of the agents raises potential 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 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. Lutetium Lu-177 dotatate is also administered in relatively large activities and requires nontrivial patient preparation.

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. There is a potential for increased morbidity from combined modality therapies typically employed when radionuclide therapy agents are used by providers unfamiliar with short- and long-term implications of radiation deposition in normal tissues. Radionuclide therapy agents are generally targeted, which is an advantage in lowering toxicity, but none of the agents are currently used as primary therapy. Patients undergoing these therapies are often older with co-morbidities, typically have had previous chemotherapy and possibly external beam radiation with their own toxicities, and toxicities are generally additive and not isolated. Product labels from the major manufacturers show adverse reactions and other issues requiring appropriate physician training and experience to address, including good institutional radiation protection practices.⁶

Additionally, there is a clear lack of a supportable technical basis to justify the changes under current NRC consideration. **There is no trustworthy and comprehensive data from NRC, Agreement State agencies, and broad scope licensees demonstrating that an AU shortage exists at all. There is likewise no evidence showing that radiopharmaceutical therapy modalities are underutilized due to NRC’s AU T&E requirements.** Previously, some radiopharmaceutical manufacturers have advocated the unsubstantiated concept of an AU shortage and have implicated said shortage in a perceived underutilization of their therapeutic radiopharmaceutical products. The theoretical notion of an AU shortage that can only be addressed by inappropriately circumventing radiation safety best practices and patient care standards is contrasted by real-world workforce trends and training pipeline data in the U.S., particularly for radiation oncology and radiology. Moreover, an ACMUI subcommittee explored AU availability in recent months and concluded in presentations in July 2018 and September 2018 that there are enough physician trainees in the traditional pipelines of nuclear medicine, radiation oncology, and nuclear radiology to cover demand.⁷ In addition to these traditional pathways, the redesigned American Board of Radiology (ABR) 16-month dual board certification in nuclear medicine and diagnostic radiology—which started in 2017 and rapidly expanded to 56 residents in 33 ACGME-accredited diagnostic radiology programs—is a new pipeline which will provide additional AUs. ACMUI

⁶ U.S. National Library of Medicine. Label: XOFIGO- radium ra 223 dichloride injection. Accessed 2019 Jan 18.

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a398400e-bd31-41a9-9696-4f7c06569ede>

U.S. National Library of Medicine. Label: ZEVALIN- ibritumomab tiuxetan. Accessed 2019 Jan 18.

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ccf29429-bf8e-4cce-bd12-1de56853fc5b>

U.S. National Library of Medicine. Label: LUTATHERA- lutetium lu 177 dotatate injection. Accessed 2019 Jan 18.

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=72d1a024-00b7-418a-b36e-b2cb48f2ab55>

⁷ Subcommittee on T&E, NRC ACMUI. Presentation: T&E for all modalities subcommittee update. 2018 September 20. <https://www.nrc.gov/docs/ML1825/ML18257A000.pdf>

previously concluded that utilization drivers of radiopharmaceutical therapy are multifactorial and involving mostly considerations outside of NRC's purview (such as referring clinicians' self-interests, financial/reimbursement considerations, availability of non-radiation-emitting and often equally effective treatment options, general fear of radiation exposure, etc.). The ACR and other likeminded stakeholders have previously recommended 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 be helpful for informing a variety of issues under current and future NRC consideration.

Ostensibly, one of industry's arguments in favor of lesser AU T&E pathways is the unsubstantiated assumption that previously-unlicensed rural facilities would begin to provide radiopharmaceutical therapy options to patients in their geographical areas. However, there are questions as to whether an increase in the denominator of AU-eligible clinicians via limited-scope AU pathways would indeed result in a commensurate increase in remotely-located licensed facilities, particularly as the therapies in question are relatively uncommonly used. There are many other considerations, barriers, and needs beyond AU eligibility before a new access point for radiopharmaceutical therapy can be established. Rural facilities would need to apply for NRC/Agreement State licenses, pay annual fees, obtain requisite RSO services, hire appropriate allied health professionals with state-required licensure/certification/recognition status (e.g., most states and the major accreditation programs have special requirements for technologist personnel),⁸ navigate complex payor/reimbursement requirements, obtain accreditation by a nationally-recognized accrediting body, purchase and handle high-cost agents, and more. **Rather, it is more likely that limited scope AU-eligible clinicians would primarily seek to be added to existing NRC/Agreement State licenses, thus substituting for appropriately trained AUs at facilities already providing these therapies. This outcome would reduce the safety and quality of care within existing licensed facilities and ultimately fail to improve access in remote geographical areas.**

The 700 hours with listed topics in 10 CFR 35.390 provide the basic regulatory minimum of the total T&E required to independently function as an AU. This paradigm allows for the ongoing relevance of NRC's regulatory requirements with minimal maintenance by agency staff and the Agreement States to keep current with the practice of medicine. If the NRC were to implement tailored T&E pathways, these pathways would need to be updated regularly to remain unobtrusive and modern, and new pathways would need to be expeditiously created for new radiopharmaceutical therapies as they arise. This would necessitate a full-fledged reform of how the NRC addresses and prioritizes medical use issues internally, perhaps even involving a cycle of ongoing maintenance rulemakings akin to regulatory cycles used by many HHS agencies, such as the Centers for Medicare and Medicaid Services (CMS). New specifications and changes would have disruptive effects on the NRC-recognized certification boards and associated training programs, which are allied with NRC in its mission to protect health and safety.

It is also unreasonable to expect that NRC's current enforcement mechanisms could adequately oversee non-expert regulated communities, as those unaccustomed to working with radiation and nuclear materials would be less likely to correctly identify, address, and report medical events. Due to the infrequency of use of these therapies, it is unlikely that limited scope AUs would have ample practice to maintain an acceptable skill/knowledge level in handling unsealed byproduct material. NRC staff would

⁸ American Society of Radiologic Technologists. Individual state (technologist) licensure information. Accessed 2019 Jan 16. <https://www.asrt.org/main/standards-and-regulations/legislation-regulations-and-advocacy/individual-state-licensure>

need to invest in additional targeted enforcement/monitoring efforts, Information Notices, guidance revisions, and workshops/meetings to educate and closely monitor non-expert AUs. Inspections would need to be more focused on those licensees that rely on limited scope AUs to perform 35.300 uses. Agreement State agencies would be bogged down in the same regulatory revision activities and implementation issues as NRC. Per statutory mandate, the increase in NRC's efforts and resources would require a commensurate increase in annual fees, which would have an adverse effect on the licensee community and, ultimately, patient access.

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 ACR opposes the idea of a new limited-scope AU status for nominally-trained clinicians who do not meet the 700 hour alternate pathway or the NRC-recognized board certification standard, and we strongly recommend that NRC not initiate a rulemaking to implement such a concept. Additionally, any reduction in T&E would undermine the NRC's existing alternate pathway.

Regardless of energy level or specific emission(s), nuclear materials are inherently different from antineoplastic agents used in chemotherapy and other hazardous materials used elsewhere in medicine for a variety of reasons (e.g., radiation dose/physics, allied health professionals involved, general public fear of radiation, security interests, etc.). The notion that alpha and/or beta emitting agents have minimal risk and require limited training and experience is evidence of a certain naiveté regarding the properties of the agents and suggests a lesser degree of care necessary in management. Issues such as spills, residual activity in tubing and syringes, unused material and care in handling, etc., require knowledge and skills acquired through years of training and experience and a culture of safety among primary providers and staff. Patients and the U.S. population at large have an inherent fear of radiation and expect that individuals authorized to use unsealed materials requiring a written directive have extensive background and expertise in radiation safety and nuclear materials.

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 are appropriate and should not be altered. Moreover, the ACR opposes any changes to implement further radiopharmaceutical categorization in NRC's regulations. To suggest that an hour more or less of any specific topic is satisfactory belies the level of T&E derived from a certification-based residency or the current alternate pathway for physicians without NRC-recognized board certification. As mentioned previously, the ABR and ABNM study guides/assessment-preparation requirements have become the de facto curricula for 4-year residency programs; the flexibility of the

NRC's current AU T&E paradigm in 10 CFR 35.390 allows the ACGME, boards, and programs to evolve appropriately to address new agents and evolving subtopics of additional interest.⁹

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?

The NRC's current minimum regulatory requirements provide reasonable assurance of adequate protection of public health and safety. Relevant ACGME-approved residency programs in nuclear medicine, radiation oncology, and nuclear radiology involve additional training and experience as well. While ACR supports periodic reassessment of NRC's T&E regulations with the regulated community, we have not seen any need for revising the experience prerequisites at this time and thus we decline to suggest unwarranted changes. We fully support the inherent flexibility of the NRC-recognized board certification paradigm as the default pathway to AU-eligibility, and believe that the current 700-hour alternate pathway is appropriate for other AUs-in-training.

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.

Any single exam demonstrates a level of knowledge at a snapshot in time, and observation and/or completion of several cases does not demonstrate competency but merely that there were no apparent problems at the moment of testing or observation. The true test of competency to perform independently as an AU lies in a career of excellence 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 radiation-related care.

Moreover, it is likely that limited-scope AUs would perform fewer and fewer cases as disruptive interventions/alternative treatments become available, thus reducing even minimal levels of competency to serve independently as AUs.

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

The ACR recommends no change to the current requirements, which were amended by the recent Part 35 update rule published on July 16, 2018. Preceptor attestations via NRC Form 313A(AUD) are appropriate for individuals without NRC-recognized board certification seeking AU eligibility. Without

⁹ 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

having the appropriate board certification in a relevant specialty, there must be a formal method for AU preceptors to document trainees' completion of NRC's regulatory prerequisites.

By contrast, specialists who obtain AU eligibility through the NRC-recognized board certification pathway have inherently demonstrated completion of NRC AU eligibility requirements. For these specialists, AU preceptor attestations would be redundant with their board certifications as well as with other sections of NRC/Agreement State forms documenting completion of T&E prerequisites, and thus the Part 35 updates in the 2018 final rule were warranted.

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

The NRC should not allow radiopharmaceutical manufacturer attestation for uses under 10 CFR 35.300. Physicians on faculty of the training programs providing the 700 hours of T&E should continue to serve as appropriate preceptors for candidates seeking AU eligibility via the alternate pathway. Manufacturers are not providing the required T&E to prospective AUs for 35.300 uses, and thus should not logically serve as preceptors for the written attestation required on NRC Form 313A(AUD).

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.]

The current curriculum and certification examinations have served the professions and public well. In addition to the NRC regulations, the current maintenance of certification (MOC) and facility accreditation requirements as sponsored by the ACR, American Society for Radiation Oncology (ASTRO), American College of Radiation Oncology (ACRO) and the American Osteopathic Association/American Osteopathic College of Radiology (AOA/AOCR) 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?

The current regulatory paradigm is sufficient and knowledge is assessed regularly for physicians who obtain AU eligibility via the default NRC-recognized board certification pathway. The American Board of Radiology (ABR), American Board of Nuclear Medicine (ABNM) and American Osteopathic Association/American Osteopathic Board of Radiology (AOA/AOBR) MOC assessment tools provide career-long and continuous assessment of knowledge and skills.

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?

By virtue of the rigor of the ACGME-approved training in nuclear medicine, nuclear radiology, diagnostic radiology and radiation oncology, and the initial certification and MOC assessment instruments of the ABR, ABNM, and AOBR, the specialties and specialty boards have continuously demonstrated a level of excellence deserving of continued NRC trust and support. The CBNE high dose/low dose certificates for

nuclear endocrinology are only recognized for 35.190 and 35.392 uses, respectively. **No other specialty boards intensively train in, or assess the necessary knowledge and skills, to provide AU-eligibility to their diplomates, as indicated by the previously referenced study guides/assessment-preparation materials.**

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 initial certification, and then career-long maintenance of certification oversight or continuing education activities. This continuous provider assessment is in parallel to continuous assessment of facilities by the facility accreditation programs of ACR, as well as those of ASTRO and ACRO.

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 are sufficient, and all of the appropriate boards have been recognized.

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.

As discussed by ACMUI during their September 2018 public meeting, there is no current or anticipated shortage in the number of prospective AU-eligible providers under the current regulatory paradigm. ACMUI found there were approximately 900 ACGME (i.e., radiation oncology, nuclear medicine, nuclear radiology, etc.) and 150-200 AOB in the current training pipeline for 35.390 uses.¹⁰ These conservative estimates represent a net increase from previous years. ACMUI also mentioned in its open discussions that radiation oncology and nuclear radiology have expanded over time in the numbers of programs and residencies; therefore, any decline or plateauing in ABNM-specific denominators is not generalizable to the full AU population.

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

The ACR values health, safety, and accessibility to care for patients and their families. Unfortunately, with cancer and other serious diseases, there is sometimes a need for remotely-located patients to travel longer distances to receive appropriate care. This is generally true of most cancer care services and other medical procedures, regardless of whether or not those services involve nuclear materials. For example, an analysis of American Society of Clinical Oncology workforce data published in the journal *Oncology* indicated that only 3% of medical oncologists practice in rural areas, and that cancer patients residing in hospital service areas with no local oncologists traveled an average of 58 minutes to receive chemotherapy.¹¹

¹⁰ Subcommittee on T&E, NRC ACMUI. Presentation: T&E for all modalities subcommittee update. 2018 September 20. <https://www.nrc.gov/docs/ML1825/ML18257A000.pdf>

¹¹ Charlton, Mary, Schlichting, Jennifer, Chioreso, Catherine, Ward, Marcia, and Vikas, Praveen. Challenges of rural cancer care in the United States. *Oncology*. 2015 Sep 15;29(9):633-40.

Regarding access to AUs specifically, facilities with NRC/Agreement State licenses to provide 35.300 uses are reasonably accessible from most geographic areas in the U.S., with similar travel needs for those in remote areas to other specialized healthcare services. In circumstances of longer travel distances to radiopharmaceutical therapy providers, patient access problems are effectively reduced by the limited number of administrations any individual patient would typically experience. This is unlike systemic chemotherapy, which is often given on a multi-administration schedule or maintenance/longer-term basis.

As noted in the previously mentioned considerations for prospective licensees, 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 outside of NRC's jurisdiction. Moreover, if a hypothetical remote/rural facility were to obtain an NRC license with authorization to provide 35.390 uses leveraging a "limited-scope AU," the volume of procedures using unsealed nuclear materials would likely be so low as to make it impossible for the non-expert AU and personnel to retain fundamental skills and knowledge. Such a scenario would introduce unacceptable levels of risk.

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

As mentioned previously, concerns from some industry stakeholders regarding limited access to AUs are poorly documented, anecdotal, and often financially conflicted. There is no trustworthy evidence showing that NRC regulations have directly limited patients' access to radiopharmaceutical therapy, or that revising NRC's AU T&E regulations would drastically increase the number and distribution of licensed facilities. As NRC ACMUI indicated in previously cited reports, the utilization drivers of these services are multifactorial and involving many considerations outside of NRC's purview. ACMUI also called to question any correlation of AU numbers and radiopharmaceutical therapy utilization rates by showing that such therapies are relatively uncommonly used even at large facilities with an abundance of clinicians and AUs who collaborate closely.¹²

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

We believe the current AU T&E requirements actually stimulate research and development, by virtue of trainee requirements for research projects, availability of a greater volume of clinical material, and access to a wider range of basic science and clinical research personnel. Only the certification-based, ACGME-approved training programs require access to comprehensive aspects of physics, cancer and radiation biology on a routine basis, such that R&D in the field are encouraged and supported. The coverage in these programs is also broadening to include components of genomics, proteomics, theranostics, and more.

D. Other Suggested Changes to the T&E Regulations

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

¹² NRC ACMUI. Final report on T&E for authorized users of alpha and beta emitters under 10 CFR 35.390. 2016 March 16. <https://www.nrc.gov/docs/ML1608/ML16089A271.pdf>

The current AU T&E prerequisites appropriately emphasize the dominion of NRC-recognized specialty boards and provide training programs with adequate flexibility under the auspices of the 700-hour regulatory minimum. Thus, the regulations should not be revised at this time.

We are aware that non-physician professionals, including nuclear pharmacists and nuclear medicine advanced associates, have leveraged NRC's current interest in less comprehensive physician T&E requirements to advocate for even more radical scenarios in which non-physician health professionals assuming AU responsibilities would circumvent the use of subspecialized physician AUs. Due to the complicated nature of cancer care beyond the expertise of nuclear pharmacists and extender professionals, these controversial ideas are fundamentally problematic from a clinical perspective, and rife with glaring legal issues beyond NRC's jurisdiction.

Authorized nuclear pharmacists (ANPs) should not directly provide or oversee patient care in substitution of appropriately subspecialized physician AUs. Such a scenario would be out of nuclear pharmacy's scope of practice, and ANPs would be unable to address patient-related problems. According to the Board of Pharmacy Specialties (BPS), there are only approximately 400 BPS board certified nuclear pharmacists,¹³ the majority of whom work in commercial settings or in large medical centers and serve primarily as suppliers to healthcare facilities—not to patients. The typical nuclear pharmacist workflow, as described by the American Pharmacist Association (APhA), is characterized by atypical, early morning hours preparing and dispensing radiopharmaceuticals,¹⁴ and thus is not conducive to supervision of non-expert physicians providing radiopharmaceutical therapy in disparate facilities. The overwhelming majority of commercial nuclear pharmacies are located in metropolitan areas and other population centers,^{15, 16} and thus controversially expanding ANPs' scope of practice to include patient care services of any kind would not increase access in remote geographical areas beyond the coverage already provided by current licensees.

By definition, a Nuclear Medicine Advanced Associate (NMAA) is an advanced-level nuclear medicine technologist working *under the supervision* of a licensed physician, who is an authorized user of radioactive materials.¹⁷ Being AUs on NRC or Agreement State licenses would be outside the recognized roles and responsibilities for these extenders and could be legally and professionally problematic. More importantly for the issues under NRC's purview, NMAA AU-eligibility would also be redundant with the inherent AU-eligibility of their supervising nuclear medicine/nuclear radiology physicians. The Nuclear Medicine Technology Certification Board (NMTCB), which administers the NMAA examination, has indicated that only 16 total technologists have obtained certification as NMAAs,¹⁸ and thus AU eligibility for these extenders would provide no perceivable access expansion.

¹³ Board of Pharmacy Specialties. Nuclear pharmacy. Accessed 2019 Jan 15. <https://www.bpsweb.org/bps-specialties/nuclear-pharmacy>

¹⁴ American Pharmacist Association. Practice topics: nuclear pharmacy. Accessed 2019 Jan 15. <https://www.bpsweb.org/bps-specialties/nuclear-pharmacy/>

¹⁵ Department of Pharmacy Practice, Nuclear Pharmacy Programs, Purdue University. Nuclear pharmacies in the US. Accessed 2019 Jan 15. <https://nuclear.pharmacy.purdue.edu/nukeinus>

¹⁶ United Pharmacy Partners (UPPI, LLC). Map of locations. Accessed 2019 Jan 15. <http://uppi.org/businesses/businesseslist.php>

¹⁷ American College of Radiology. Digest of council actions, 2017-2018. Sec 6, appendix m. Nuclear medicine advances associates: roles and responsibilities. Adopted 2011.

¹⁸ Nuclear Medicine Technology Certification Board. Nuclear medicine advanced associate exam. Accessed 2019 Jan 15. <https://www.nmtcb.org/specialty/NMAAExam.php>

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

We are currently unaware of AU T&E-specific requirements that are outside of NRC's regulatory authority.

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?

No regulatory changes are necessary as the current regimen is not burdensome to the NRC, Agreement States, or medical community. The NRC's medical stakeholder community has not requested a tailored, limited-scope AU pathway for 10 CFR 35.390 uses or identified the AU T&E prerequisites as problematic. Less comprehensive AU prerequisites for those without NRC-recognized board certification would be misaligned with NRC's mission and radiopharmaceutical therapy practice standards, and would be fundamentally unhelpful for patients seeking safe and effective care.

The ACR respects that the NRC must be attentive to all public stakeholders, including radiopharmaceutical manufacturers and commercial pharmacies, and we welcome open dialog and collaboration on regulatory issues; however, there is a concerning lack of justification for continued exploration and regulatory implementation of less comprehensive AU T&E pathways. Likewise, it is likely that tailored T&E requirements would fail the ostensible purpose of incentivizing the establishment of many previously-unlicensed patient access locations. Therefore, we strongly urge NRC staff to recommend against any rulemaking related to tailored pathways to AU eligibility. The current AU T&E regulatory paradigm in 10 CFR Part 35, Subpart E is sufficient and NRC regulations are not to blame for the perceived underutilization of certain radiopharmaceuticals.

Thank you in advance for your time and consideration. As always, the American College of Radiology welcomes the opportunity for continued dialogue with NRC. Should you have any questions on the points addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Gloria Romanelli, ACR Senior Director of Government Relations, at 703-716-7550 / gromanelli@acr.org, or Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 703-716-7546 / mpeters@acr.org.

Sincerely,



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