

Advisory Committee on the Medical Uses of Isotopes (ACMUI)
Training and Experience (T&E) for All Modalities Subcommittee

Draft Report

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Subcommittee Charge

In 2016, the U.S. Nuclear Regulatory Commission's (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee on Training and Experience (T&E) Requirements for All Modalities was charged to periodically review the T&E requirements for the medical use of unsealed byproduct material (Title 10 *Code of Federal Regulations* (10 CFR) Part 35 Subparts D-H), and to make recommendations for changes, as needed.

Subcommittee Sub-charge:

The Subcommittee should re-prioritize its work such that the review of the T&E requirements for 10 CFR 35.300 uses is conducted prior to the review of the T&E requirements for 10 CFR 35.200. As part of the re-prioritized work and in light of the NRC's tasking, the Subcommittee should consider the development of a limited-scope AU pathway.

Background

On March 10, 2016, the ACMUI held a public teleconference meeting to discuss the report of the Subcommittee on the T&E Requirements of Authorized Users of Alpha, Beta, and Gamma Emitters under 10 CFR 35.390. During this teleconference meeting, the Committee unanimously endorsed the Subcommittee's report and recommendationsⁱ, which included maintaining the existing 700-hour T&E requirement (alternate pathway). Additionally, it was recommended that a separate subcommittee be formed to conduct periodically review the T&E requirements for all modalities under 10 CFR Part 35.

The Subcommittee developed a data driven standardized review template that would provide a comparative format for future review and reassessment. To optimize this review process, the Subcommittee intended to begin the review with 10 CFR 35.100, followed by 35.200, 35.300, etc. The Subcommittee completed its review of 10 CFR 35.100 with no suggested revisions. However, because of ongoing concerns about patient access to unsealed byproduct material for which a written directive is required, the Subcommittee was directed to review the T&E requirements for 10 CFR 35.300 before reviewing 35.200.

In August 2017, the Commission voted on the 10 CFR Part 35 Rulemaking package and included direction to the NRC staff to review 10 CFR 35 Subpart E and evaluate the possibility of tailored T&E for different categories of radiopharmaceuticals, delineate how these categories would be created, recommend the appropriate T&E requirements, and whether these requirements would be satisfied based on hours of training or would require a formal assessment of competency.

In January 2018, the U.S. Food and Drug Administration (FDA) approved a therapeutic radiopharmaceutical, lutetium-177 dotatate, with the potential for greater use than previously approved therapeutic radiopharmaceuticals. In addition, there was a decrease in first time candidates sitting for the American Board of Nuclear Medicine (ABNM) certification examination. These two

observations heightened concerns about a potential Authorized User (AU) shortage in the future. Thus, the ACMUI proposed the reconsideration of an alternate AU pathway for 10 CFR 35.390.ⁱⁱ

Subcommittee Review, Comments and Recommendations

Topic 1: Potential AU shortage

To address concerns about a potential future shortage of AUs, the Subcommittee reviewed the current pathways for AU certification. Traditionally nuclear medicine, nuclear radiology, diagnostic radiology, and radiation oncology graduates of Accreditation Council for Graduate Medical Education (ACGME) approved residencies seek board certification (and hence, AU status) by the NRC-deemed status boards of the American Boards of Radiology (ABR), Nuclear Medicine (ABNM) and Osteopathic Radiology. In 2016, the ABR supported a redesigned AU eligibility pathway consisting of 16 months of Nuclear Radiology/Nuclear Medicine (NR/NM) training, incorporated into any 48-month ACGME accredited Diagnostic Radiology Residency. This revised program would satisfy the NRC’s T&E requirements for 10 CFR 35.390. Upon completion of the radiology residency, the graduate trainee is then eligible to sit for the board certification exams of the ABR in Nuclear Radiology and/or the ABNM.

To explore the concern for a potential future AU shortage, the Subcommittee reviewed the 2018-2019 ACGME website, which provided the following information on the current number of potential future AUs in-training.

	Programs***	Program Length (years)	Total Residents	~ Graduates/year
Nuclear Medicine (NM)	40	1-3	79	50
Nuclear Radiology (NR)	17	1	11	11
ABR Redesigned*(rDR)	33	4	56	14
Radiation Oncology (RO)	94	4	775	194
Diagnostic Radiology (DR)	194	4	4,695	1,174
Osteopathic Radiology**(OR) --		4	150-200	50
Total:			5,816	1,493

*2019 American Board of Radiology personal communication

**2018 American Board of Osteopathic Radiology personal communication

***T&E satisfied for 35.300 for NM/NR/RO/rDR: 35.390; DR/OR: 35.290, 35.392, 35.394

The current pipeline of AUs in-training for 35.390 is over 900 which includes trainees in NM, NR, DR, and RO. As of 2018, the ABNM reported 3,591 practicing ABNM diplomats. Along with the current practicing AUs, the nearly 270 annual 35.390 AU graduates, and accounting for retiring AUs, the Subcommittee **concluded** that there are no objective data to support an AU shortage at the present time.

Topic 2: Limited-scope AU pathway

Although there is no evidence that there is a current AU shortage, given the likelihood that the number of available therapeutic radiopharmaceuticals and the demand for these therapies will increase, the Subcommittee explored whether the NRC should consider developing a limited-scope AU pathway tailored to specific radiopharmaceuticals.

Radionuclide therapy poses the highest risk and highest impact of all nuclear medicine procedures, and if doses are not properly handled or administered, these therapies can cause unintentional serious organ or tissue injury. The newer therapeutic radionuclides have become increasingly more complex administrations, with the potential for multi-organ or tissue toxicities, and hence require a basic competency in radiation therapy and radiation safety. A potential limited-scope AU pathway for radionuclide therapy must ensure that the basic knowledge topics in 10 CFR 35.390 are obtained, thereby attaining an equivalent level of therapeutic competency and competency in radiation safety.

When investigating the feasibility of a limited-scope AU pathway for 10 CFR 35.390, the NRC staff (with ACMUI input) proposed a list of required basic knowledge topics for AUs involved in radionuclide therapy. The proposed curriculum began with the knowledge topics in 10 CFR 35.390ⁱⁱⁱ. Due to the complexity and overlap of these basic knowledge topics, the Subcommittee concluded that it is not feasible to tailor the T&E requirements for a limited-scope AU for each specific radiopharmaceutical nor is it feasible to create categories for specific therapeutic radionuclides since each such category would encompass nearly all the knowledge topics in 10 CFR 35.390. The NRC staff (with external stakeholder input from the medical community) and the Subcommittee **agreed** that the knowledge topics in 10 CFR 35.390 are the basic minimum knowledge required for any radionuclide therapy.

In considering the above, the Subcommittee **does not recommend** a limited-scope AU pathway for radionuclide therapies requiring a written directive. Unlike the iodine-131 NaI limited-scope AUs under 10 CFR 35.392 and 35.394 (endocrinologists), the emerging radionuclide therapies have multiple contraindications (versus iodine-131 NaI specific to thyroid therapy) and more toxicities. It would be too cumbersome to develop and provide oversight for specific T&E requirements within the regulations to fit each radionuclide therapy. All of the classroom and laboratory training areas and work experience topics contained in 35.390 are applicable to any radionuclide therapy, and are essential for radiation safety of the patient, personnel and public. It would be difficult in defining a limited-scope authorization and what radionuclides or radiopharmaceuticals are to be included. Each therapeutic radiopharmaceutical has unique radiation safety issues, which require a comprehensive understanding of all the T&E topics in 35.390, regardless of the types of radiation emissions, chemical properties or mode of administration.

During a public NRC meeting held on December 11, 2018, a novel “team approach” was proposed where an onsite Authorized Nuclear Pharmacist (ANP) would prepare the radionuclide for therapy and handle the radiation safety component, while the limited-scope AU would administer the “patient ready” dose and manage patient care. The perceived benefits of an “AU partnership” should be carefully reviewed. Although well-intended, a fragmented approach to a therapeutic procedure can have the unintended consequence of making things worse.^{iv} Furthermore, if an onsite ANP is available, a fully trained physician AU is also likely available for the entire radionuclide therapy. There are also far fewer ANPs than AUs, and ANPs are generally concentrated (as are AUs) in urban and not rural areas. The safe and effective administration of radionuclide therapy is best accomplished by a comprehensively trained AU who is responsible for the entire therapeutic procedure, and who has the thorough knowledge and understanding of the therapy to include the various factors and potential toxicities and serious hazards that can occur to the patient, personnel and the public.

Topic 3: Competency Assessment for the limited-scope AU pathway

In the initial limited stakeholder outreach, the majority of responders favored using an examination to confirm the successful acquisition of the 10 CFR 35.390 knowledge topics and to confirm an individual’s competency to independently function as a comprehensive or limited-scope AU under 10 CFR 35.390. It is also critical to validate that the proposed curriculum was successfully obtained. For this confirmation

of proficiency, the NRC staff and the Subcommittee **agree** that a competency assessment is necessary. This assessment should not be based on hours or preceptor attestation, but rather on an initial and continued competency evaluation over time. The Subcommittee **supports** broader input from the medical community to create an AU competency assessment with final approval by the NRC.

The Subcommittee further explored the periodic reassessment of AU competency, particularly in relation to the frequent or infrequent performance of radionuclide therapy. This infrequency concept has raised similar concerns in the board recertification process, which is generally 7-10 years between recertification exams. The American Board of Medical Subspecialties (ABMS), a non-profit organization of 24 medical specialty boards which serves the public in quality healthcare through professional and educational standards^v, has supported a program of continuing professional certification for physician Lifelong Learning and Self-Assessment. The American Boards of Radiology and Nuclear Medicine are ABMS member boards. To promote continued professional competency for their diplomates, the ABR and ABNM have transitioned or are transitioning to this continuous longitudinal assessment.

In regards to radionuclide therapy, this infrequency concept in procedure performance was also reviewed by the Subcommittee. Because of the ability to eliminate and destroy tissue, therapeutic radionuclide procedures pose a much higher risk to the patient, personnel and public than diagnostic procedures. The potential for a limited-scope AU and the higher likelihood for the infrequent performance of radionuclide therapy in rural areas would make it difficult for physicians to retain basic AU competency in radionuclide therapy.

To attest to the successful acquisition of the AU knowledge topics in 10 CFR 35.390, the overall limited stakeholder and Subcommittee **support** a formal competency certification and a continuous certification process. The goal of certification is to validate that the AU candidate has achieved a predetermined level of competence. In the current context, this certification is to confirm the acquisition of a basic knowledge curriculum and the ability to independently function as an AU for a specific radionuclide therapy or therapies. Although the Subcommittee **does not recommend** adoption of a limited-scope AU pathway for therapy, if the NRC pursues such a pathway, the Subcommittee **strongly recommends** an initial formal competency assessment and competency reassessment through ongoing longitudinal reassessment with specific emphasis on radiation safety.

The entity or entities that will administer this formal competency assessment and reassessment must develop a methodology that ensures that passing these examinations is empirically determined. This latter aspect is the Angoff Method which is a widely used standard in test development and creates a test that will be legally defensible and meet the Standards for Educational and Psychological Testing.^{vi}

Summary

In summary, the ACMUI Subcommittee on Training and Experience Requirements for All Modalities addressed the NRC staff request to assess the feasibility of a limited-scope AU pathway for 10 CFR 35.390, which was initially predicated on the concern about a potential future shortage of AUs. At the present time, there are no objective data to support an AU shortage. The Subcommittee **does not recommend** the development of a limited-scope AU pathway for the administration of unsealed byproduct material where a written directive is required. If the NRC moves forward in pursuing an alternative limited-scope AU pathway, the Subcommittee **strongly recommends** that the limited-scope AU must successfully acquire the knowledge topics in 10 CFR 35.390 which would be a minimum requirement for AUs involved in radionuclide therapy. The Subcommittee also concluded that due to the complexity and overlap in these basic knowledge topics, it would be difficult to safely and practically create specific categories for therapeutic radiopharmaceuticals.

Despite the ACMUI Subcommittee's recommendation against this action, if the NRC chooses to pursue the creation of a limited-scope AU pathway for unsealed byproduct material where a written directive is required, the Subcommittee **strongly recommends** that the AU candidate must acquire the basic knowledge topics in 10 CFR 35.390 and satisfactorily complete a formal competency assessment. Furthermore, the individual's continued status as a limited-scope AU is dependent on successfully maintaining a formal periodic reassessment of competency. This final and most critical component in the attainment and maintenance of any AU status will optimize patient care while ensuring the protection of the public's health and safety.

Subcommittee Position and Recommendations

- The Subcommittee **strongly supports and reaffirms the Committee's 2016 position on** maintaining the current and existing AU pathways (board certification and alternate pathway) as codified in the regulations, which are adequate for protecting public health and safety. Radionuclide therapy poses the highest risk and highest impact of all nuclear medicine procedures.
- The Subcommittee concludes that there is no objective data to confirm an AU shortage.
- The Subcommittee **does not recommend** a limited-scope AU pathway for unsealed byproduct material for which a written directive is required.
- The Subcommittee **unanimously agrees** that in order to ensure the safety of patients, personnel and the public, if the NRC chooses to pursue the creation of a limited-scope AU pathway for unsealed byproduct material where a written directive is required, the AU candidate must acquire the basic knowledge topics in 10 CFR 35.390 and satisfactorily complete a formal competency assessment. Furthermore, the individual's continued status as a limited-scope AU is dependent on successfully maintaining a formal periodic reassessment of competency.

The Subcommittee will review and evaluate the T&E requirements under 10 CFR 35.392, 35.394, and 35.396 following the Committee's discussion and vote on this report.

ⁱ Advisory Committee on the Medical Uses of Isotopes Subcommittee on , Final Report, March 16, 2016 (NRC's Agency Wide Documents Access and Management System (ADAMS) Accession No. ML16089A271)

ⁱⁱ Advisory Committee on the Medical Uses of Isotopes Subcommittee on Training and Experience Requirements for All Modalities, Subcommittee Draft Interim Report, February 19, 2018 (ADAMS Accession No. ML18051A725)

ⁱⁱⁱ <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0390.html>

^{iv} Stange KC The Problem of Fragmentation and the Need for Integrative Solutions. Ann Fam Med. 2009 Mar;7(2):100-103.

^{vi} <https://www.apa.org/science/programs/testing/standards>