ACMUI Training and Education Subcommittee Recommends Not Changing Current AU Requirements

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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.

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

The Subcommittee draft interim report issued on February 19, 2018 stated there were two reasons for reasonable concern for a near-future decline in patient access to care, including (1) U.S. Food and Drug Administration's approval of Lutetium-177 DOTATATE for treatment of certain neuroendocrine tumors, and (2) the decrease in the number of first-time candidates sitting for the Certification Examination of the American Board of Nuclear Medicine.

The Subcommittee considered the establishment of a limited authorized user pathway that would shorten the current requirement for 700 hours of training and experience for radioisotope therapies.

The ABNM responded in a letter dated July 31, 2018 that it was strongly opposed to changing the current requirements. Data was provided regarding the number of ABNM diplomates, number of candidates taking the certification examination, and positive changes in educational pathways resulting in increasing numbers of trainees eligible for dual certification by the ABNM and ABR. The ABNM letter is available at http://abnm_wordpress_uploads.s3.amazonaws.com/wordpress/wp-content/uploads/ABNM-NRC_ACMUI_SubcommitteeTrainingExperience_Ltr-180731.pdf. The Subcommittee subsequently sought additional stakeholder input on four specific questions: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

The ABNM responded in a letter dated January 26, 2019 providing additional data and justification for maintaining the current requirements. The ABNM letter is available at http://abnm_wordpress_uploads.s3.amazonaws.com/wordpress/wp-content/uploads/ABNM-comment-Docket-ID-NRC-2018-0230.pdf. After considering stakeholder feedback, the Subcommittee issued a draft report on February 7, 2019 stating it does NOT recommend the development of a limited-scope AU pathway for the administration of unsealed byproduct material where a written directive is required.

The ABNM was pleased with the recommendation of the Subcommittee, but notes that a final decision has not been made. 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 recommended that the AU candidate must acquire the basic knowledge topics in 10 CFR 35.390 and satisfactorily complete a formal competency assessment.

The ABNM will closely monitor developments. Diplomates are encouraged to visit the Subcommittee website at https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html for additional updates, and to provide feedback.