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 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-NRC_ACMUI_SubcommitteeTrainingExperience_Ltr-180731.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.