

ABNM Statement on ACMUI Changes in Authorized User Training and Education

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As a result of “concerns of various stakeholders” the Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) is considering whether the 700-hour training requirement to be an authorized user (AU) for parenteral radionuclide therapy is “placing a hardship on patient access” to alpha and beta therapeutic radiopharmaceuticals. The February 19, 2018, draft report of the ACMUI Subcommittee on Training and Experience (<https://www.nrc.gov/docs/ML1805/ML18051A725.pdf>) noted 2 developments since the ACMUI last considered the training issue nearly 15 years ago: (1) U.S. Food and Drug Administration approval on January 26, 2018, of ¹⁷⁷Lu-DOTATATE for treatment of neuroendocrine tumors and the likely “considerable demand for this agent”; and (2) the “precipitous decrease in the number of first-time candidates” sitting for the American Board of Nuclear Medicine (ABNM) certification examination. A follow-up staff evaluation report on July 5, 2018, recommended reconsideration of the existing pathways to AU status with certain caveats, including the need for greater and broader stakeholder input (<https://www.nrc.gov/docs/ML1818/ML18186A517.pdf>).

In a letter sent to the ACMUI on July 31, 2018, the ABNM expressed its strong belief that the current requirement for 700 hours of supervised training and experience should not be changed and that reducing the minimum requirement for 700 hours of supervised training and experience for unsealed radioisotope therapy raised concerns for patient safety (https://abnm_wordpress_uploads.s3.amazonaws.com/wordpress/wp-content/uploads/ABNM-NRC_ACMUI_Subcommittee-TrainingExperience_Ltr.pdf). The ABNM took issue with the ACMUI statement that the number of candidates sitting for the 2016 certification examination indicated a future shortage of AUs. The number of initial ABNM certificates issued each year has been relatively constant from 1977 to 2015, with an average of 72 (range, 50–107 per year). Although a decrease in the number of candidates taking the ABNM certification examination was seen in 2016, the number of initial certificates issued from 2016 to 2018 has been stable with an average of 45 (range, 43–49 per year). More than 3,600 diplomates are currently active (not deceased or retired), and there is no evidence of a shortage of AUs.

The ACMUI subcommittee draft interim report also noted a decrease in the number of Accreditation Council for Graduate Medical Education–accredited nuclear medicine training programs and residents, from 57 programs with 161 residents in academic year 2007/2008 to 41 programs with 75 residents in 2017/2018. The ABNM responded that the decrease in the number of programs and trainees

is partly the result of an increase in the number of nuclear medicine physicians who are also certified in diagnostic radiology by the American Board of Radiology (ABR). Certification by the ABR decreases the duration of nuclear medicine training required for ABNM certification from 36 to 16 months, creating the appearance of decreasing numbers of residents, when it is the duration of training that is decreasing. Contributing to this trend

is the increasing availability of dual training pathways in which residents training in nuclear medicine are counted as diagnostic radiology residents rather than nuclear medicine residents, consistent with the requirements of the ACGME and the ABR. The ABNM believes that dual training will result in better-trained physicians to meet the needs of patients in the era of molecular imaging and therapy. The ABNM sees no evidence that workforce issues have decreased patient access to care and believes that concern for potential future issues has not taken into consideration recent positive changes in nuclear medicine training.

Several recommendations and observations were made at the ACMUI meeting held on September 20 and 21, 2018: (1) review existing AU pathways to maintain safety, maximize patient access, and clearly define AU scope of practice; (2) need for comprehensive training in radiation physics, radiation biology, radiation instrumentation and mathematics, radiation protection and safety, patient release, and applicable regulations; (3) competency must be determined objectively for initial assessment and for maintenance of competency; (4) NRC staff should monitor potential AU shortages for 10 CFR 35.300 and include geographic data and practice patterns as part of this monitoring; and (5) greater stakeholder input is needed. The notes from this meeting are available on the NRC website (<https://www.nrc.gov/docs/ML1825/ML18257A000.pdf>). At Newsline press time, 2 public meetings for stakeholder input had been scheduled for December 11, 2018, and January 10, 2019. More information on these public meetings is available on the NRC website (<https://www.nrc.gov/pmns/mgt>).

The ABNM urges its diplomates to provide their input to the NRC. The ABNM also urges its diplomates to improve patient access to care by making parenteral radionuclide therapy available in all hospitals and outpatient clinics at which there are qualified nuclear medicine physicians.



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