

The Distinction Between an AU and an ABNM-Certified MD

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The Nuclear Regulatory Commission (NRC) is considering establishing a pathway for limited authorized user (AU) status for physicians wishing to treat patients with parenteral radionuclides. This pathway would be for physicians seeking AU status by the alternate non-board-certified pathway. The current alternate pathway includes a requirement for 700 hours of training and experience, which consists of a minimum of 200 hours of classroom and laboratory training, and 500 hours of supervised work experience. The NRC is responding to unfounded concerns for a decline in access to care due to a future shortage of AUs (<http://jnm.snmjournals.org/content/60/1/17N.full.pdf+html?sid=6db73698-63a3-496a-965b-4998ed52d18d>). The initial public comment period was October 29, 2018, to January 29, 2019. In a letter dated January 26, 2019, the American Board of Nuclear Medicine (ABNM) commented that the current requirements should not be changed and that reducing current requirements raised concern for patient and public safety (http://abnm_wordpress_s3.amazonaws.com/wordpress/wp-content/uploads/ABNM-comment-Docket-ID-NRC-2018-0230.pdf).

Based on comments received from the ABNM and many other stakeholders, the Training and Education Subcommittee of the Advisory Committee on the Medical Use of Isotopes issued a final report on February 27, 2019, recommending maintaining the current requirements and against establishment of a limited AU pathway (<https://www.nrc.gov/docs/ML1905/ML19058A598.pdf>). The NRC opened a second comment period from May 9 to June 3 (<https://www.federalregister.gov/documents/2019/05/02/2019-08996/draft-approaches-for-addressing-training-and-experience-requirements-for-radiopharmaceuticals>). (See also the article on page N1 of this *JNM* Newsline issue.) The ABNM participated in a teleconference on May 14 and repeated its support for maintaining the current requirements. In response to NRC's consideration of a performance-based approach that would remove prescriptive training and education requirements, the ABNM stated that allowing licensees to develop and use their own policies and procedures to make self-determinations of whether their credentialed physicians should be an AU for 1 or more radiopharmaceuticals under 10 CFR.300 would raise serious concerns about patient safety.

Regardless of whether the NRC changes the regulatory requirements for AUs, there is a distinction between an AU and an ABNM-certified physician. An AU must have supervised work experience that involves: (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of

unsealed byproduct material; (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; (F) [Reserved]; and (G) Administering dosages of radioactive drugs to patients or human research subjects from 3 categories (oral administration of ≤ 1.22 GBq (33 mCi) of ^{131}I -sodium iodide for which a written directive is required; oral administration of > 1.22 GBq (33 mCi) ^{131}I -sodium iodide; and parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, β radiation characteristics, α radiation characteristics, or photon energy of < 150 keV for which a written directive is required. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under §35.1000. This work experience must involve a minimum of 3 cases for which the individual is requesting AU status.

An AU is trained in the safe handling and correct administration of a radionuclide, as well as minimizing public radiation exposure. NRC regulations do not include training in the practice of medicine, which requires physicians to provide appropriate, effective, timely, efficient, and equitable health care, as well as avoiding harm to patients. For example, giving a patient twice the medically appropriate amount of a parenteral radionuclide would not be a violation of NRC regulations if the patient received the amount indicated on the written directive. Ironically, it may be a violation if the patient received the medically appropriate amount of radionuclide when the written directive indicated a higher amount.

Training program directors and other AUs who attest to trainees' education and work experience must ensure that all NRC requirements are met. Participating only in the administration of a radionuclide is insufficient, but trainees who receive all of the required training are qualified to be AUs.

Being an AU does not mean an individual is a physician who is qualified to manage patients. Certification by the ABNM is a credential used by organizations to determine if a physician is qualified to use radionuclides for diagnosis and treatment of patients. The ABNM requires certified physicians to also meet the Accreditation Council for Graduate Medical Education Nuclear Medicine program requirements for parenteral therapy, which include the NRC requirements, plus patient selection, evaluating the risks and benefits of therapy, obtaining informed consent, and counseling patients and their families about radiation safety issues, as well as scheduling and performing posttherapy follow-up. ABNM certification indicates that nuclear medicine physicians are qualified to manage patients as part of the medical treatment team.

The ABNM strongly believes that the current NRC training and education requirements to be an AU for parenteral therapy should not be changed but also recognizes that being an AU is not equivalent to being an ABNM-certified physician who is qualified to manage patients.