

NRC Vetoes T&E Changes; Approves ^{82}Rb and Emerging Tech Modernization

In a public meeting held on January 28, Nuclear Regulatory Commission (NRC) commissioners voted to disapprove staff recommendations to change training and experience (T&E) requirements for Authorized Users (AUs) of radiopharmaceuticals. The proposed changes had been the source of comment and protest from major professional societies and their members. In 2020, NRC staff formally recommended that the commission pursue regulatory changes to the T&E requirements, moving to board certification as the sole factor for determining and obtaining AU status and modifying NRC criteria to allow for additional medical specialty board diplomates (beyond nuclear medicine and radiation oncology) to qualify as AUs. In voting down this proposal, one commissioner noted that the proposed changes had suggested “that the current training and experience framework could be viewed as encroaching on the practice of medicine. I disagree. Ensuring that AUs meet training and experience requirements necessary for radiological safety does not insert NRC into the actual practice of medicine. The broad support among medical organizations for NRC’s licensing role makes it clear that the medical community does not view the current framework as encroaching on the practice of medicine.”

SNMMI was among the groups that opposed T&E changes and submitted comments in multiple formats to the NRC. In 2020, Vasken Dilsizian, MD, then SNMMI President, testified before the Commission during a public hearing. He noted that expansion of medical specialty training requirements was not within the purview of the NRC. Moreover, Nuclear Medicine, Radiation Oncology, and Diagnostic Radiology with 16-month Nuclear Medicine/Nuclear Radiology (NM/NR) pathways are the only Accreditation Council for Graduate Medical Education (ACGME)–approved training programs with specific goals and objectives pertaining to administration of radioactive material, and such training must be completed under supervision of board-certified physicians trained in this area.

Feedback from stakeholders was considered by the commissioners in making their decision. Another commissioner stated in his final review: “Many stakeholders offer persuasive arguments that the current T&E framework is working effectively to ensure radiological safety and is not resulting in a shortage of authorized users to administer radiopharmaceuticals.” In a February 4 statement, SNMMI praised the NRC for this decision.

Current pathways for obtaining AU status remain:

- Certification by a medical specialty board (e.g., the American Board of Nuclear Medicine) recognized by the NRC or an Agreement State;
- Completion of 200 hours of classroom training and 500 hours of supervised work experience in an ACGME-accredited program (Nuclear Medicine, Diagnostic Radiology with a 16-month NM/NR pathway, or Radiation Oncology); and
- Previous identification as an AU on an NRC or Agreement State license or permit.

^{82}Rb Generators and Emerging Medical Technologies

Along with voting on AU T&E requirements, the NRC approved initiation of rulemaking to modernize 10 *Code of Federal Regulations (CFR)* Part 35 to accommodate the increasing medical applications of radioisotopes and new advances in medical technologies. NRC staff recommended updating Part 35 to establish generally applicable performance-based requirements for emerging medical technologies that would focus on the essential safety-related elements necessary to ensure radiation safety for workers, patients, and the general public. The revised regulation would also include performance-based requirements for ^{82}Rb generators, gamma stereotactic radiosurgery units, and ^{90}Y -microspheres. Many stakeholders had expressed an interest in having a regulatory framework well-suited to the advancement and integration of innovative radiopharmaceuticals.

Part 35 does not currently address ^{82}Rb generators, and NRC has relied on enforcement discretion in this area. But, as explained by NRC staff in their proposed rulemaking plan: “Longstanding reliance on temporary enforcement guidance to exercise enforcement discretion is inconsistent with NRC Enforcement Policy and is not a substitute for resolving the underlying technical issues associated with calibration and dosage measurement for ^{82}Rb generators.”

NRC will open comment periods and hold stakeholder response sessions to address proposed changes.

*Nuclear Regulatory Commission
SNMMI*