NRC Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

On May 2 the U.S. Nuclear Regulatory Commission (NRC) published a notice in the *Federal Register* announcing a 30-day public comment period and 2 public meetings on the NRC staff's draft approaches regarding training and experience (T&E) requirements for administration of radiopharmaceuticals requiring a written directive. This request marked the second comment period on this issue in 2019. The notice not only solicited feedback through June 3 but included a list of questions designed to solicit more information from the affected nuclear medicine community and others. This is one of several information-gathering activities intended to help the agency decide whether to open this topic up for rule making.

In a May 16 press release encouraging individuals to submit comments in response to the notice, SNMMI noted that it remained engaged in responding to the NRC on this issue, having submitting comments in July 2018 and January 2019. Additional comments were submitted in response to the May 2 solicitation. The society does not support any reduction in T&E requirements and listed several key concerns: (1) that any reduction in T&E requirements would compromise the safety of patients, caregivers, and family members; (2) that parenteral radionuclide therapy can be administered safely only by personnel with an extensive understanding of radiation physics, radiopharmacy, pharmacokinetics, dosimetry, and radiation biology, as well as the principles and practices of radiation safety; and (3) that no shortage of Authorized Users (AUs) has been identified to warrant a change in the current requirements.

The NRC announcement noted that this new comment period was a result of input received during the November 2018 public comment period and from its Advisory Committee on Medical Uses of Isotopes T&E Subcommittee's report dated February 27, 2019. NRC staff drafted several possible approaches, including:

- A status quo decision, with no changes to the current T&E requirements for radiopharmaceuticals requiring a written directive under 10 CFR 35.300.
- Tailored T&E requirements: The 4 approaches under this section would modify the existing T&E requirements under 10 CFR 35.390, "Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required." The limited AU approaches in this category would require a set amount of T&E tailored to specific radiopharmaceuticals, and the "emerging radiopharmaceuticals" approach would tailor T&E requirements for each new radiopharmaceutical as it is developed, similar to the approach for regulating new technologies under 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." These tailored T&E approaches include:
  - Limited AU for α- or β-emitting radiopharmaceuticals: Under this approach, any physician could complete at least 400 hours of T&E to be authorized to administer any α- or β-emitting radiopharmaceutical. T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to α- or β-emitting radiopharmaceuticals. Preceptor attestation would be required.
  - Limited AU for unit-dose, patient-ready radiopharmaceuticals: Under this approach, any physician could complete at least 400 hours of T&E to be authorized to administer any unit-dose, patient-ready radiopharmaceutical. The T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to unit-dose, patient-ready radiopharmaceuticals. Preceptor attestation would be required.
  - Limited AU for any single parenteral radiopharmaceutical: Under this approach any physician could complete at least 400 hours of T&E to be authorized to administer any 1 parenteral radiopharmaceutical. The T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to the radiopharmaceutical the physician wishes to administer. Preceptor attestation would be required. Limited AUs who initially complete at least 400 hours of T&E and then wish to administer a different radiopharmaceutical would be required to complete, minimally, an additional 80 hours of tailored, supervised work experience for each additional radiopharmaceutical.
  - Emerging radiopharmaceuticals: Much like NRC regulations in 10 CFR 35.1000, under this approach the NRC would conduct individual reviews of each new emerging radiopharmaceutical to determine specific T&E requirements. T&E requirements could be tailored to consider potential users of the radiopharmaceutical (e.g., non–nuclear medicine or non–radiation oncology physicians wishing to administer the radiopharmaceutical for their patients with indicated cancers), thus creating alternate T&E pathways for each new radiopharmaceutical.
- Performance-based approaches: These approaches would remove prescriptive T&E requirements from the regulations and instead focus oversight on performance-based aspects of a licensee's medical program for the administration of radiopharmaceuticals.

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that his method of choice when delivering an opinion was often "totally unvarnished." In his presence, both students and colleagues were always keenly aware of his no-nonsense attitude and benefited from his critiques and guidance. In national and international meetings in which he served as session chair, discussions after the presentations were always interesting and lively. Audiences in these meeting sessions enjoyed the open scientific discussion and memorable point/counterpoint exchanges. The discussions often led to focusing of ideas and resulted in better scientific collaborations.

His passing is a tremendous loss for the nuclear medicine community, but his contributions to this field will continue to influence and guide our future. For those of us who were fortunate to have met and worked with Monte, we owe a special debt of gratitude for the indelible impact he made on our lives and careers.

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  - Competency-based evaluation: Under this approach, proposed AUs would be required to demonstrate competency in radiation safety topics and radiation safety–related job duties through a formal competency evaluation (e.g., an examination or preceptor attestation).
  - Credentialing of AUs: Under this approach, the NRC would no longer review and approve T&E qualifications for all AUs under 10 CFR part 35. Instead, licensees would develop and use their own policies and procedures to make self-determinations of whether their credentialed physicians have the appropriate T&E to be an AU for 1 or more radiopharmaceuticals under 10 CFR 35.300. Licensees would be required to maintain a training program that ensures compliance with the requirements in 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," and 10 CFR part 20, "Standards for Protection Against Radiation."
- Team-based approaches: These could remove prescriptive T&E requirements for AUs, focus training requirements on the competency of the entire team, or revise the current 700-hour T&E requirement for AUs based on pairing the AU with another individual with expertise in administering radiopharmaceuticals.
  - Radiopharmaceutical team: Licensees would need a team to administer radiopharmaceuticals under 10 CFR 35.300. The team would minimally include an AU, a radiation safety officer, and a nuclear medicine technologist.
  - Licensees would need both an AU and an authorized administrator to administer radiopharmaceuticals under 10 CFR 35.300.
  - Partner limited-trained AUs with licensed nuclear pharmacists: The T&E for AUs would be at least 400 hours; however, the AU would be required to physically partner with an authorized nuclear pharmacist (ANP) for all administrations of radiopharmaceuticals. Unlike the other team-based approaches, prescriptive T&E would be required for the AU in this approach because of the AU's more prominent role in administration of radiopharmaceuticals. The minimum of 400 hours of T&E for the physician partnering with an ANP would be focused on supervised work experience and patient cases, and preceptor attestation would be required. The AU would be responsible for administration of radiopharmaceuticals in accordance with the written directive, and the ANP would be responsible for radiation safety–related duties.

It is unclear which approach or mix of approaches the NRC will choose. A decision on new rule making is expected later this year. SNMMI continues to monitor this topic closely.

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