The NRC Staff Evaluation of Training and Experience Requirements for Radiopharmaceuticals Under 10 CFR 35.300

Organization of Agreement States
2019 Annual Meeting
August 20, 2019

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Current Training and Experience (T&E) Regulations

10 CFR 35.390 provides three ways a physician can be approved as an authorized user (AU) to use radiopharmaceuticals requiring a written directive:

- Certification by a medical specialty board whose certification is recognized by the NRC or an Agreement State.
- *Completion of T&E, also known as the alternate pathway: 200 hours classroom and lab training and 500 hours supervised work experience for a total of 700 hours T&E (requires casework and preceptor attestation).*
- Previous identification as an AU on an NRC or Agreement State license or permit.

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Stakeholder Concerns

Since revisions to the T&E regulations in 2002 and 2005, stakeholders have raised concerns that the 700-hour requirement in the alternate pathway is overly burdensome for physicians ineligible for the board certification pathway.

- The requirement could create a shortage of AUs, thus limiting patient access to radiopharmaceuticals.

SRM-M170817

In Staff Requirements Memorandum M170817 (August 17, 2017; ML17229B284), the Commission directed to staff to evaluate:

- Whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals;
- How those categories should be determined;
- What the appropriate T&E requirements would be for each category; and
- Whether the requirements should be based on hours of T&E or focused more on competency.

SECY-18-0084

Staff's initial evaluation of T&E for 10 CFR 35.300 (August 28, 2018; ML18135A277):

- It may be feasible to establish tailored T&E requirements for different categories of radiopharmaceuticals, and to create "limited AU" statuses.
- There are viable options for creating a competency-based approach to demonstrating acceptable T&E for limited authorized user status.
- *However, the staff needs to conduct more extensive outreach before making a recommendation to the Commission.*

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Medical Community Feedback From Two Public Comment Periods

- 83 FR 54380 (Oct. 29, 2018 – Jan. 29, 2019) asked for comments on tailoring the T&E requirements; 84 FR 18874 (May 3 – July 3, 2019) asked for comments on the staff's draft approaches for potentially revising T&E.
- Nuclear medicine and radiation oncology communities strongly support maintaining the status quo, and oppose any reductions to T&E and creation of limited AU pathways.
- Non-traditional physicians wishing to treat patients with "patient-ready" radiopharmaceuticals support tailored T&E; suggest 80 hours of T&E.

OAS and Agreement State Feedback To Date

- *Initial comment period:* OAS and some Agreement States oppose creating additional limited AU pathways, but the OAS suggested consideration of more performance-based T&E requirements.
- *Second comment period:* Some Agreement States support status quo, but OAS and other Agreement States suggest that T&E requirements be revised so that the regulators are no longer reviewing and approving T&E for physicians to become AUs.
    - *It was commented that the current T&E requirements are not aligned with the NRC's Medical Policy Statement*.

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

The ACMUI T&E Subcommittee final report was issued on February 27, 2019 (ML19058A598):

- Supports maintaining the current T&E requirements;
- There is no objective data to confirm an AU shortage;
- Does not recommend adoption of a limited-scope AU pathway; and
- If the NRC pursues a limited-scope pathway, strongly recommends an initial formal competency assessment and periodic reassessments.

Draft SECY Paper and Options for Agreement State Comment

- RCPD-19-011 (August 12, 2019) provided the draft SECY for comment. Agreement State and OAS input will inform the staff's recommended option for the Commission.

Comments are due by Friday, October 18th.

- Options fall under two general approaches:
  1) Revise T&E regulatory framework to remove prescriptive requirements and the NRC and Agreement States no longer review and approve T&E for AUs.
  2) Maintain or enhance the existing T&E regulatory framework

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Approach 1. Removal of Prescriptive T&E Requirements and NRC and Agreement State Review and Approval of AUs

Option 1a, Specialty Board Credentialing – Physicians must be certified by any medical specialty board.

Option 1b, Licensee Credentialing – Licensees develop their own policies and procedures for credentialing their physicians.

Option 1c, NRC-Recognized Specialty Board Credentialing – Physicians must be certified by a medical specialty board that has been recognized by the NRC as meeting *high-level* board certification criteria.

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Approach 2. Maintain and/or Enhance the Existing T&E Framework

Option 2a, Status Quo – No changes to the current T&E requirements.

Option 2b, Tailored Requirements –T&E would be tailored and reduced for use of individual or categories of radiopharmaceuticals.

Option 2c, Emerging Radiopharmaceuticals – Individual reviews of each emerging radiopharmaceutical to determine drug-specific T&E and other requirements

Option 2d, Team-Based Requirements – T&E would be reduced based on pairing AUs with other individuals with radiation safety training**.**

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Next Steps

Agreement State and ACMUI Review Draft SECY Paper

August - October 2019

Agreement State Comments Due

October 18, 2019

ACMUI T&E Subcommittee Public Teleconference on Draft SECY Paper

Mid-to-Late October 2019

Finalize Commission Paper

November - December 2019

Deliver Paper to Commission

Late December 2019

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For More Information

- The NRC's Training and Experience Evaluation Web site: https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html
- The T&E docket (NRC-2018-0230) at Regulations.gov: https://www.regulations.gov/docket?D=NRC-2018-0230
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