Evaluation of Training and Experience for Radiopharmaceutical Use

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

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Authorized User Training & Experience

The NRC's training and experience (T&E) requirements for physicians seeking to become an Authorized User are listed in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35. Specifically, the T&E requirements in Subpart E of 10 CFR 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive. An attestation may be required to confirm that these requirements are met.

1. A physician can be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State.
2. A physician can complete a structured educational program and supervised work experience under an Alternate Pathway. The required 700 hours breaks down to a minimum of 200 hours of classroom and laboratory training, and 500 hours of supervised work experience.
3. A physician can be authorized if previously identified as an Authorized User (AU) on an NRC or Agreement State license or permit.

Why We Are Evaluating

The NRC is evaluating: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined (such as by risks posed by groups of radionuclides or by delivery method); (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of T&E or focused more on competency.

Is 700 hours appropriate? How should competency be assessed?

Do the current NRC requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals?

Should the NRC create tailored T&E requirements for different categories of radiopharmaceuticals?

What should the categories be and how should the requirements be applied?

How You Can Participate

The NRC is conducting more extensive outreach with the medical community focused on assessing options for tailoring the T&E requirements for medical uses authorized under 10 CFR 35.300.

- Provide feedback: A *Federal Register* notice will be published with detailed questions written by NRC staff. The NRC will request feedback on these questions from interested stakeholders.
- Attend NRC public meetings and webinars in November, December, and January.
- Send letters or e-mails to the NRC with your feedback.
- Keep track of the NRC's evaluation at the T&E Web site: www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html

If you only have time to participate in one way, please submit a response to the questions posted in the *Federal Register* notice.

References

SRM-M170817:
(ADAMS Accession No. ML17229B283)

SECY-18-0084:
(ADAMS Accession No. ML18135A276)

T&E Evaluation Web site:
www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html