UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 1, 2018

ALL AGREEMENT STATES, VERMONT

U.S. NUCLEAR REGULATORY COMMISSION *FEDERAL REGISTER* NOTICE AND PUBLIC MEETINGS REGARDING TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS (STC-18-065)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards: (1) published a notice in the *Federal Register* on October 29, 2018, requesting comments on training and experience (T&E) requirements for different categories of radiopharmaceuticals; and (2) plans to hold four public meetings on this topic during the comment period which ends January 29, 2019.

Background: The NRC is evaluating its regulations germane to the T&E required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material." In SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817," the NRC staff determined that while it may be feasible to develop tailored T&E requirements for certain categories of radiopharmaceuticals under Subpart E, more extensive outreach to Agreement States, the medical community, and the public is needed. Agreement State and stakeholder input received during this outreach effort will be used by the staff to determine whether changes to the NRC's T&E requirements for authorized users are recommended.

Discussion: The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

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. This 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.
3. A physician can be authorized if previously identified as an authorized user on an NRC or Agreement State license or permit (i.e., grandfathered).

In its evaluation of the T&E requirements, the NRC staff is considering whether an additional pathway should be created or if the alternate pathway (number 2 above) should be revised. Specifically, the staff 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; (3) what the appropriate T&E requirements would be for each category; and (4) whether those requirements should be based on hours of training and experience, or focused more on competency.

On October 29, 2018, the NRC published a series of questions on T&E in the *Federal Register* (83 FR 54380). The *Federal Register* notice (FRN) is enclosed with this letter and can also be accessed at https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf. The NRC will carefully consider responses to these questions and would appreciate feedback from the Agreement States on whether changes to the current T&E regulations are warranted. The comment period for the T&E evaluation will end on January 29, 2019. Please follow the directions in the FRN on how to submit written comments. The NRC is using Regulations.gov to accept written comments on the T&E docket (NRC-2018-0230).

The NRC will conduct four public meetings scheduled for November 14 and December 11, 2018, and January 10 and January 22, 2019, and will accept oral comments provided during the meetings. Two of the meetings will be held at NRC Headquarters in Rockville, MD, and all four meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting page will be updated with meeting details and registration instructions at least 10 days before the meetings: https://www.nrc.gov/pmns/mtg.

In addition to the four public meetings described above, the NRC is coordinating with the Organization of Agreement States to schedule a webinar for the Agreement States. The Agreement State webinar will held on December 13, 2018, and participation details will be provided to the Agreement States in a forthcoming RCPD letter.

The input that the NRC receives during the comment period will assist the NRC staff in making a recommendation to the Commission on whether the T&E requirements should be revised. The NRC staff will coordinate with the Agreement States on developing any potential rulemaking recommendations in accordance with the charter for the NRC/Agreement State working group on rulemaking. The current schedule projects that the Agreement States will have the opportunity to review and comment on the draft paper to the Commission in June and July 2019.

Additional information on the NRC's T&E evaluation can be found at https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html.

If you have any questions on this correspondence, please contact me at (301) 415-3340, or the individuals named below:

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Enclosure:
Training and Experience
Federal Register notice

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