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

May, 2, 2019

ALL AGREEMENT STATES, VERMONT

U.S. NUCLEAR REGULATORY COMMISSION *FEDERAL REGISTER* NOTICE AND PUBLIC MEETINGS REGARDING DRAFT APPROACHES FOR TRAINING AND EXPERIENCE REQUIREMENTS FOR RADIOPHARMACEUTICALS (STC-19-023)

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 May 2, 2019, requesting comments on draft approaches the staff has developed regarding training and experience (T&E) requirements for radiopharmaceuticals (84 FRN 18874); and (2) plans to hold two public meetings on the draft approaches during the comment period, which ends June 3, 2019.

Background: The NRC is evaluating its regulations for 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 was needed. On October 29, 2018, the NRC published an initial *Federal Register* notice (FRN) announcing a three-month public comment period on the staff's T&E evaluation (83 FR 54380). Since the end of the initial public comment period, the NRC staff has developed several draft approaches regarding the T&E requirements for radiopharmaceuticals requiring a written directive.

Discussion: The T&E requirements in Subpart E of 10 CFR Part 35 provide three ways that a physician can be authorized to administer 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. The 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: (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 T&E, or if they should be performance-based (such as requiring a competency evaluation or licensee credentialing of authorized users).

The NRC staff has developed several draft approaches regarding the NRC's T&E regulations for administration of radiopharmaceuticals requiring a written directive and is soliciting comments on those draft approaches in an FRN that was published on May 2, 2019 (84 FR 18874). The FRN is enclosed with this letter and can also be accessed at https://federalregister.gov/d/2019-08996. The FRN asks a series of questions about each of the draft approaches. The comment period on the draft approaches will end on June 3, 2019.

The NRC will conduct two public meetings scheduled for May 14, 2019, and May 23, 2019, and will accept oral comments provided during these meetings. The May 14 meeting will be open to members of the public for in-person attendance at the NRC's headquarters in Rockville, MD, and both meetings will be accessible for remote participation by moderated bridge line and webinar. The NRC's public meeting Web site will be updated with meeting details at least 10 days before the meetings: https://www.nrc.gov/pmns/mtg.

To participate in the meetings via webinar, you must register in advance using the following URLs:

- Tuesday, May 14, 2019, 1:00 p.m. – 4:00 p.m.:
  https://attendee.gotowebinar.com/register/26839476715014924
  Bridge Line: 888-452-5182
  Pass Code: 2649150

- Thursday, May 23, 2019, 10:00 a.m. – 12:00 p.m.:
  https://attendee.gotowebinar.com/register/4099285410908048653
  Bridge Line: 888-452-5182
  Pass Code: 7476312

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

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/RA Kevin Williams for/

Andrea L. Kock, Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

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