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

September 14, 2018

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTICE OF AVAILABILITY OF SECY-18-0084, "STAFF EVALUATION OF TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINISTERING DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS IN RESPONSE TO SRM-M170817" STC-18-062

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) staff has provided the Commission with initial results, status, and next steps related to the staff's evaluation of training and experience (T&E) requirements for administering different categories of radiopharmaceuticals for which a written directive is required in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," Subpart E, "Unsealed Byproduct Material—Written Directive Required."

Background: In the staff requirements memorandum (SRM)-M170817, the Commission directed the NRC staff to evaluate: (1) whether it makes sense to establish tailored training and experience requirements for different categories of radiopharmaceuticals; (2) how those categories should be determined; (3) what the appropriate training and experience 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.

Discussion: In response to the SRM, the NRC staff evaluated the knowledge topics that should be covered by the T&E requirements in 10 CFR Part 35 Subpart E and then solicited feedback from medical and regulatory stakeholders. The NRC staff determined from this evaluation that it may be feasible to establish tailored T&E requirements for categories of radiopharmaceuticals under 10 CFR Part 35 Subpart E. This could be accomplished by creating an alternative means of approving the limited administration of certain categories of radiopharmaceuticals (i.e., limited authorized user (AU) status). The NRC staff also considered some initial options for how these categories could be determined and what the appropriate T&E requirements could be for each category. The NRC staff also determined that a competency-based approach to the T&E requirements for a limited AU should be considered. The NRC staff plans to conduct more extensive outreach with the medical community focused on how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, and how the T&E requirements should be met (e.g., hours of training, demonstration of competency). As part of that outreach, the NRC staff will consider whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required," rather than solely for a limited AU status.

SECY-18-0084 can be found on the NRC's public Web site at:

https://www.nrc.gov/docs/ML1813/ML18135A276.html

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

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