



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

February 6, 2020

**ALL AGREEMENT STATES**

AVAILABILITY OF SECY-20-0005, "RULEMAKING PLAN FOR TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL (10 CFR PART 35)" (STC-20-008)

**Purpose:** To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) has published SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)."

**Background:** In August 2017, the Commission directed NRC staff to evaluate its regulations for training and experience (T&E) required for a physician to become an authorized user (AU) 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." Specifically, the Commission directed the staff to determine 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.

The staff's initial evaluation of the T&E requirements is documented in [SECY-18-0084](#), "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (Agencywide Documents Access Management System (ADAMS) Accession No. ML18135A276). In SECY-18-0084 the staff determined that while it may be feasible to develop tailored T&E requirements for certain categories of radiopharmaceuticals, more extensive outreach to the medical community was needed. Subsequently, the staff conducted two public comment periods and coordinated with the Agreement States and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) to further inform their evaluation of the T&E requirements and develop their recommendation to the Commission.

**Discussion:** [SECY-20-0005](#), "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)" (ADAMS Accession No. ML19217A318) documents the staff's policy considerations, outreach efforts, coordination with the Agreement States and the ACMUI, information gathering activities, and proposed options for the Commission's consideration regarding the T&E requirements for radiopharmaceuticals. The staff is recommending the Commission approve initiation of a rulemaking option that would require that physicians be certified by an NRC-recognized or Agreement State-recognized medical specialty board to become AUs. As part of this recommended rulemaking, the NRC, in coordination with the Agreement States and the ACMUI, would revise its board recognition criteria so that certification by specialty boards other than the existing nuclear medicine and radiation oncology boards would be an acceptable T&E pathway for the use of radiopharmaceuticals.

SECY-20-0005 was delivered to the Commission for its consideration on January 14, 2020. The NRC will notify the Agreement States of any future updates regarding the Commission's review of the rulemaking plan. If the Commission directs initiation of a rulemaking, the staff will continue to coordinate with the Agreement States on rulemaking activities in accordance with [SA-801A](#), "Agreement State Participation in Rulemaking Working Groups," dated January 16, 2019 (ADAMS Accession No. ML18263A239), throughout all stages of rule development.

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

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Enclosure:

SECY-20-0005, "Rulemaking Plan for  
Training and Experience Requirements  
for Unsealed Byproduct Materials  
(10 CFR Part 35)"

SUBJECT: AVAILABILITY OF SECY-20-0005, "RULEMAKING PLAN FOR TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL (10 CFR PART 35)" (STC-20-008) **DATED:** FEBRUARY 6, 2020

**ADAMS Accession No.: ML20024E489 (letter); ML19217A318 (SECY package) \*via email**

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