Advisory Committee on the Medical Uses of Isotopes
Comments on the Draft SECY Paper Entitled
"Staff Evaluation of Training and Experience Requirements for Administering Radiopharmaceuticals"
Draft Report Submitted on: July 5, 2018

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Charge:
To review and provide recommendations for the draft SECY paper entitled "Staff Evaluation of Training and Experience Requirements for Administering Radiopharmaceuticals."

Introduction:

In June 2015, because of stakeholder concerns that a shortage of AUs caused by the 700 hours of training and experience (T&E) required to become an AU under Title 10 *Code of Federal Regulations* (10 CFR) 35.300 (10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required") was limiting patient access to therapeutic radiopharmaceuticals, the ACMUI formed a subcommittee to look into this matter. The charge of the subcommittee was to determine if the 700 hour T&E requirement placed a hardship on patient access to alpha and beta emitting therapeutic radiopharmaceuticals and if necessary, to make recommendations for potential changes and establish recommendations for the total number of hours of T&E for Use of Unsealed Byproduct Material for which a written directive is required (10 CFR 35.390). The subcommittee concluded that the current requirement of 700 hour T&E for AUs did not adversely affect patient access to these radiopharmaceuticals and that no change in the T&E Requirements was warranted.

The subcommittee also noted that the current T&E requirements had not been updated in nearly 15 years and recommended that, in the future, periodic T&E reviews be conducted. This recommendation led to the creation of the Subcommittee on Training and Experience for All Modalities. This subcommittee created a standardized template for T&E review which was completed for 10 CFR 35.100; however, due to ongoing patient access concerns, the subcommittee was directed to expedite the review of 10 CFR 35.300, specifically 10 CFR 35.390.

During the March 1, 2018 public ACMUI teleconference meeting, the T&E Subcommittee reported[1] that two recent developments identified potential future problems with patient access to 10 CFR 35.300 radiopharmaceuticals. The first was a potential increase in therapeutic procedures related to the recent US Food and Drug Administration (FDA) approval for broad use of the therapeutic radiopharmaceutical ^{177}lutetium dotatate. The second was a continued decrease in the number of nuclear medicine physicians in-training and sitting for the American Board of Nuclear Medicine (ABNM) initial certification examination. Due to the potential future increase in the number of procedures and a concomitant decrease in AUs, the subcommittee recommended that an alternate AU pathway should be reconsidered.

Summary of Draft SECY Paper:

This draft paper addresses the NRC staff's initial recommendations, based on limited stakeholder outreach, for T&E requirements for different categories of radiopharmaceuticals with a specific focus on 10 CFR Part 35 on the "Medical use of byproduct material, Subpart E, Unsealed byproduct material-written directive required."

After the final rule revision of 10 CFR Part 35 in August 2017, the Commission tasked[2] the NRC staff to evaluate the possibility of a limited AU T&E pathway addressing the following:

1. Its feasibility for certain categories of radiopharmaceuticals,

2. How to develop such categories,

3. The appropriate T&E requirements for such categories, and

4. Whether the T&E requirements should be based on hours or competency.

Under 10 CFR Part 35 Subpart E, the staff considered the possibility of an alternate limited AU pathway with tailored T&E requirements for certain categories of radiopharmaceuticals. Options for such categories were considered along with appropriate corresponding T&E and the documentation of training competency. More extensive stakeholder outreach is planned to address the feasibility of a limited AU status with tailored T&E requirements and competency assessment.

To evaluate the feasibility of a limited AU pathway, the NRC staff first determined the knowledge topics for a T&E curriculum. This curriculum included the current T&E categories in 10 CFR 35.390 which would then be tailored to the specific category of radiopharmaceutical with additional knowledge topics as needed.

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[1] https://www.nrc.gov/docs/ML1805/ML18051A725.pdf

[2] SRM-M170817, "Staff Requirements - Affirmation Session, 10:30 A.M., Thursday, August 17, 2017, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)," dated August 17, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17229B283). The 10 CFR Part 35 rule addressed by this SRM was provided to the Commission in SECY-16-0080, "Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-A163)," dated June 17, 2016 (ADAMS Accession No. ML16123A342).

Staff then solicited stakeholder input on:

1. The fundamental and specific radiopharmaceutical knowledge required in 10 CFR 35.390 to safely administer the radiopharmaceuticals. Stakeholder response: overall support of the proposed knowledge topics;

2. How to obtain this knowledge: Stakeholder response: varied (e.g., keep the current T&E, only American Board of Radiology (ABR) or ABNM certification, competency assessment, radiopharmaceutical administration requirement); and

3. How to evaluate the acquisition and independent application of this knowledge: Stakeholder response: varied but will require NRC and stakeholder collaboration to determine this assessment.

Other concerns:

1. Categorizing radiopharmaceuticals: varied stakeholder and NRC responses;

2. How to administer the T&E requirements: consider using the reactor operator licensing program as a benchmark;

3. NRC staff estimate of the required T&E: 90-300 classroom hours or approximately 200 hours; and

4. Competency assessment method(s): examination developed by the medical community (written, hybrid) with vs without a preceptor attestation; potential formation of new specialty boards.

Conclusion: It may be feasible to develop a limited AU status for certain categories of radiopharmaceuticals with a competency-based approach for tailored T&E requirements and knowledge and skills assessment.

Subcommittee Comments:

1. The ACMUI T&E subcommittee recommended that development of an alternate AU pathway be reconsidered.

2. The stakeholder outreach has been limited, and likely related to time constraints. Staff should consider a broader stakeholder outreach. This outreach could assist in:
   a. defining the categories of radiopharmaceuticals for a limited AU status;
   b. tailoring the limited T&E requirements; and
   c. assessing the success of the knowledge and skills obtained.

3. Collaboration with the medical community and other stakeholders to develop a competency-based assessment tool (e.g., examination) is commendable.

4. Minimizing the T&E requirements, and thus one's knowledge and skills potentially jeopardizes patient, personnel and public safety.

5. The initial projection of AUs was underestimated in that only nuclear medicine physicians were considered. For the 2017-2018 academic year, the total number of residents who could potentially meet the AU T&E requirements in 10 CFR 35.390 is nearly 900. These are residents in radiation oncology, nuclear medicine, nuclear radiology, and the redesigned American Board of Radiology pathway. Data on osteopathic AUs and on AUs leaving the workforce are not available. Although this revised estimate of the total number of future AUs is encouraging, reconsideration of an alternate AU pathway should still be explored.

6. The subcommittee is concerned about estimating the required T&E classroom hours for an alternate pathway. Given that the curriculum for a limited status AU, has not been established, the subcommittee feels that it is premature to address the issue of "hours". The subcommittee feels strongly that should a decision be made to proceed with a limited AU status, the T&E requirements must be based on the knowledge and skills necessary to maintain patient, personnel and public safety and not based on a predefined number of hours.

Subcommittee Recommendations:

1. The ACMUI T&E Subcommittee recommends reconsideration of the existing pathways to AU status. This reconsideration should have the goals of

    a. maintaining maximal safety for the patient, personnel and the public,
    b. maximizing patient access to current and future radiopharmaceuticals, and
    c. clearly delineating the AU's scope of practice.

2. The educational program must be all inclusive for the limited AU status. The didactic component necessary to obtain limited AU under 10 CFR 35.390 must comprehensively cover the knowledge topics required for all AUs involved in 10 CFR 35.300, thereby ensuring the safe use of radiopharmaceuticals for the patient, personnel and the public.

3. Assessment method(s) to assess AU competency must be objective and document both initial and maintenance of competency for the limited AU status.

4. Greater and broader stakeholder input is needed.

5. The NRC staff should conduct ongoing monitoring for potential AU shortage for 10 CFR 35.300. Data on the geographic distribution and practice patterns of AUs should be included in this surveillance.