The NRC Staff Evaluation of Training and Experience Requirements for Radiopharmaceuticals: *Draft Approaches for Comment*

May 23, 2019

Medical Radiation Safety Team
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards

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Agenda

10:00 – 10:05 a.m. Welcome and Webinar Information

10:05 – 10:45 a.m. NRC Presentation on the Draft Approaches, Submitting Written Comments, and Next Steps

10:45 – 12:00 p.m. Your Comments on the Record

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Welcome and Purpose of Today's Webinar

- Provide background information on the NRC staff's evaluation of training and experience (T&E) requirements for administering radiopharmaceuticals requiring a written directive 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."
- Describe the staff's draft approaches regarding the T&E requirements.
- Listen to and accept comments on the draft approaches for the T&E *Federal Register* docket (NRC-2018-0230).

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General Webinar Information

- Handouts available under the "Handouts Tab," also attached to the Meeting Notice, and on the Training and Experience Evaluation Web site.
- Training and Experience = "T&E"
- Authorized User(s) = "AU(s)"
- **Today's webinar is being transcribed by a court reporter.**
  - All comments will be captured on the T&E docket (NRC-2018-0230) and included in our review.
- **Oral and written comments have equal weight.**

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Background: Current T&E Regulations

Current regulations provide three ways a physician can be approved as an AU to administer radiopharmaceuticals requiring a written directive:

- Certification by a medical specialty board whose certification is recognized by the NRC or an Agreement State.
- *Completion of T&E, also known as the alternate pathway: 200 hours classroom and lab training and 500 hours supervised work experience for a total of 700 hours T&E (requires preceptor attestation).*
- Previous identification as an AU on an NRC or Agreement State license or permit.

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Background: SRM-M170817

In Staff Requirements Memorandum M170817 (August 17, 2017; ML17229B284), the Commission directed to staff to evaluate:

- Whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals;
- How those categories should be determined;
- What the appropriate T&E requirements would be for each category; and
- Whether the requirements should be based on hours of T&E or focused more on competency.

Background: Initial Public Comment Period

- *Federal Register* notice dated October 29, 2018 (83 FR 54380) asked about the NRC's existing T&E requirements, tailored T&E pathways, and patient access.
- All comments and transcripts are on Regulations.gov at docket ID NRC-2018-0230.
- Citing protection of patient health and public safety, there was strong support for maintaining the current T&E requirements and opposition to any reduction in T&E and creation of limited AU pathways.
- Support for tailored T&E requirements from physicians wishing to treat their patients with patient-ready radiopharmaceuticals, also concerns regarding patient access in rural areas.

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ACMUI

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) endorsed the T&E Subcommittee's draft report:

- Supports maintaining the current T&E requirements,
- There is no objective data to confirm an AU shortage,
- Does *not* recommend adoption of a limited-scope AU pathway, and
- If the NRC pursues a limited-scope pathway, strongly recommends an initial formal competency assessment and periodic reassessments.

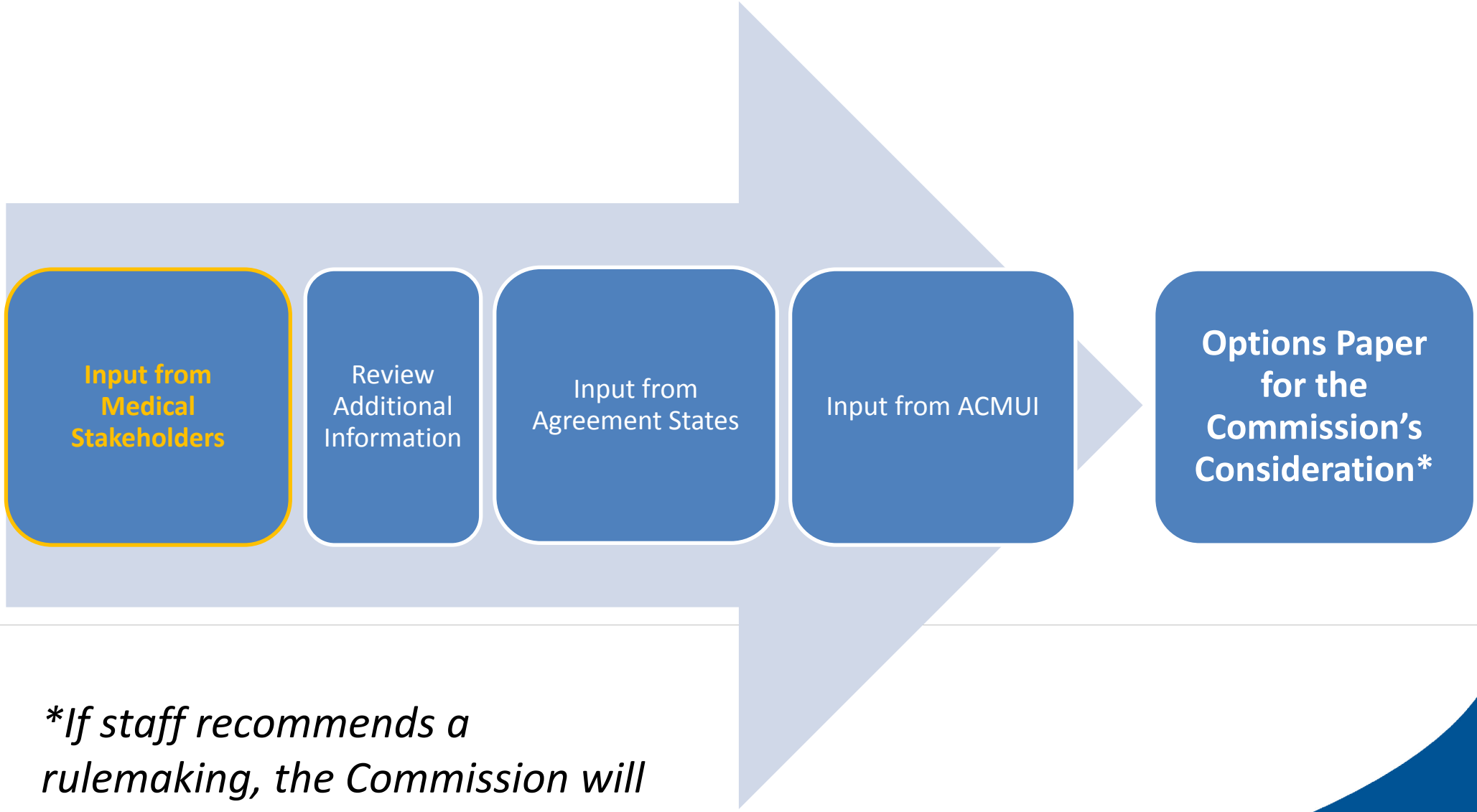
T&E Subcommittee final report issued on February 27, 2019 (ML19058A598).

The Organization of Agreement States

Organization of Agreement States (OAS) comments dated January 29, 2019 (ML19030B764):

- Most Agreement States found the current AU pathways reasonable and accessible;
- There is not consensus among the Agreement States on the need for tailored T&E requirements, creating limited AU pathways would add complexity to already-complex regulations; and
- The OAS suggested the NRC consider a less prescriptive approach to T&E requirements.

The NRC's T&E Evaluation



**If staff recommends a rulemaking, the Commission will vote on whether the staff should proceed with rulemaking.*

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The Current T&E *Federal Register* Notice

- The current T&E *Federal Register* notice (84 FR 18874) was published on May 2, 2019: https://www.govinfo.gov/content/pkg/FR-2019-05-02/pdf/2019-08996.pdf
- The FRN asks for comments on the staff's **draft approaches** regarding the T&E requirements and asks a series of **specific questions** about the approaches.
- The FRN opened the comment period from Friday, May 2 through Monday, June 3, 2019, and announced two public meetings (today and May 23).

III.A. Status Quo

- No changes to current T&E requirements for radiopharmaceuticals requiring a written directive under 10 CFR 35.300.

  - **Question 1:** If the "Status Quo" is maintained, how should the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals?
  - **Question 2:** Is there a challenge with the current T&E requirements–such as concerns regarding patient access to radiopharmaceuticals–that should be addressed through a rulemaking?

III.B. Tailored T&E Requirements Approaches

B.1. Limited AU for Alpha- or Beta-Emitting Radiopharmaceuticals

B.2. Limited AU for Unit-Dose, Patient-Ready Radiopharmaceuticals

B.3 Limited AU for Any One Parenteral Radiopharmaceutical

B.4 Emerging Radiopharmaceuticals

- **Question 3:** How should the complexity of the radiopharmaceutical administration protocol be considered in establishing the T&E requirements for the limited approaches?

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III.B. Tailored T&E Requirements Approach:

B.1. Limited AU for Alpha- or Beta-Emitting Radiopharmaceuticals

- Limited AUs administer any alpha- or beta-emitting radiopharmaceutical.
- At least 400 hours of T&E – 200 hours of classroom and laboratory training plus a minimum 200 hours of supervised work experience focused on alpha- or beta-emitting radiopharmaceuticals.
- Preceptor attestation required.

- **Question 4:** How should the NRC categorize radiopharmaceuticals with mixed emissions?

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III.B. Tailored T&E Requirements Approach:

B.2. Limited AU for Unit-Dose, Patient-Ready Radiopharmaceuticals

- Limited AUs administer any unit-dose, patient-ready radiopharmaceuticals.
- At least 400 hours of T&E – 200 hours of classroom and laboratory training plus a minimum 200 hours of supervised work experience focused on unit-dose, patient-ready radiopharmaceuticals.
- Preceptor attestation required.

  - **Question 5:** How should the NRC define "patient-ready"?

III.B. Tailored T&E Requirements Approach:

B.3. Limited AU for Any One Parenteral Radiopharmaceutical

- Limited AUs administer any one parenteral radiopharmaceutical.
- At least 400 hours of T&E – 200 hours of classroom and laboratory training plus a minimum 200 hours of supervised work experience focused on that one radiopharmaceutical.
- Each additional radiopharmaceutical requires another minimum 80 hours of tailored, supervised work experience.
- Preceptor attestation required.

III.B. Tailored T&E Requirements Approach:

B.4. Emerging Radiopharmaceuticals

- Individual reviews of each new emerging radiopharmaceutical by the NRC to determine specific T&E requirements for each new radiopharmaceutical.
- T&E requirement could be tailored to consider the potential users (e.g., non-nuclear medicine or non-radiation oncology physicians).

III.C. Performance-Based Approaches

C.1. Competency-Based Evaluation

C.2. Credentialing of Authorized Users

III.C. Performance-Based Approach:
C.1. Competency-Based Evaluation

- Proposed AUs demonstrate competency in radiation safety topics and radiation safety-related job duties through a formal evaluation.
  - **Question 6:** How could a competency-based evaluation ensure appropriate training and experience for AUs?

III.C. Performance-Based Approach:
C.2. Credentialing of AUs

- NRC is not involved in the review and approval process of T&E under 10 CFR Part 35.
- Licensees required to develop and use their own policies and procedures to determine whether their credentialed physicians have the appropriate T&E to be an AU.
- Licensees maintain training programs to ensure compliance with 10 CFR 35.41 (written directive required administration procedures) and 10 CFR Part 20 (radiation protection).

- **Question 7:** How could physicians in small practices be credentialed (i.e., physicians not associated with hospitals or other large institutions with credentialing boards)?

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III.D. Team-Based Approaches

D.1. Radiopharmaceutical Team
D.2. Team AUs With Authorized Administrators
D.3. Partner Limited-Trained AUs With Authorized Nuclear Pharmacists

Question 8: For the team-based approaches, how should the AU's radiation safety responsibilities be clearly distinguished from other members of the team?

III.D. Team-Based Approach:
D.1. Radiopharmaceutical Team

- A team (at a minimum – an AU, a Radiation Safety Officer, and a Nuclear Medicine Technologist) would be required to administer radiopharmaceuticals.
- T&E would be performance-based – licensees develop polices and procedures that address how their teams meet the requirements in 10 CFR 35.41 and 10 CFR Part 20.

III.D. Team-Based Approach:

D.2. Team AUs with Authorized Administrators

- Both AU and authorized administrator (AA) would be required for radiopharmaceutical administrations.
- An AA is an individual that a licensee authorizes to administer radiopharmaceuticals.
- T&E for the AU is performance-based and focuses on written directives, patient release criteria, and medical event reporting.
- T&E for AAs includes training on radiation safety, preparation and administration protocols, written directives, patient release criteria, and medical event reporting.

III.D. Team-Based Approach:
D.3. Partner Limited-Trained AUs with Authorized Nuclear Pharmacists

- AUs would physically partner with an authorized nuclear pharmacist (ANP) to administer radiopharmaceuticals.
- At least 400 hours of T&E for AUs
- T&E for AUs focuses on supervised work experience and preceptor attestation would be required.
- The AU would be responsible for radiopharmaceutical administrations and the ANP would be responsible for all other radiation safety-related duties.

- **Question 9:** How should the radiation safety responsibilities be divided between the AU and the ANP?

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Additional Questions in the FRN

- **Question 10:** What are the advantages and disadvantages of the draft approaches?
- **Question 11:** Are there significant costs or benefits associated with any of the approaches?
- **Question 12:** Would any of the draft approaches impact patient access to radiopharmaceuticals or address stakeholder concerns of overly burdensome (regulatory) requirements?

Additional Questions in the FRN, continued

- **Question 13:** For the draft approaches that consider tailored hours of T&E, what are the appropriate numbers of hours and what radiation safety topics should comprise the limited T&E?

- **Question 14:** Should the NRC consider inclusion of a formal radiation safety competency assessment and periodic reassessments for any of the draft approaches above? If so, who should establish and administer these assessments?

- **Question 15:** How would the draft approaches impact the medical organizations that use the NRC's T&E requirements as a basis for establishing their training programs?

Additional Questions in the FRN, continued

- **Question 16:** Are there concerns regarding implementation and/or viability for any of the approaches discussed above?
- **Question 17:** Are there any unintended consequences of the draft approaches?
- **Question 18:** Which of the draft approaches best positions the NRC to effectively regulate future radiopharmaceuticals?
- **Question 19:** Should the NRC continue to play a role in the review and approval of AUs?

Submitting Written Comments

Submit written comments via Regulations.gov by July 3, 2019

- Go to www.regulations.gov and search NRC-2018-0230
- Direct comment submission link: https://www.regulations.gov/comment?D=NRC-2018-0230-0155
- The NRC quickly receives comments submitted to Regulations.gov, but it takes a few weeks for comments to be publicly posted.
- Comments will also be available in ADAMS.
- The NRC will consider, but not provide a response to, comments.

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Next Steps

Comment Period and Public Meetings
May 2 – July 3, 2019

Evaluation of Comments and Development of Draft Commission Paper
July 2019

ACMUI and Agreement States Review Draft Commission Paper
August – October 2019

ACMUI T&E Subcommittee Public Teleconference on Draft Paper
Mid- or Late October 2019

Finalize Commission Paper
November - December 2019

Deliver Paper to Commission
Late December 2019

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For More Information

- The NRC's Training and Experience Evaluation Web site: https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html
- The T&E docket (NRC-2018-0230) at Regulations.gov: https://www.regulations.gov/docket?D=NRC-2018-0230
- **NRC T&E contacts:**
  - Sarah Lopas, Project Manager Sarah.Lopas@nrc.gov and (301) 415-6360
  - Maryann Ayoade, Health Physicist Maryann.Ayoade@nrc.gov and (301) 415-0862

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Comments

- To make a comment over the phone, press "*" then "**1**".
- You can also submit shorter comments or questions using the Webinar "Question" function.
- All comments and questions are being transcribed by a court reporter.
- **Please begin by providing your name.**
- If you are responding to a specific question from the FRN, please include the question number if you can.
- Please speak clearly so the court reporter can obtain an accurate transcript.