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

May 14, 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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Agenda

1:00 – 1:05 p.m. Welcome and Meeting Information

1:05 – 1:45 p.m. NRC Presentation on the Draft Approaches, Submitting Written Comments, and Next Steps in the T&E Evaluation

1:45 – 4:00 p.m. Your Comments on the Record

We will take a 10-minute break before the midway point of the meeting.

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Welcome and Purpose of Today's Meeting

- 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).

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

General Meeting Information

- In the room: Please sign in and handouts are available.
- On the phone: Handouts available via Webinar, Meeting Notice, and Training and Experience Evaluation Web site.
- Training and Experience = “T&E”
- Authorized User(s) = “AU(s)”
- **Today’s meeting 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.**

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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.

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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.

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.

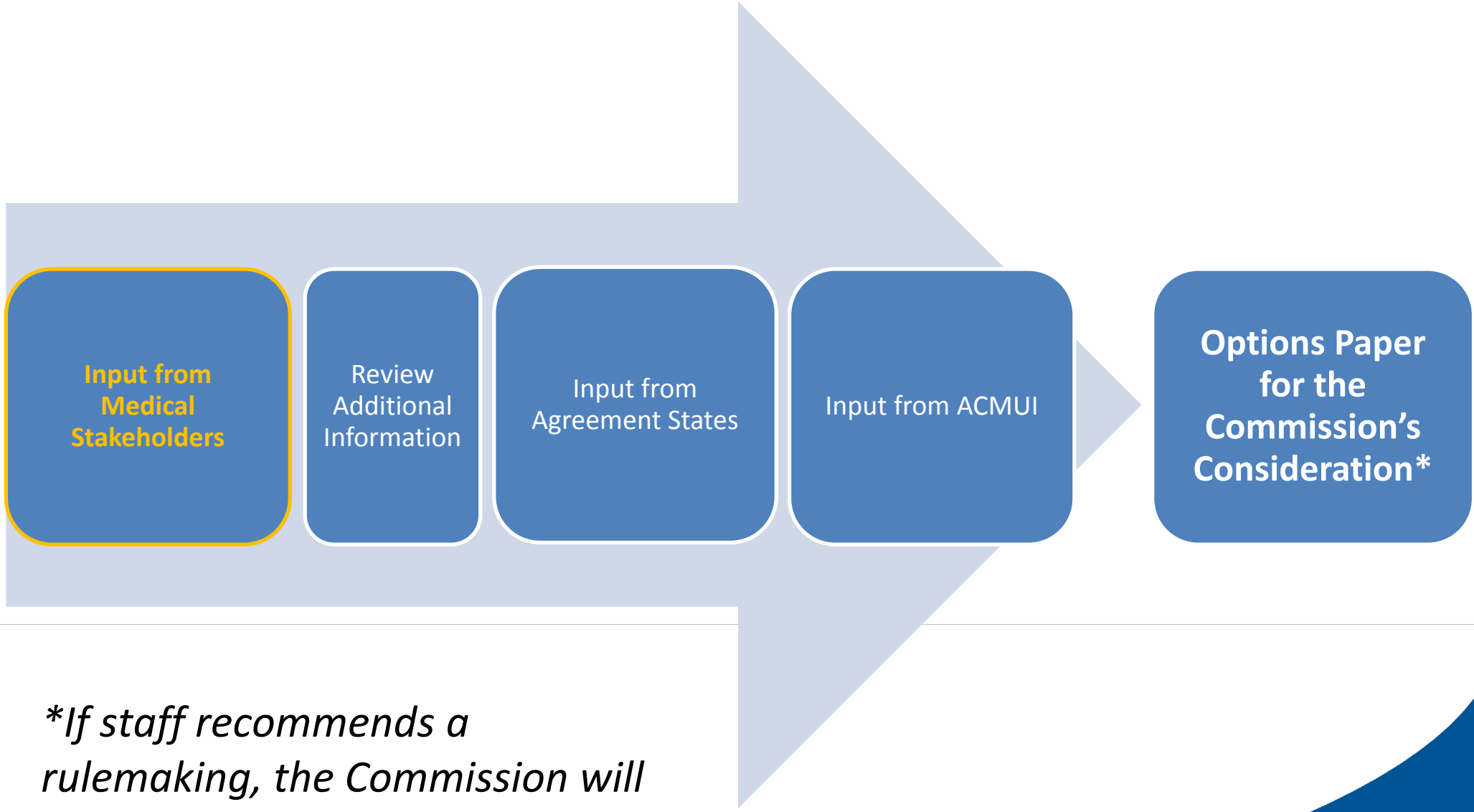
T&E Subcommittee final report issued on February 27, 2019 (ML19058A598).

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.*

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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).

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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?

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 experienced focused on alpha- or beta-emitting radiopharmaceuticals.
- Preceptor attestation required.

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

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 experienced focused on unit-dose, patient-ready radiopharmaceuticals.
- Preceptor attestation required.

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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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 experienced 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)?

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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?

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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 June 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.

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

One Additional Public Comment Meeting

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

Next Steps

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

Evaluation of Comments and Development of Draft Commission Paper
June 2019

ACMUI and Agreement States Review Draft Commission Paper
July – September 2019

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

Finalize Commission Paper
October - November 2019

Deliver Paper to Commission
Late 2019

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment