# The NRC Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals

December 11, 2018

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

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

1:05 – 1:30 p.m. NRC Presentation

1:30 – 4:00 p.m. Comments for the Record

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

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# Welcome

- Christian Einberg, Chief of the Medical Safety and Events Assessment Branch in the NRC's Division of Materials Safety, Security, State, and Tribal Programs – Office of Nuclear Material Safety and Safeguards

# Purpose of Today's Meeting

- Provide information on the NRC 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."
- Listen to and accept comments on the T&E *Federal Register* docket (NRC-2018-0230).

# General Meeting Information

- In the room: Please sign in and handouts are available.
- On the phone:  Handouts available via Webinar, Meeting Notice, and Medical ToolKit Web site.
- Training and Experience will often be referred to as “T&E”.
- Authorized User(s) will often be referred to as “AU(s)”.
- **Today’s meeting is being transcribed by a court reporter.**
  - All comments made today will be captured on the T&E docket (NRC-2018-0230) and included in our review.
  - If you speak a comment today, you do not need to again submit that same comment on Regulations.gov.
- ***Oral and written comments have equal weight.***

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# Current T&E Regulations

Current regulations provide three ways a physician can be approved as an authorized user (AU) to administer unsealed byproduct materials or 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.

# Current T&E Regulations, continued

Training and Experience Requirements in 10 CFR 35, Subpart E:

1) 10 CFR 35.390 – Training for use of unsealed byproduct material for which a written directive is required.
2) 10 CFR 35.392 – Training for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries.
3) 10 CFR 35.394 – Training for oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries.
4) 10 CFR 35.396 – Training for the parenteral administration of unsealed byproduct material requiring a written directive.

# Background – Stakeholder Concerns

- Since revisions to the NRC's T&E regulations in 2002 and 2005, stakeholders have raised concerns that the 700-hour requirement (10 CFR 35.390) is overly burdensome for physicians not board-certified or grandfathered.
  - The requirement could create a shortage of AUs, thus limiting patient access to radiopharmaceuticals.
- In 2015 and 2016, the NRC staff and the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) separately reviewed the T&E requirements and determined no changes were needed.
- The NRC continues to work with the ACMUI on the T&E evaluation.

# Background – SRM M170817

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

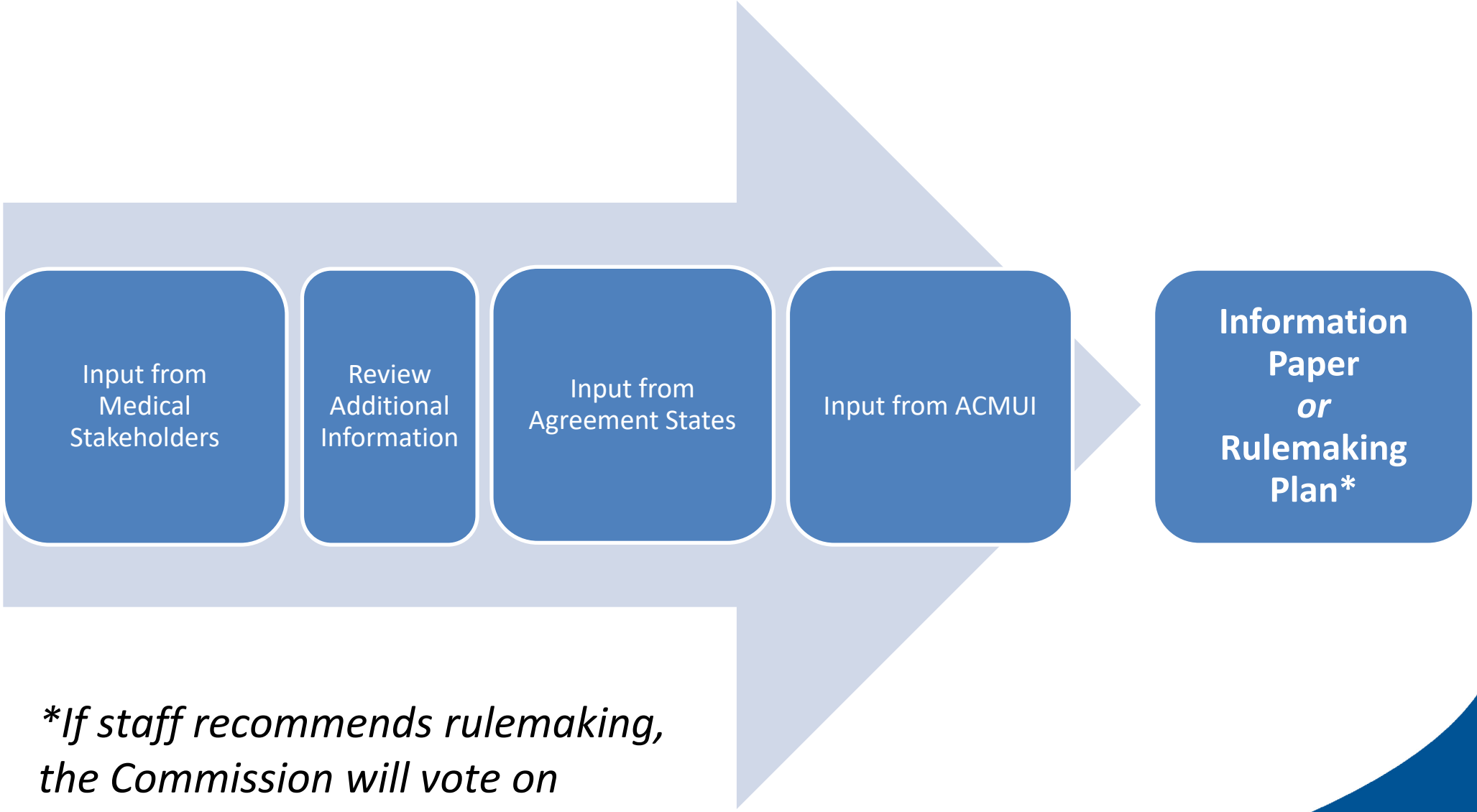
- Whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals;
- How those categories should be determined;
- What the appropriate T&E requirements would be for each category; and
- Whether the requirements should be based on hours of T&E or on competency.

# Background – SECY-18-0084

In 2018, staff conducted an initial evaluation of T&E under 10 CFR Part 35, Subpart E, and documented their review in SECY-18-0084 (August 28, 2018; ML18135A277):

- It may be feasible to establish tailored T&E requirements for different categories of radiopharmaceuticals, and to create "limited authorized user" statuses.
- There are viable options for creating a competency-based approach to demonstrating acceptable T&E for limited authorized user status.
- *However,* the staff needs to conduct more extensive outreach before making a recommendation to the Commission.

# The NRC's T&E Evaluation




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

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# T&E *Federal Register* Notice

- The T&E *Federal Register* notice (83 FR 54380) was published on October 29, 2018: https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23521.pdf
- Opened the comment period from October 29, 2018 through January 29, 2019.
- The *Federal Register* notice (FRN) asks a series of specific questions on the NRC's T&E requirements.

# Questions in the FRN

## *A. Tailored Training & Experience Requirements*

1) Are the current pathways for obtaining AU status reasonable and accessible, are they adequate for protecting public health and safety?

2) Should the NRC develop a new tailored T&E pathway? What would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements?

3) Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status?

4) How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?

# Questions in the FRN, continued

***B. NRC's Recognition of Medical Specialty Boards***

The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit Web site: https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html.

1) What boards other than those already recognized by the NRC (American Board of Nuclear Medicine, American Board of Radiology, American Osteopathic Board of Radiology, Certification Board of Nuclear Endocrinology) could be considered for recognition for medical uses under 10 CFR 35.300?

2) Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

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# Questions in the FRN, continued

***C. Patient Access***

1) Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical?

2) Are there certain geographic areas with an inadequate number of AUs?

3) Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals?

4) Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine?

# Questions in the FRN, continued

***D. Other Suggested Changes to the T&E Regulations***

1) Should the NRC regulate the T&E of physicians for medical uses?

2) Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

3) How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

# Submitting Written Comments

Submit written comments via Regulations.gov by
**January 29, 2019**

- Go to www.regulations.gov and search NRC-2018-0230
- Direct comment submission link: https://www.regulations.gov/comment?D=NRC-2018-0230-0001
- The NRC immediately receives comments submitted to Regulations.gov, but it takes a few weeks for comments to be publicly posted.
- Comments will also be posted to ADAMS.
- The NRC will consider, but not provide a response to, comments.

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# Two More Public Comment Meetings

- Thursday, **January 10, 2019**, 1:00 p.m. – 4:00 p.m. EST
  - In-person meeting at NRC headquarters and webinar

- Tuesday, **January 22, 2019**, 10:00 a.m. – 12:00 p.m. EST
  - Webinar only

**Meeting details and registration information are available at https://www.nrc.gov/pmns/mtg.**

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# Next Steps

**Comment Period and Public Meetings**
October 29, 2018 – January 29, 2019

**Evaluation of Comments, Review Additional Information, ACMUI T&E Report**
February – March 2019

**Development of Draft Commission Paper**
March – May 2019

**ACMUI and Agreement States Review Draft Commission Paper**
May – August 2019

**ACMUI T&E Subcommittee Public Teleconference on Draft Paper (*TENTATIVE*)**
August 2019

**Finalize Commission Paper**
August and September 2019

**Deliver Paper to Commission**
Fall 2019

# 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

- In the Room:  Please use a microphone so you can be heard by people on the phone.
- On the Phone:  Press  ***1**  on your phone to ask a question or make a comment.
- Your comments are being transcribed by a court reporter.
- Please begin by providing your name.
- Please speak clearly so the court reporter can obtain an accurate transcript.

# A. Tailored Training and Experience Requirements

1. Are the current pathways for obtaining AU status reasonable and accessible?
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety?
3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. *[Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low-energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]*

# A. Tailored Training and Experience Requirements

4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?

# A. Tailored Training and Experience Requirements

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
   a. Describe what the requirements should include:
      i. Classroom and laboratory training – What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified.
      ii. Work experience - What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
      iii. Competency - How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered?
   b. Should a preceptor attestation be required for the fundamental T&E?
   c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation?
   d. Who should establish and administer the curriculum and examination?
   e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

# B. NRC's Recognition of Medical Specialty Boards

1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

# C. Patient Access

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

# D. Other Suggested Changes to the T&E Regulations

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?
3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?