[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0230]

Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft approaches for training and experience requirements; request for comment and notice of public meetings.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) would like input on draft approaches the staff has developed that would potentially revise the training and experience (T&E) requirements for radiopharmaceuticals requiring a written directive. The input will be used to determine whether regulatory changes to the NRC's T&E requirements for authorized users (AUs) are warranted and potential advantages, disadvantages, and other considerations associated with each approach.

DATES: Submit comments by June 3, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration for comments received on or before this date. Two public meetings to solicit comments will be held on May 14, 2019 and May 23, 2019.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID **NRC-2018-0230**. Address questions about NRC dockets IDs in regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail:

Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6360, e-mail: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0230** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID **NRC-2018-0230**.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number

for each document referenced is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID **NRC-2018-0230** in your comment submission. The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at http://www.regulations.gov and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On August 17, 2017, the Commission issued a staff requirements memorandum (SRM), SRM-M170817 (ADAMS Accession No. ML17229B284) directing the staff to evaluate: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and (4) whether those

requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the NRC staff documented its initial results, status, and next steps related to this evaluation in SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (ADAMS Package Accession No. ML18135A276).

In SECY-18-0084, the staff concluded that it may be feasible to establish tailored T&E requirements however, additional outreach with the medical community was needed to determine whether and how to tailor those requirements. Revising the T&E requirements could provide additional pathways for physicians to become AUs for specific types of radiopharmaceuticals under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required."

As part of the needed additional outreach discussed in SECY-18-0084, the NRC published a notice in the *Federal Register* on October 29, 2018 (83 FR 54380) requesting comments on the staff's evaluation of the T&E requirements for radiopharmaceuticals under 10 CFR 35.300. The NRC held four public meetings on this topic and collected public comments through January 29, 2019. Public comments and meeting transcripts are available on the Federal Rulemaking Web site at https://www.regulations.gov/ under Docket ID **NRC-2018-0230**. Following the conclusion of the initial public comment period, the staff developed several draft approaches to address the directions in SRM-M170817. The NRC is now interested in obtaining input on these draft approaches.

During the comment period between May 2, 2019 and June 3, 2019, the NRC will hold two public meetings to discuss the draft approaches in this document and accept oral comments on those draft approaches. Both public meetings will be available for remote participation by moderated bridge line and webinar and one meeting will also be

open for in-person attendance at the NRC's headquarters in Rockville, Maryland. The public meetings are scheduled for May 14, 2019 (webinar and in-person attendance) and May 23, 2019 (webinar-only). The public meetings will be noticed on the NRC's public meeting Web site at least 10 calendar days before each meeting. Members of the public should monitor the NRC's public meeting Web site at https://www.nrc.gov/pmns/mtg. The NRC will also post the meeting notices on the Federal Rulemaking Web site at https://www.regulations.gov/ under Docket ID **NRC-2018-0230**.

The NRC may post additional materials related to this document, including public comments, on the Federal Rulemaking Web site. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder **NRC-2018-0230**; (2) click the ''Sign up for E-mail Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

III. Draft Approaches for Comment

The NRC staff has developed the following draft approaches based on input received during the initial public comment period and the Advisory Committee on Medical Uses of Isotopes T&E subcommittee's report dated February 27, 2019 (ADAMS Accession No. ML19058A598). The NRC is requesting comments on the draft approaches, including potential advantages, disadvantages, and other considerations associated with each and whether some approaches could be revised, combined, or if more than one approach could be implemented. The NRC staff is also requesting input on specific questions associated with the approaches.

A. Status Quo

"Status Quo" presents no changes to the 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?

B. Tailored Training and Experience Requirements

The four approaches under this section would modify the existing T&E requirements under 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required." The approaches described under Sections B.1, B.2, and B.3 would require a set amount of T&E tailored to the specific radiopharmaceuticals, and the "Emerging Radiopharmaceuticals" approach described under Section B.4 would tailor T&E requirements for each new radiopharmaceutical as they were developed, similar to the approach for regulating new technologies under 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

- **Question 3:** How should the complexity of the radiopharmaceutical administration protocol be considered in establishing the T&E requirements for the limited approaches described in Sections B.1 and B.2 below?

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

   Under this approach, any physician could complete at least 400 hours of T&E to be authorized to administer any alpha- or beta-emitting

radiopharmaceutical. The T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to alpha- and beta-emitting radiopharmaceuticals. Preceptor attestation would be required.

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

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

   Under this approach, any physician could complete at least 400 hours of T&E to be authorized to administer any unit-dose, patient-ready radiopharmaceutical. The T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to unit-dose, patient-ready radiopharmaceuticals. Preceptor attestation would be required.

   - **Question 5:** Under what conditions should a radiopharmaceutical be considered “patient ready” such that the T&E requirements could be tailored?

3. *Limited AU for Any One Parenteral Radiopharmaceutical*

   Under this approach any physician could complete at least 400 hours of T&E to be authorized to administer any one parenteral radiopharmaceutical. The T&E would consist of 200 hours of classroom and laboratory training and a minimum of 200 hours of supervised work experience tailored to the radiopharmaceutical they wish to administer. Preceptor attestation would be required. Limited AUs who have initially completed their at least 400 hours of T&E and then wish to administer a different radiopharmaceutical would be

required to complete, minimally, an additional 80 hours of tailored, supervised work experience for each additional radiopharmaceutical.

4. *Emerging Radiopharmaceuticals*

Like the NRC's regulations at 10 CFR 35.1000, under this approach the NRC would conduct individual reviews of each new emerging radiopharmaceutical to determine T&E requirements specific to the new radiopharmaceutical. The T&E requirements could be tailored to consider potential users of the radiopharmaceutical (e.g., non-nuclear medicine or non-radiation oncology physicians wishing to administer the radiopharmaceutical for their patients with indicated cancers), thus creating alternate T&E pathways for each new radiopharmaceutical.

C. Performance-Based

The approaches described in this section would remove prescriptive T&E requirements from the regulations and instead would focus oversight on the performance-based aspects of a licensee's medical program for the administration of radiopharmaceuticals.

1. *Competency-Based Evaluation*

Under this approach, proposed AUs would be required to demonstrate competency in radiation safety topics and radiation safety-related job duties through a formal competency evaluation (e.g., an examination or preceptor attestation).

- **Question 6:** How could a competency-based evaluation ensure appropriate training and experience for AUs administering radiopharmaceuticals?

2. *Credentialing of Authorized Users*

Under this approach, the NRC would no longer review and approve T&E qualifications for all AUs under 10 CFR part 35. Instead, licensees would develop and use their own policies and procedures to make self-determinations of whether their credentialed physicians have the appropriate T&E to be an AU for one or more radiopharmaceuticals under 10 CFR 35.300. Licensees would be required to maintain a training program that ensures compliance with the requirements in 10 CFR 35.41, "Procedures for administrations requiring a written directive," and 10 CFR part 20, "Standards for Protection Against Radiation."

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

D. Team-Based

Team-based approaches could remove prescriptive T&E requirements for AUs, focus training requirements on the competency of the entire team, or revise the current 700-hour T&E requirement for AUs based on pairing the AU with another individual with expertise in administering radiopharmaceuticals.

- **Question 8:** How should the AU's radiation safety responsibilities be clearly distinguished from other members of the team?

1. *Radiopharmaceutical Team*

Licensees would need a team to administer radiopharmaceuticals under 10 CFR 35.300. The team would minimally consist of an AU, a radiation safety officer, and a nuclear medicine technologist. Additional team members could include an authorized medical physicist, a health physicist, an authorized

nuclear pharmacist, and other physicians that manage patient care. The T&E for the radiopharmaceutical team approach would be performance-based: licensees would develop policies and procedures to address how their teams would meet the requirements in 10 CFR 35.41 and 10 CFR part 20.

2. *Team AUs with Authorized Administrators*

   Licensees would need both an AU and an authorized administrator (AA) to administer radiopharmaceuticals under 10 CFR 35.300. AAs would be individuals authorized by the licensee to administer radiopharmaceuticals in accordance with the written directive (e.g., a nuclear medicine technologist or a nuclear medicine advanced associate). The T&E for AUs would be performance-based and focus on the licensee's policies and procedures for written directives, reporting medical events, and patient release criteria. Because AAs would be physically administering radiopharmaceuticals, AAs would be required to have training on radiation safety, written directives, preparation and administration protocols (or vendor training, if available), patient release criteria, and medical event reporting.

3. *Partner Limited-Trained AUs with Authorized Nuclear Pharmacists*

   The T&E for AUs would be at least 400 hours, however, the AU would be required to physically partner with an authorized nuclear pharmacist (ANP) for all administrations of radiopharmaceuticals. Unlike the approaches in Sections D.1 and D.2 above, prescriptive T&E would be required for the AU in this approach due to the AU's more prominent role in the administration of radiopharmaceuticals. The minimum of 400 hours of T&E for the physician partnering with an ANP would be focused on supervised work experience and patient cases, and preceptor attestation would be required. The AU would be

responsible for administration of radiopharmaceuticals in accordance with the written directive, and the ANP would be responsible for radiation safety-related duties.

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

IV. Additional Questions for Consideration

The NRC is requesting input on the following questions as they relate to the draft approaches discussed above.

- **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?
- **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?

- **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?

Dated at Rockville, Maryland, this 29th day of April 2019.

For the Nuclear Regulatory Commission.

/RA/

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