UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 9, 2019

MEMORANDUM TO: Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

FROM: Sarah L. Lopas, Project Manager **/RA/**
Medical Safety and Events Assessment Branch
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Office of Nuclear Material Safety and Safeguards

SUBJECT: SUMMARY OF PUBLIC MEETING TO ACCEPT COMMENTS ON THE U.S. NUCLEAR REGULATORY COMMISSION'S EVALUATION OF TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINSTERING DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS (83 FR 54380)

Meeting Identifier: 20181166

Date of Meeting: Tuesday, December 11, 2018

Location: Webinar and Commission Hearing Room, One White Flint Building, NRC Headquarters, Rockville, MD

Type of Meeting: Category 3

Purpose of the Meeting:

To solicit comments from the public and stakeholders on the U.S. Nuclear Regulatory Commission's (NRC) evaluation of the training and experience (T&E) requirements for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of Title 10 of the Code of Federal Regulations (10 CFR) Part 35, "Medical Use of Byproduct Material."

General Details:

On October 29, 2018, the NRC published a *Federal Register* notice (FRN) requesting comments on the NRC's T&E requirements for administering different categories of radiopharmaceuticals requiring a written directive in accordance with the NRC's regulations under 10 CFR 35.300. The FRN (83 FR 54380) can be accessed in the NRC's Agencywide

Documents Access and Management System (ADAMS; https://www.nrc.gov/reading-rm/adams.html) under Accession No. ML18276A166, or on the *Federal Register* Web site at https://www.federalregister.gov/documents/2018/10/29/2018-23521/training-and-experience-requirements-for-different-categories-of-radiopharmaceuticals.

The publication of the FRN opened a three-month public comment period to obtain input on whether the NRC should tailor its T&E requirements for administering different categories of radiopharmaceuticals requiring a written directive. The NRC is interested in obtaining input from as many stakeholders as possible, including members of the Advisory Committee on the Medical Uses of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. Four public meetings were planned to accept oral comments, and written comments can be submitted on the Federal government's rulemaking Web site, www.Regulations.gov, by searching docket ID "NRC-2018-0230." The comment period ends on January 29, 2019.

On November 1, 2018, the NRC published the December 11 meeting notice, which contained information on how to attend in-person, and webinar registration and bridge line instructions for remote attendees (ADAMS Accession No. ML18344A046). Ahead of the meeting, 25 people registered for the webinar and 9 people registered to attend the meeting in-person.

The meeting began at 1:00 p.m. EST and included a 30-minute presentation from NRC staff on the staff's planned evaluation of T&E under 10 CFR 35.300. The NRC's slide presentation can be found in ADAMS at Accession No. ML18341A142. Following the staff's presentation, the meeting was then opened to receive public comments. All meeting participants who wanted to provide a comment were given the opportunity to speak. The meeting was transcribed by a court reporter, so staff could capture the comments for the T&E docket (NRC-2018-0230). The meeting transcript can be found in ADAMS at Accession No. ML19002A566. Approximately 34 people participated in the meeting: 18 people logged into the webinar, 4 people called into the bridge line but did not log into the webinar, and 12 people attended in-person. Six participants provided comments. A list of meeting participants who attended in-person and logged into the webinar is enclosed. The meeting concluded at 2:44 p.m. EST.

Summary of Comments Received:

The first commenter stated that the current geographic distribution of authorized users (AUs) has a detrimental effect on patient access to radiopharmaceuticals, especially in more rural areas of the United States. To address this issue, the commenter urged the Commission to consider enabling the "teaming" of onsite nuclear pharmacists with a limited authorized user physician (who may have 80 or 200 hours of T&E versus 700). The commenter stated that instead of reducing T&E, this approach would allow the nuclear pharmacist and a specialist physician to "team up" to fill the full T&E requirements as they pertain to radiation protection, patient care, and safety. The commenter stated that nuclear pharmacists undergo 700 hours of T&E to become an authorized nuclear pharmacist, and that nuclear pharmacists have more responsibility for radiation safety, handling, use, and transport than anyone else in the nuclear medicine system. The commenter stated that the nuclear pharmacist could handle the radiation safety aspect of the treatment, and the physician could focus on the patient care aspect. The commenter stated that this team approach could dramatically expand the service area for

nuclear medicine procedures because nuclear pharmacists are more broadly spread across rural markets. The commenter cited critical shortages of physicians in rural areas as reported by the National Rural Healthcare Association and said there was no reason to be believe that the distribution of AUs differed from the general physician statistics.

The next commenter echoed the above comments regarding teaming a nuclear pharmacist with a physician. The commenter stated that the NRC should keep in mind the future expansion of nuclear medicine and the idea that radiopharmaceuticals requiring a written directive will become a greater portion of therapies available to patients. The commenter also stated that the team approach was like the "dual authorized user situation" that the NRC was familiar with in the past. The commenter stated that in situations where there are several rounds of treatment associated with a particular therapy, improving geographic distribution and thus access could be very helpful to those patients, who may currently face long travel distances to receive treatment.

Another commenter suggested that the NRC should be open to all avenues that would improve patient access to radiopharmaceuticals, however, the commenter acknowledged the need to balance public and worker safety with improving patient access. The commenter stated that the NRC should continue their dialogue with industry to learn more about specific categories of radiopharmaceuticals, such as specific routes of administration or unique practice setting requirements, and how, through additional opportunities for training and education, additional competencies could be gained so more patients could access these therapies. The commenter spoke about a University of New Mexico online training program for nuclear pharmacists that offers 200 online didactic hours, and coordinates with and mentors on-site preceptors to deliver 500 hours of supervised experience. With the above-referenced online training program as an example, the commenter encouraged an open mind regarding how T&E could be achieved. The commenter also mentioned that the above-referenced online training helped to address recentness-of-training issues. Later in the meeting the commenter discussed the idea that currently there are "clinician pharmacists" who work under the supervision of a physician to administer pharmaceutical therapies for diseases that require drug-intensive treatment. The commenter then reiterated that nuclear pharmacists have the most experience working with radiopharmaceuticals and they could bring value in terms of drug administration, whereas the physician would make treatment decisions and write directives. The commenter thought that specializing training, perhaps drug- or isotope-specific, could have value. The commenter also noted a current bill in Congress to designate pharmacists as "providers" could have some bearing on the NRC's evaluation.

One commenter asked for clarification that the T&E evaluation was only addressing "higher risk" radiopharmaceuticals used for therapy, and not the "lower risk" radiopharmaceuticals that are used for diagnostics. NRC staff confirmed the commenter's understanding that the current evaluation is examining radiopharmaceuticals under 10 CFR 35.300. Another commenter disagreed with the terms "high" and "low" risk when describing radiopharmaceuticals.

In response to the previous comments regarding teaming an authorized nuclear pharmacist with a limited authorized user, another commenter asked for clarification on whether that the NRC was open to the idea of other individuals besides physicians becoming AUs or teaming up with AUs to meet T&E requirements. NRC staff confirmed that they were open to all ideas and comments regarding T&E, including how and by whom those requirements could be met. The

commenter also expressed some concern about whether the NRC's consideration of T&E requirements broached clinical patient care aspects. The commenter later expressed surprise that the NRC didn't have patient access data readily available and supported the idea that the NRC should request patient access data from the Agreement States.

The final commenter of the day stated that there was and should be a clear delineation between physicians who undergo years of specialized training in nuclear medicine, and nuclear pharmacists or other non-AU individuals. The commenter did not support comments made earlier in the meeting regarding individuals other than physicians being able to meet limited T&E requirements to administer certain categories of radiopharmaceuticals. The commenter stated that quality of care of could be impacted if these non-AU routes are considered, and that the point was "not profit, but patient care." The commenter also pointed out that new therapies coming down the pipeline had significant toxicities associated with them, and they were not simple injections, furthering supporting his argument that only rigorously trained physicians should be authorized to administer these therapies.

A complete accounting of the comments is contained in the meeting transcript, which is available in ADAMS at Accession No. ML19002A566.

Next Steps: The NRC staff will consider the comments received during this meeting, and during the rest of public comment period, as part of its evaluation of the 35.300 T&E requirements. The NRC staff will document its evaluation and recommendation in a report to the Commission, which is planned to be published in fall 2019. The NRC's Web site on the T&E requirements evaluation will be regularly updated and can be found at: https://www.nrc.gov/materials/miau/med-use-toolkit/training-experience-evaluation.html. All meeting transcripts and written comments will be available on the regulations.gov T&E docket site: https://www.regulations.gov/docket?D=NRC-2018-0230. Additional public comment meetings on T&E are scheduled for January 10, 2019 and January 22, 2019. The NRC's public meeting schedule Web site contains participation details for these upcoming meetings: https://www.nrc.gov/pmns/mtg.

ENCLOSURE:
As stated

C. Einberg

SUBJECT: SUMMARY OF DECEMBER 11, 2018 PUBLIC MEETING TO ACCEPT COMMENTS ON THE U.S. NUCLEAR REGULATORY COMMISSION'S EVALUATION OF TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINSTERING DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS (83 FR 54380) DATED JANUARY 9, 2019

ENCLOSURE:
As stated

DISTRIBUTION:
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M. Ayoade, NMSS
J. Fisher, NMSS

ADAMS Accession Nos.: PKG ML19002A615; Meeting Summary ML19002A614
NRC Slide Presentation ML18341A142; Meeting Notice ML18344A046,
Meeting Transcript ML19002A566

***via email**

OFFICE	NMSS/MSST/MSEB/PM	NMSS/MSST/MSEB/TL	NMSS/MSST/MSEB/BC
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DATE	01/03/19	01/08/19	01/09/19
OFFICE	NMSS/MSST/MSEB/PM		
NAME	SLopas		
DATE	01/09/19		

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Public Meeting to Accept Comments on the U.S. Nuclear Regulatory Commission's Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals (83 FR 54380)

December 11, 2018

Meeting Participants

Name	Affiliation (if applicable)
Janice Campbell	Beaumont
James Cordes	Neal Gross Court Reporters
Guiliana Del Guercio	CRD Associates
Dawn Edgerton	Inteleos
Elizabeth Franklin	Atrium Health
Jennifer Gersman	Northwestern Medicine
Tina Getachew	American College of Radiology
Vicki Larue	National Jewish Health
Ralph Lieto	St. Joseph Mercy Health System
Melissa Martin	Therapy Physics
Jeff Norenberg	National Association of Nuclear Pharmacies (NANP)
Francis O'Neill	State of Vermont
Michael Peters	American College of Radiology
Craig Piercy	Bose Public Affairs on behalf of NANP
Carmine Plott	Novant Health
Aria Razmaria	UCLA Medical Center
Gloria Romanelli	American College of Radiology
Joseph Rubin	MWW on behalf of UPPI
Michael Sheetz	University of Pittsburgh School of Medicine
Cindy Tomlinson	American Society for Radiation Oncology
John Witkowski	United Pharmacy Partners (UPPI)
Maryann Ayoade	NRC/NMSS/MSST/MSEB
Lisa Dimmick	NRC/NMSS/MSST/MSEB
Christian Einberg	NRC/NMSS/MSST/MSEB
Jennifer Fisher	NRC/NMSS/MSST/MSEB
Ed Harvey	NRC/NMSS/MSST/MSEB
Esther Houseman	NRC/NMSS/OGC
Donna-Beth Howe	NRC/NMSS/MSST/MSEB
Janelle Jessie	NRC/COMM/OCMJB
Sarah Lopas	NRC/NMSS/MSST/MSEB
Joan Olmstead	NRC/NMSS/MSST/FSTB
Katie Tapp	NRC/NMSS/MSST/MSEB

ENCLOSURE