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

November 30, 2018

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

SUBJECT: SUMMARY OF PUBLIC MEETING (WEBINAR) 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: 20181146

Date of Meeting: Wednesday, November 14, 2018

Location: N/A - Webinar

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.

Also on October 29, 2018, the NRC published the November 14 meeting notice, which contained webinar registration and bridge line information (ADAMS Accession No. ML18313A077). Approximately 32 people registered for the webinar ahead of the meeting.

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. ML18312A413. 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. ML18330A113. Approximately 32 people participated in the meeting: 25 of the 32 logged into the webinar and the remaining 7 called into the bridge line but did not log into the webinar. Six participants provided comments. A list of meeting participants who logged into the webinar or identified themselves during their comments is enclosed. The meeting concluded at 2:24 p.m. EST.

Summary of Comments Received:

One commenter on behalf of the American Society for Radiation Oncology expressed strong opposition to any reduction in the T&E requirements in 10 CFR 35.390; stating that they believe the current requirements are appropriate, and that they protect the safety of patients, the public, and practitioners. The commenter further discussed how radiopharmaceuticals are highly effective at treating cancer, but they have possibly harmful side effects if not used correctly and under the supervision of a highly trained physician. The commenter also noted that changing the T&E requirements could create confusion and complexity for licensees, the NRC, and the Agreement States. The commenter also stated that it may be difficult to categorize radiopharmaceuticals—new radiopharmaceuticals may not clearly or easily fit into a category, thus requiring additional NRC rulemaking and delaying patient access to radiopharmaceuticals.

Another commenter opposed to reducing T&E requirements stated that when considering T&E, one must consider the physician's background in fundamentals of radiation protection and radiation physics; and that training in radiology sciences cannot be simply counted in hours. The commenter warned that if the physician seeking limited authorization comes from a field where none of this is part of their regular job duties, decreasing the number of hours required for

T&E could potentially be harmful. The commenter pointed out that T&E not only prepares a physician for administration of radiopharmaceuticals in an uncomplicated setting, but that it also prepares a physician to handle potential complications during administration.

In contrast, one commenter strongly supported developing tailored T&E requirements, citing evidence that the NRC already has proved this approach works with their regulations under 35.392 and 35.394 for sodium iodide administration. The commenter stated that using a "one-size-fits-all approach" for T&E was not beneficial to oral administrations, because oral therapeutic radiopharmaceuticals pose less risk than other (parenteral) radiopharmaceuticals. The commenter further stated that imposing identical requirements for all radiopharmaceuticals contradicted the NRC's risk-informed regulatory approach. The commenter stated that if a physician was seeking limited authorization with no flexibility beyond administration of one relatively safe, unit-dosed agent, 700 hours of T&E was overly burdensome and not warranted. The commenter pointed out that medical oncologists were skilled in administering very toxic and potentially harmful chemotherapy drugs, and that certifying a medical oncologist to administer a single radiopharmaceutical, also administered via syringe, should not require 700 hours of T&E. In support of manufacturer attestation, this commenter also pointed out that under other NRC medical regulations, manufacturers are permitted to provide attestation for physicians.

Another commenter affirmed the need for the NRC to gather geographic distribution information of authorized users, and if possible, break that data down by authorized use (35.390, 35.392, 35.394, and 35.396).

Another commenter spoke regarding how the current required T&E could encourage physicians to be dedicated to the field of nuclear medicine, which could potentially encourage and advance research in nuclear medicine. The commenter contrasted this to a doctor who only wanted to administer a single radiopharmaceutical and therefore was unlikely to contribute in a greater way to the field of nuclear medicine. This commenter pointed out that most research and advancement in nuclear medicine is being accomplished in countries other than the U.S., and that simply allowing more single-use physicians would not help the U.S. catch up in that regard.

A commenter from an Agreement State suggested that to better inform its evaluation, the NRC should conduct a review of medical events to determine whether the authorization pathway or the amount of T&E had any connection to events. The commenter suggested that even if this information wasn't contained in the Nuclear Materials Events Database (NMED), that perhaps the Agreement States would have this more detailed information. Another commenter pointed out that NMED reports are not available to authorized users or licensees.

A complete accounting of the comments is contained in the meeting transcript, which is available in ADAMS at Accession No. ML18330A113.

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 December 11, 2018, 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 NOVEMBER 14, 2018 PUBLIC MEETING (WEBINAR) 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 NOVEMBER 30, 2018

ENCLOSURE:
As stated

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

ADAMS Accession Nos.: PKG ML18333A385; Meeting Summary ML18333A384
NRC Slide Presentation ML18312A413; Meeting Notice ML18313A077,
Meeting Transcript ML18330A113

***via email**

OFFICE	NMSS/MSST/MSEB/PM	NMSS/MSST/MSEB/TL	NMSS/MSST/MSEB/BC
NAME	SLopas	LDimmick*	CEinberg*
DATE	11/28/18	11/29/18	11/30/18
OFFICE	NMSS/MSST/MSEB/PM		
NAME	SLopas		
DATE	11/30/18		

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Public Meeting (Webinar) 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)

November 14, 2018

Meeting Participants

Name	Affiliation (if applicable)
Scott Bloomberg	Foley Hoag LLP
David Crowley	North Carolina Dept. of Health and Human Services
Robert Dansereau	New York Dept. of Health
Christina Gervasi	McManus Group
Tina Getachew	American College of Radiology
Munir Ghesani	NYU Medical Center
Eric Gingold	Jefferson University Hospital
Richard Green	Cardinal Health
Alan Jackson	Henry Ford Hospital
Raymond Johnson	JPS Health
Caitlin Kubler	Society for Nuclear Medicine and Molecular Imaging
Ralph Lieto	
James Logan	Bayer
Amin Mirhadi	Cedar-Sinai Hospital
Josephine Piccone	
Aria Razmaria	UCLA Medical Center
Gloria Romanelli	American College of Radiology
A. Robert Schleipman	Partners Healthcare
Sheila Shaffer	Beaumont
Michael Sheetz	University of Pittsburgh School of Medicine
Cindy Tomlinson	American Society for Radiation Oncology
Forrest Weston	Texas Dept. of State Health Services
Scott Fuller	St. Luke's Health Service
Maryann Ayoade	NRC/NMSS/MSST/MSEB
Christian Einberg	NRC/NMSS/MSST/MSEB
Ed Harvey	NRC/NMSS/MSST/MSEB
Donna-Beth Howe	NRC/NMSS/MSST/MSEB
Janelle Jessie	NRC/COMM/OCMJB
Sarah Lopas	NRC/NMSS/MSST/MSEB

ENCLOSURE