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

June 4, 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
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

SUBJECT: SUMMARY OF MAY 23, 2019, WEBINAR TO ACCEPT COMMENTS ON THE U.S. NUCLEAR REGULATORY COMMISSION STAFF'S DRAFT APPROACHES REGARDING TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINISTERING RADIOPHARMACEUTICALS (84 FR 18874)

Meeting Identifier: 20190478

Date of Meeting: Thursday, May 23, 2019

Location: N/A - Webinar

Type of Meeting: Category 3

Purpose of the Meeting: To solicit comments from the public and stakeholders on the NRC staff's draft approaches regarding the training and experience (T&E) requirements for a physician to become an authorized user (AU) 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 May 2, 2019, the NRC published a *Federal Register* notice (FRN) requesting comments on the staff's draft approaches regarding the T&E requirements for administering radiopharmaceuticals requiring a written directive in accordance with the NRC's regulations under 10 CFR 35.300. The FRN (84 FR 84874) 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. ML19136A353, or on the *Federal Register* Web site athttps://www.federalregister.gov/documents/2019/05/02/2019-08996/draft-approaches-for-addressing-training-and-experience-requirements-for-radiopharmaceuticals.

The publication of the FRN opened a one-month public comment period to obtain input on the staff's draft approaches. The NRC is interested in obtaining input from as many medical and regulatory stakeholders as possible, including professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. Two public meetings (May 14 and May 23) 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 was originally scheduled to end on June 3, 2019; however, the NRC granted a 30-day extension to allow stakeholders more time to submit their comments. An FRN was published on May 23, 2019, announcing the 30-day extension (84 FR 23812). The comment period now ends on July 3, 2019.

On May 1, 2019, the NRC published the official public notice for the May 23 meeting, which contained information on webinar registration and bridge line instructions for remote attendees (ADAMS Accession No. ML19134A181). Ahead of the meeting, 43 people pre-registered for the webinar. The May 23 meeting, which was webinar only, began at 10:00 a.m. EDT and included a 45-minute presentation from NRC staff on background information regarding the staff's evaluation of T&E under 10 CFR 35.300, and the staff's draft approaches regarding the T&E requirements. The NRC's slide presentation can be found in ADAMS at Accession No. ML19141A131. 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. ML19149A525. Approximately 40 people participated in the meeting: 30 people logged into the webinar and 10 people called into the bridge line but did not log into the webinar. Four participants asked questions and provided comments. A list of participants who logged into the webinar is enclosed. The meeting concluded at 11:23 a.m. EDT.

Summary of Comments Received:

The first commenter identified as a member of the Nuclear Medicine Residents Organization, which is part of the American College of Nuclear Medicine. The commenter stated that reducing the amount of T&E required to administer radiopharmaceuticals would be dangerous. The commenter pointed out that each nuclear medicine patient is unique and the radiopharmaceutical dose and associated patient care given by the physician AU is tailored to the patient's unique needs and considerations like exact diagnosis, imaging findings, diet, other medications, and home life. The commenter said they did not understand how a limited amount of training could account for the experience gained during a nuclear medicine residency. The commenter stated that allowing limited-trained AUs to administer radiopharmaceuticals would be like "experimenting" with patients' health. The commenter also pointed out that nuclear medicine is expensive ("tens of thousands of dollars sometimes"), errors are very costly, and nuclear medicine couldn't afford that kind of "economic hit." The commenter spoke again later in the meeting and acknowledged that while authorized nuclear pharmacists (ANPs) may have greater experience than AUs in handling radiopharmaceuticals, they did not believe that ANPs should be involved in the administration of radiopharmaceuticals.

The next commenter identified as a member of United Pharmacy Partners, Inc. and began by pointing out that cardiologists were able to receive limited AU training and that led to a revolution in nuclear cardiology, including formation of a professional society and a medical specialty board certification program. The commenter stated that much of the training an ANP and an AU receives is "parallel," and noted there is special expertise that both parties have.

The commenter stated that pairing a limited-trained AU with an ANP could allow the parties' knowledge and experience to complement each another and radiopharmaceuticals could be safely handled and administered. The commenter did note the need to clearly define the roles and responsibilities of each team member for any of the team-based approaches. The commenter also expressed support for the idea that a limited curriculum could be developed to adequately train non-nuclear or non-radiologist physicians to work with ANPs. The commenter said that teaming ANPs with limited-trained AUs could expand patient access to alpha- and beta-emitting radiopharmaceuticals. (Following this comment, NRC Health Physicist Maryann Ayoade clarified that while some of the classroom and laboratory training required to become an ANP and an AU may be similar, the work experience portion of the training requirements differ.)

The third commenter identified as a nuclear medicine resident and strongly opposed creation of any limited-trained AU pathways. The commenter stated that "we should not be subjecting patients to low-level trained physicians or support staff" for radiopharmaceutical therapies. The commenter did not support the team-based approach involving a limited trained AU and an ANP–the commenter stated that this situation would subject patients to undue risk.

The final commenter objected to the NRC's use of the term "patient ready." The commenter said that "patient-ready" only refers to the shipping of unit-dose delivery systems, and that the form of the radiopharmaceutical is irrelevant to the AU's use of these therapies and patient care. The commenter said that "patient ready" is a term weighted by the pharmaceutical industry to "diminish the responsibilities of AUs to patients, care team members, regulators, and the public."

A complete accounting of the comments and questions is contained in the meeting transcript, which is available in ADAMS at Accession No. ML19141A119.

Next Steps: The NRC staff will consider the comments received during this meeting and the previous public comment meeting held on May 14, 2019 (ADAMS Accession No. ML19144A259), 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 late 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.

ENCLOSURE:
As stated

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DATE: June 4, 2019

ENCLOSURE:
As stated

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

ADAMS Accession Nos.: PKG ML19155A374; Meeting Summary ML19155A372
NRC Slide Presentation ML19141A131; Meeting Notice ML19141A414,
Meeting Transcript ML19149A525

***via email**

OFFICE	NMSS/MSST/MSEB/PM	NMSS/MSST/MSEB/TL	NMSS/MSST/MSEB/BC
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DATE	05/31/19	06/03/19	06/04/19
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NAME	SLopas		
DATE	06/04/19		

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Public Meeting to Accept Comments on the U.S. Nuclear Regulatory Commission Staff's Draft Approaches Regarding Training and Experience Requirements for Administering Radiopharmaceuticals (84 FR 18874)

May 23, 2019

Meeting Participants

Name	Affiliation (if known)
Michael Baxter	AlphaNet, Inc.
Janice Campbell	Beaumont Hospital
Ashley Cockerham	Mercurie Consulting
David Crowley	State of North Carolina
Ariel Doucet	Virtua Health System
Lisa Forney	Commonwealth of Pennsylvania
Sandy Gabriel	
Tina Getachew	American College of Radiology
Noelle Geier	Froedtert Health Clinics
Jenny Goodman	State of New Jersey
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals, Inc.
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging
Georgia Lawrence	American College of Nuclear Medicine
Lisa Lemen	
Vicki LaRue	State of New Jersey
Michael Peters	American College of Radiology
Aria Razmaria	UCLA Medical Center
Erin Reynolds	Commonwealth of Pennsylvania
Joseph Rubin	United Pharmacy Partners, Inc.
Judith Schuerman	State of Louisiana
Devin Shiple	Neal R. Gross and Co.
Michael Snee	State of Ohio
Michael Sheetz	University of Pittsburgh
Jared Thompson	State of Arkansas
Cindy Tomlinson	American Society for Radiation Oncology
John Witkowski	United Pharmacy Partners, Inc.
Daniel Yokell	Massachusetts General Hospital - Harvard Medical School
	NRC Attendees
Maryann Ayoade	NRC/NMSS/MSST/MSEB
Lisa Dimmick	NRC/NMSS/MSST/MSEB
Chris Einberg	NRC/NMSS/MSST/MSEB
Jennifer Fisher	NRC/NMSS/MSST/MSEB
Ian Irvin	NRC/OGC
Andrea Kock	NRC/NMSS/MSST
Sarah Lopas	NRC/NMSS/MSST/MSEB
Michelle Simmons	NRC/RIV/DNMS/MIB
Irene Wu	NRC/NMSS/MSST/MSEB

ENCLOSURE