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

May 24, 2019

MEMORANDUM TO: Christian Einberg, Chief
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Division of Materials Safety, Security, State,
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Office of Nuclear Material Safety and Safeguards

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

SUBJECT: SUMMARY OF MAY 14, 2019, PUBLIC MEETING TO ACCEPT COMMENTS ON THE U.S. NUCLEAR REGULATORY COMMISSION STAFF'S DRAFT APPROACHES REGARDING TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINSTERING RADIOPHARMACEUTICALS (84 FR 18874)

Meeting Identifier: 20190471

Date of Meeting: Tuesday, May 14, 2019

Location: Webinar and Commission Hearing Room, U.S. Nuclear Regulatory Commission (NRC) Headquarters, Rockville, MD

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 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, subsequent to the May 14th public meeting, 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 meeting notice, which contained information on how to attend in-person, and webinar registration and bridge line instructions for remote attendees (ADAMS Accession No. ML19134A181). Ahead of the meeting, 53 people pre-registered for the webinar and 5 people registered to attend the meeting in-person at NRC headquarters.

The meeting began at 1:00 p.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. ML19133A090. 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. ML19141A119. Approximately 61 people participated in the meeting: 41 people logged into the webinar, 15 people called into the bridge line but did not log into the webinar, and 5 external participants attended in-person. Fifteen participants asked questions and provided comments. A list of meeting participants who attended in-person and logged into the webinar is enclosed. The meeting concluded at 3:02 p.m. EDT.

Summary of Comments Received:

The first commenter spoke on behalf of the American Association of Physicists in Medicine (AAPM) and stated that any arbitrary reduction in the T&E requirements would compromise safety for patients, staff, and the general public. The commenter said there was no need for a change to the current T&E requirements, and that the Advisory Committee on the Medical Uses of Isotopes (ACMUI) looked at the distribution of AUs in the U.S. and "there seemed to be quite enough." The commenter noted there are portions of the U.S. where healthcare was limited but that this included not just AUs but also medical oncologists in general. The commenter's third point was that the decrease in use of some radionuclide therapies was not due to a lack of AUs, nor the refusal of AUs to administer the therapies, but instead the fact that referrals from medical oncologists had decreased markedly because facilities had found better ways to treat those cancers. The commenter's fourth point was that all radionuclide therapies require the same amount of T&E for the AU to develop a broad understanding of the effects, doses, and hazards.

The second commenter strongly supported the current 700-hour T&E requirement. The commenter was the Executive Director of the American Board of Nuclear Medicine (ABNM) and noted that ABNM was aware of situations where program directors were pressured by superiors

to provide attestations for physician trainees who hadn't fulfilled all the requirements under the alternate pathway (10 CFR 35.390(b)(1)). The commenter believed that the performance-based approach where hospitals develop their own policies and procedures to credential physicians and name AUs would exacerbate this problem. The commenter also stated that preceptor-based attestation alone would not be sufficient to ensure safety. Based on ABNM pass/fail rates for their initial board examination and periodic re-examinations, the commenter expressed support for adding an initial formal competency assessment and periodic reassessments to the existing alternate pathway.

The third commenter identified as a nuclear medicine physician and stated that according to a radiopharmaceutical company, radiopharmaceutical therapies currently comprise 13 percent of nuclear medicine practice, but that percentage was expected to grow to 30 by 2030. Because of this, the commenter stated that appropriate T&E requirements were necessary to create highly trained, skilled, and competent AUs. The commenter requested a 30-day extension to the public comment period. The commenter requested that as part of the evidence to support changing the T&E requirements, the NRC provide a full list of citations or violations (i.e., medical events) that were related to T&E. The commenter noted that 700 hours may have been set arbitrarily in the past, however it has been shown to work over time. The commenter said that a reduction of T&E to 400 hours was arbitrary with no supporting evidence. The commenter stated that competency should be assessed in four ways – certification by a recognized medical specialty board, passing a radiation safety exam, work experience in an accredited laboratory, and periodic (e.g., annual) proficiency testing through a laboratory exercise and graded quiz. The commenter strongly opposed the team-based approaches but noted that a multi-disciplinary team effort was best suited to treat oncology patients. Regarding FRN question 7 regarding how to credential physicians in small practices, the commenter did not support credentialing physicians in small practices (in rural areas) due to their potential lack of infrastructure to handle radiopharmaceutical therapies. The commenter stated that people living in rural areas understand they must travel for medical specialty or sub-specialty expertise. The commenter said that tailored T&E requirements would be difficult to establish and "horrendously difficult" to regulate. The commenter cited lutetium-177 prostate-specific membrane antigen (PSMA) and actinium-225 PSMA as new radiopharmaceuticals that would likely gain wider use in the near future.

The fourth commenter expressed support for the previous comments and reiterated that because radiopharmaceutical therapy is very complex, there should be no relaxation of the T&E requirements and the current requirements should be maintained. The commenter stated that the medical oncologists they worked with had "no desire" to administer radiopharmaceuticals and because they knew it was best left in the hands of nuclear medicine and radiation oncology physicians. The commenter also supported initial and ongoing competency assessments for AUs. Later in the meeting this commenter also raised concerns about how the physician credentialing approach would be implemented, specifically in that some hospitals may have a financial incentive to implement more lenient T&E requirements, including less rigorous documentation of their physicians' T&E. The commenter stated that if the NRC no longer approved and reviewed T&E, that T&E should be left entirely in the hands of the medical specialty boards, and not left up to medical institutions.

The fifth commenter was opposed to establishing limited AU pathways because they said it may result in medical uses of radiopharmaceuticals at facilities that could not provide needed medical care and may not have physical systems in place to ensure radiation safety. The commenter stated that the best place to receive radiopharmaceutical therapy was at a facility

with an entire team of medical professionals, including fully-trained AUs, who have extensive training and experience in safely performing radiopharmaceutical therapy – these facilities could handle complications if they arose. The commenter stated that based on the current number of AUs and those in the pipeline of the medical specialty boards, and even with the expected increase in future radiopharmaceutical therapies, the commenter did not believe there was an AU shortage.

The sixth commenter submitted a comment via the webinar on behalf of the American Pharmacists Association, Academy of Pharmacy Practice and Management, Nuclear Pharmacy Practice Specialist Special Interest Group. The commenter stated that in restructuring the T&E requirements, the NRC should carefully recognize and consider the various healthcare team members involved in safely handling and administering radiopharmaceuticals, including the important role of authorized nuclear pharmacists (ANPs). The commenter stated that the T&E requirements may need to be decreased but it may be difficult to quantify T&E by hours versus competency-based training.

The next commenter asked how the NRC would consider Subpart N, "Enforcement," of 10 CFR Part 35 in each of its draft approaches, and how the NRC would provide oversight to prevent an AU from providing false information to credentialing boards. The commenter stated that currently there is no way for the public to know when this happens. NRC staff member, Ms. Sophie Holiday, responded that the NRC and Agreement States' allegation processes would investigate concerns regarding false credentialing information, and appropriate action would be taken if concerns were substantiated.

The eighth commenter stated that for any of the team-based approaches, the AU who is part of the team should be a fully-trained AU. The commenter did not support performance-based T&E for AUs in the team-based approach – they believed a set number of hours should be required for the AU. The commenter also did not support the tailored T&E approach of "any one radiopharmaceutical." The commenter said that an AU needed broader training than just focusing on one specific radiopharmaceutical.

The next commenter spoke on behalf of United Pharmacy Partners, Inc. (UPPI) and noted the significant number of new radiopharmaceuticals coming down the pike. The commenter noted that the ACMUI, during the February 26, 2019 public teleconference on T&E (ADAMS Accession No. ML19072A259) called UPPI's "limited-trained AU paired with an ANP" idea "novel," "well-intentioned," and "worth of extensive consideration." The commenter stated that ANPs had the same basic 700 hours of T&E as AUs, and so the T&E should be considered equivalent. NRC staff member, Maryann Ayoade, later pointed out that there were important differences in the T&E for ANPs and AUs, and the T&E was not equivalent. The commenter later asked about the status of the NRC's effort to map facilities licensed to use materials under 10 CFR 35.300. NRC staff member Sarah Lopas responded that staff was still working on that effort and maps of those facilities would be included as an enclosure to the staff's T&E Commission paper.

A commenter representing Bayer Healthcare noted that their radiopharmaceutical, Xofigo, represented a different type and scale of radiation risk based on its emission type, dosage, and administration protocol, and that Bayer strongly supported the physician credentialing approach or any risk-informed approach for T&E.

The eleventh commenter identified as a radiation safety office for several facilities and a representative of AAPM. The commenter noted that AAPM supported the current T&E requirements. The commenter brought up concerns about supervision by the AU when a team member other than the AU administered the radiopharmaceutical. Considering that T&E is solely focused on AUs, the commenter was interested in hearing other stakeholders' opinions on supervision requirements for AUs.

The twelfth commenter spoke on behalf of the American College of Nuclear Medicine (ACNM) and stated that ACNM was in favor of "status quo." The commenter stated that both alpha- and beta-emitting radiopharmaceuticals posed unique concerns and safety issues for patients, so they "should not be taken lightly." The commenter stated that patient safety needed to be protected and thus the NRC should not reduce the T&E requirements.

The thirteenth commenter identified as a radiology resident and they supported previous comments in support of maintaining the current T&E requirements. The commenter addressed FRN question number 18 regarding which approaches would best position the NRC to regulate the future of radiopharmaceuticals – the commenter stated that they believed this was best done through the training programs of the ABNM, the American Board of Radiology, and the other recognized medical specialty boards. The commenter did not support small-practices self-determining whether their physicians had appropriate T&E to be AUs. The commenter thought that the "physician credentialing" option would result in differing standards of care across facilities. The commenter stated that the currently recognized medical specialty boards, together with the NRC, have a successful history in ensuring the safe use of radiopharmaceuticals, and because of this, they did not support deviating from the current requirements and system.

A question was asked regarding when new NRC Forms 313 and 313a would be available, and if the T&E evaluation would impact those forms. NRC staff member Donna-Beth Howe answered that licensees should follow the instructions that replaced the posted forms and submit T&E information accordingly, until the new forms were available, which would likely be at the end of summer 2019. (The current T&E evaluation has no impact the forms.)

The final commenter suggested that the NRC should conduct a risk assessment of each radiopharmaceutical. They said the current T&E regulations are overly burdensome and aren't based on risk, and they prevent physicians from administering medically-approved agents for their patients in need of these therapies. The commenter disagreed with the notion that all radiopharmaceuticals posed similar risks and therefore there was no need to create a spectrum of T&E based on risk.

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 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. One additional public comment webinar on the staff's draft approaches for the T&E requirements was held on Thursday, May 23, 2019. A summary of that meeting and the meeting transcript will be posted on the T&E Web site within 30 days of the meeting.

ENCLOSURE:
As stated

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DATE: May 24, 2019

ENCLOSURE:
As stated

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M. Ayoade, NMSS
J. Fisher, NMSS

ADAMS Accession Nos.: PKG ML19144A259; Meeting Summary ML19144A256
NRC Slide Presentation ML19133A090; Meeting Notice ML19134A181,
Meeting Transcript ML19141A119

***via email**

OFFICE	NMSS/MSST/MSEB/PM	NMSS/MSST/MSEB/TL	NMSS/MSST/MSEB/BC
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DATE	05/22/19	05/23/19	05/24/19
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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 14, 2019

Meeting Participants

Name	Affiliation (if known)
John Aarsvold	Emory Hospital
Sukhjeet Ahuja	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Michael Baxter	AlphaNet, Inc.
Gholam Berenji	VA Greater Los Angeles Healthcare System
Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Janice Campbell	Beaumont Hospital
Dalton Clark	SNMMI
David Crowley	State of North Carolina
Victor Diaz	State of New Mexico
Ariel Doucet	Virtua Health System
Mike Fuller	State of Virginia
Sandy Gabriel	
Munir Ghesani	SNMMI
Sheamus Gleason	Bayer Healthcare
Leonie Gordon	Medical University of South Carolina
Erin Grady	American College of Nuclear Medicine
Bennett Greenspan	SNMMI
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals, Inc.
Stanley Hampton	Lilly
Dan Hill	Cardinal Health
Robert Hobbs	Johns Hopkins Medical Institute
Christopher Kessler	Marshfield Clinic
Richard Martin	AAPM
Kimberly Mason	Cardinal Health
Andy McKinley	American Society of Nuclear Cardiology
Chris Mitchell	Kettering Health
Dominique Newallo	Emory Hospital
Niki Noll	State of Pennsylvania
Justin Peacock	Brooke Army Medical Center
Michael Peters	American College of Radiology
Joseph Rubin	United Pharmacy Partners, Inc.
David Schuster	Emory University
George Segall	American Board of Nuclear Medicine (ABNM)
Michael Sheetz	University of Pittsburgh
Arif Sheikh	Mount Sinai Hospital
Megan Shober	State of Wisconsin
George Segall	ABNM
Jeff Siegel	
Rachel Semon	Advanced Accelerator Applications

ENCLOSURE

Name	Affiliation (if known)
Daniel Szatkowski	Washington University St. Louis
Bruce Thomadsen	AAPM
Cindy Tomlinson	American Society for Radiation Oncology
Ed Truskowski	State of New Jersey
Karl Von Ahn	State of Texas
Steven Walter	
	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
Sophie Holiday	NRC/NMSS/MSST/MSEB
Donna-Beth Howe	NRC/NMSS/MSST/MSEB
Ian Irvin	NRC/OGC
Kellee Jamerson	NRC/NMSS/MSST/MSEB
Harriet Karagiannis	NRC/RES
Andrea Kock	NRC/NMSS/MSST
Christine Lipa	NRC/RIII/DNMS
Sarah Lopas	NRC/NMSS/MSST/MSEB
Kevin Williams	NRC/NMSS/MSST
Irene Wu	NRC/NMSS/MSST/MSEB