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

January 22, 2019

MEMORANDUM TO: Christian Einberg, Chief
Medical Safety and Events Assessment Branch
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 JANUARY 10, 2019 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: 20181167

Date of Meeting: Thursday, January 10, 2019

Location: Webinar and Three White Flint 1C3/1C5, 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 January 10 meeting notice, which contained information on how to attend in-person, and webinar registration and bridge line instructions for remote attendees (ADAMS Accession No. ML19004A129). Ahead of the meeting, 22 people registered for the webinar and 1 person registered to attend the meeting in-person.

The meeting began at 1:00 p.m. EST and included a 25-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. ML19002A616. 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. ML19014A270. Approximately 45 people participated in the meeting: 28 people logged into the webinar, 11 people called into the bridge line but did not log into the webinar, and 6 people attended in-person. Nine 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 2:37 p.m. EST.

Summary of Comments Received:

Public comments started off with some clarifying questions regarding the NRC's efforts to map NRC licensees that are authorized to use 10 CFR 35.300 materials. The NRC clarified that the maps would be of individual States, and that staff plans to issue a voluntary request for this information from the Agreement States.

The first commenter stated the current requirement of 700 hours of T&E was excessive for doctors who wished only to administer patient-ready, containerized doses of radiopharmaceuticals (i.e., non-imagining radiotherapy doses). The commenter supported tailored T&E categories for medical oncologists, hematologists, and urologists. The commenter stated that these physicians would like to treat and monitor their patients rather than send them elsewhere for treatment, and that many physicians wishing to administer patient-ready doses of radiopharmaceuticals may already be well-trained and experienced in safely administering toxic chemotherapy treatments. The commenter also cited the burden of travel for these patients and that in some cases it may hamper the decision to receive radiotherapy. Later in the meeting, in response to concerns about safety from other commenters, the commenter suggested that the

NRC should review the safety profile of AUs who were grandfathered-in to administer 10 CFR Part 35.300 therapies via the NRC's revised 10 CFR Part 35 medical regulations.

The second commenter stated that nuclear medicine advanced associates (NMAAs) should be considered for AU designation. The commenter stated that NMAAs are midlevel providers that work under the supervision of a physician, are credentialed and board-certified, and undergo a rigorous classroom and residency training program that meets the requirements of 10 CFR 35.390. The commenter stated that allowing NMAAs to be AUs would improve patient access to radiopharmaceuticals while not compromising the current T&E requirements.

The third commenter supported the idea of allowing NMAAs to become AUs by citing that NMAAs complete masters-level coursework in imaging sciences and post-graduate education via board certification. The commenter stated that NMAAs are knowledgeable in the physics and biochemistry of radiopharmaceuticals, and they have experience in hot labs and radiopharmacies. The commenter stated this education was in addition to years of primary experience as a nuclear medicine technologist. The commenter stated that the benefit of allowing NNMAs to become AUs is that it would not require the NRC to change the T&E requirements, and the commenter did not support any decrease in T&E.

The fourth commenter began by stating their opposition to a recent editorial in a medical journal claiming that the NRC was considering changes to their T&E regulations to make more money for the agency. The commenter thanked the NRC for undertaking this evaluation and stated that their interest in the matter was to improve patient care. In the commenter's experience, they were aware of "tremendous difficulties' with regard to AU availability, in both cities and rural areas. The commenter cited patients having troubles finding in-network AUs, and hospitals "competing" with one another and not referring patients to other hospitals. The commenter also cited the difficulty that sick patients face when they must travel long distances to receive treatments. The commenter was interested in the NRC's facility mapping efforts and suggested that the staff should look at what AUs are actually administering 10 CFR 35.300 therapies, because in many cases, fully-authorized AUs may not be offering those treatments for a variety of reasons. The commenter stated that 700 hours of required T&E was limiting patient access to radiopharmaceuticals and they encouraged the NRC to examine other options. The commenter also expressed support for product-specific, manufacturer-provided training as a way to meet T&E requirements.

NRC branch chief, Chris Einberg, followed-up on this comment by clarifying that the NRC is funded by Congress, 90 percent of that funding is recovered through licensing fees, and this money is returned directly to the U.S. Treasury's general fund. Mr. Einberg further clarified that the NRC issues licenses to medical facilities, and that AUs are then listed on those licenses—the NRC does not license AUs. Therefore, adding new AUs to a license would not affect the yearly licensing fee that the NRC assesses. Furthermore, additional fees generated by new licensees would be commensurate with the new work associated with them (e.g., more license amendment reviews and inspections).

The fifth commenter expressed support for teaming an authorized nuclear pharmacist (ANP) with a limited-trained medical oncologist to improve patient access to radiopharmaceuticals while not changing the overall T&E requirements, because, as the commenter pointed out, ANPs undergo 700 hours of T&E to safely handle radiopharmaceuticals. The commenter stated

that this team approach would ensure patient safety. The commenter also discussed the disparity of radiopharmaceutical availability in rural areas of the country due to a shortage of AUs in those areas. The commenter suggested that the team approach could help ease this disparity.

The sixth commenter opposed creating any limited AU statuses and said that some commenters were confusing diagnostic applications of radiopharmaceuticals with therapeutic administrations. The commenter also disagreed with the idea of allowing ANPs to administer radiopharmaceuticals. The commenter cited that many international countries require five years of T&E for their nuclear medicine physicians, and they questioned whether limited AUs with less T&E would be able to respond to a medical event such as a spill or other contamination issue. Generally the commenter thought that any reduction in T&E would be "dumbing down" the requirements for very complex therapies. The commenter stated that it was not within the NRC's purview to determine who could practice nuclear medicine, and that therapy was more complicated than diagnostic nuclear medicine. The commenter pointed out that the volume of prostate cancer patients being treated with radiopharmaceuticals over the next few years would increase and due to incontinence associated with the disease, the potential for contamination from body fluids would be high. The commenter said that offices of non-nuclear medicine physicians would not be equipped to handle unsealed sources and potential spills and contamination.

The seventh commenter reiterated support for NMAAs to become AUs, and they clarified that NMAAs were physician extenders who always worked under the supervision of a physician AU. The commenter stated that NMAAs extended the services and expertise of the nuclear medicine physicians and nuclear radiologists while ensuring those physicians remained in control of complex clinical decisions.

The eighth commenter represented a pharmaceutical company and said the biggest barrier to the distribution of their therapy–which they stated was specifically designed for safe administration–was a lack of nuclear medicine AUs and hesitation of patients to be treated by a different physician at a different facility. The commenter appreciated the staff's effort to evaluate tailored T&E categories.

Dr. Donna-Beth Howe of the NRC asked a clarifying question regarding whether there would be enough ANPs available that they would be able to leave their radiopharmacies in order to participate in a team-approach AU situation at a site other than their radiopharmacies. The commenter responded that they envisioned that all treatments would be scheduled for one day a week, and that they don't anticipate their team approach would be wide-spread, but it would open up access in some lesser-served areas. Dr. Howe also asked how the proposal to allow NMAAs to administer radiopharmaceuticals under the supervision of a physician AU would differ from the current requirements in 10 CF 35.27, "Supervision." The commenter clarified that they believed it would help to free up physician AUs if NMAAs were able to administer the entire dose without physician supervision. The commenter pointed out that while some therapies are relatively quick to administer (for example, Xofigo), other therapies and perhaps more coming down the line can take 2-3 hours to administer. If the physician isn't tied up that entire time they

could focus their care on more patients. Another commenter clarified that it would be analogous to a nurse practitioner, who is also considered a "physician extender." The commenter also expressed some skepticism if ANPs were wide-spread enough to help with alleviate patient access issues.

The ninth and final commenter pointed out that they recognized the important role of physician extenders, such as NMAAs, in the future of nuclear medicine, but they wanted to point out that they oppose any changes to our regulations that would allow non-nuclear medicine physicians an easier pathway to become AUs. The commenter pointed out that physician extenders would potentially be working under the supervision of limited AUs who would be less experienced with unsealed therapeutic doses of radiopharmaceuticals. The commenter stated that administering Xofigo was not as simple as it was being portrayed by some commenters, and that it involved clinical decisions about dosing and dosimetry. The commenter also pointed out that radiotherapies had serious side effect profiles, and the commenter wondered how a limited-trained AU would handle a complication like a patient going into cardiac arrest during treatment. The commenter theorized that NMAAs, working under the supervision of a limited-trained AU, may find themselves in a situation where the physician was ill-equipped to handle a treatment complication or medical event. The commenter also stated that creating a limited AU status would potentially dilute nuclear medicine expertise in general.

A complete accounting of the comments is contained in the meeting transcript, which is available in ADAMS at Accession No. ML19014A270.

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. A final public comment webinar on T&E is scheduled for Tuesday, January 22, 2019, at 10:00 a.m. EST. The NRC's public meeting schedule Web site contains participation details for this webinar: https://www.nrc.gov/pmns/mtg.

ENCLOSURE:
As stated

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ENCLOSURE:
As stated

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J. Fisher, NMSS

ADAMS Accession Nos.: PKG ML19019A022; Meeting Summary ML19019A023
NRC Slide Presentation ML19002A616; Meeting Notice ML19004A129,
Meeting Transcript ML19014A270

***via email**

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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)

January 10, 2019

Meeting Participants

Name	Affiliation (if applicable)
Jenna Abbott	State of Illinois
Mary Burkhart	State of Illinois
Richard Siska	
Jane Cordis	
Whitney Cox	State of Illinois
Johannes Czernin	UCLA Medical Center
Scott Degenhardt	
Miguel de la Guardia	Cook Children's
Adam Ekstedt	State of Illinois
Cal Gray	United Pharmacy Partners, Inc. (UPPI)
Richard Green	Cardinal Health
Shaemus Gleason	Bayer
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals, Inc.
Stanley Hampton	Eli Lilly and Company
Vicki Larue	National Jewish Health
David Lawrenz	State of Kansas
James Logan	Bayer
Cindi Luckett-Gilbert	
Richard Martin	American Association of Physicists in Medicine
Samuel Mehr	Nebraska Cancer Specialists
Eric Mollen	Neal Gross Court Reporters
Francis O'Neill	State of Vermont
Michael Peters	American College of Radiology
Aria Razmaria	UCLA Medical Center
Joseph Rubin	MWW on behalf of UPPI
Michael Sheetz	University of Pittsburgh School of Medicine
Richard Sheriff	UPPI
Catherine Sinotte	Nuclear Medicine Technology Certification Board
David Stephens	State of Arkansas
Cindy Tomlinson	American Society for Radiation Oncology
John Witkowski	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
Sara Forster	NRC/RIII/DNMS/MLB
Ian Irvin	NRC/NMSS/OGC
Donna-Beth Howe	NRC/NMSS/MSST/MSEB

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Name	Affiliation (if applicable)
Janelle Jessie	NRC/COMM/OCMJB
Andrea Kock	NRC/NMSS/MSST
Sarah Lopas	NRC/NMSS/MSST/MSEB
Gretchen Rivera-Capella	NRC/NMSS/MSST/MSLB