UNITED STATES
NUCLEAR REGULATORY COMMISSION
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February 27, 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 JANUARY 22, 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: 20181168

Date of Meeting: Tuesday, January 22, 2019

Location: 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 (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 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. Four public meetings were held to accept oral comments, and written comments were accepted via the Federal government's rulemaking Web site, www.Regulations.gov under docket ID "NRC-2018-0230."

On November 1, 2018, the NRC published the January 22 meeting notice, which contained webinar registration and bridge line information (ADAMS Accession No. ML19015A162). Thirty-five people registered in advance for the webinar.

The webinar began at 10:00 a.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. ML19011A462. Following the staff's presentation, the webinar was then opened to receive public comments. All webinar participants who wanted to provide a comment were given the opportunity to speak. The webinar was transcribed by a court reporter so staff could capture the comments for the T&E docket (NRC-2018-0230). The webinar transcript can be found in ADAMS at Accession No. ML19029B476. Approximately 31 people logged into the webinar, and 7 people called into the bridge line but did not log into the webinar. Eight participants provided comments. A list of the 31 participants who logged into the webinar is enclosed. The meeting concluded at 11:35 a.m. EST.

Summary of Comments Received:

Public comments began with the first commenter's opposition to creating tailored T&E requirements for certain radiopharmaceuticals, and opposition to any reduction in hours of required T&E. The commenter stated that AUs should have the full range of competency no matter which therapeutic agents they are using. The commenter said that in the future there will be more agents with different features and risks, and so having fully-trained AUs was necessary to safely handle these new agents. The commenter stated that there was no evidence of a shortage of AUs or an issue with patient access to radiopharmaceuticals. The commenter further went on to say they believed that competency was a better way to assess expertise rather than the fulfillment of a certain number of hours. The commenter said competency could be tested by the appropriate boards or by an accredited nuclear medicine or radiology department.

The next commenter questioned whether the partial government shutdown would impact the NRC staff's T&E requirements evaluation. The NRC staff answered that a letter addressed to the Agreement States that required review by the Office of Management and Budget was delayed by the partial shutdown, but staff didn't expect that delay would impact the overall schedule of the T&E requirements evaluation. The commenter encouraged the NRC to require the Agreement States to provide data on their licensees authorized to use 10 CFR 35.300 materials and the associated AUs. The commenter thought this data was necessary to achieve a better understanding of patient access to radiopharmaceuticals. The commenter stated that the current NRC requirements are an acceptable methodology for assuring AUs have the appropriate T&E. The commenter also stated that the Nuclear Materials Events Database

(NMED) had insufficient and inconsistent levels of detail regarding medical events, and they were skeptical that the NRC staff's review of medical events would result in any new and significant information.

The third commenter said that while the NRC's T&E requirements were, at one time, historically appropriate, they are not necessarily germane to some of today's new radiopharmaceuticals. The commenter said that the T&E requirements should only be justified by radiation risk to patients, and they should have nothing to do with the practice of medicine. The commenter disagreed with the NRC's characterization of "categories" of radiopharmaceuticals, because even within a given category, not all radiopharmaceuticals pose the same radiation safety risk. The commenter suggested that T&E should be tailored for a specific therapy agent, and not an entire category of radiopharmaceuticals. The commenter pointed out that the current requirements under 10 CFR 35.390 are not reasonable, because if a physician wants to administer only one type of therapy that poses less radiation safety risk than sodium iodide I-131, that physician must compete the full 700 hours of T&E. The commenter stated that the NRC needed to objectively assess the associated risk for a given radiopharmaceutical, including how it's supplied, its ease of administration, the intended administered activity, half-life and purity, radio-contaminant levels, route of elimination from the body, waste disposal, potential dose to others and patient release issues, and potential for internal contamination. The commenter acknowledged that while this approach would increase regulatory complexity, it would be risk-informed and appropriate, and the regulatory complexity would be justified by the increase in patient access to therapeutic radiopharmaceuticals.

The next commenter identified as a nuclear medicine technician and a radiation safety officer (RSO) for a nuclear pharmacy. They respectfully disagreed with the previous commenter's suggestions and stated that the current T&E requirements did not need to be changed. The commenter stated that the only individuals in favor of creating tailored T&E requirements were representatives of the pharmaceutical industry, because they wanted to sell their products and proctor physicians. The commenter said that allowing industry to provide preceptor attestations was a "big mistake." The commenter also disagreed with a comment from a previous public meeting that suggested teaming an authorized nuclear pharmacist with a limited-AU physician. The commenter theorized that there may be less authorized nuclear pharmacists in the U.S. than physician AUs and didn't understand how this team approach would address patient access. Generally, the commenter did not support non-physicians being eligible for AU status. The commenter disagreed with the idea that there is a shortage of AUs. The commenter stated that instead of actually caring about patient access, physicians desiring a limited-AU status are "self-serving" and only care about keeping their patients in-house for radiopharmaceutical therapy.

The fifth commenter pointed out that it's not the number of AUs that is the problem, it's the number of treating AUs that is the problem. The commenter talked about their experience with sick patients being unable to receive treatment with Xofigo due to in-fighting between AUs at the same hospital. The commenter also cited an example where the preceptors at one hospital were not allowed to sign attestations for physicians at a "competing" hospital. The commenter supported the previous comment regarding creating tailored T&E for specific radiopharmaceuticals. The commenter pointed out that there are significant differences between alpha- and beta-emitters and that it didn't make sense to have those therapies grouped together in such a way that they required the same amount of T&E.

An earlier commenter spoke up after this comment and said that even with alpha-emitters, the AU needs to understand the full range of basic science and clinical expertise. The commenter reiterated that even alpha- and beta-emitters are still potentially dangerous, and especially so when given in combination with other therapies. The commenter did not support allowing physicians without a working background in radiation science to administer radiopharmaceuticals. The commenter further went on to address some of the comments heard earlier in the meeting – that they were unaware of any infighting amongst AUs, and pointing out that people in rural communities had to travel long distances for many medical treatments, not just radiopharmaceutical therapy.

The next commenter identified as an RSO and a nuclear medicine technician, and they concurred that there is a lack of AUs for radiopharmaceutical therapy. The commenter stated that their hospital sees patients from the entire State of Texas because there are so few AUs actually offering therapy. The commenter supported the idea of creating pathways that would allow other physicians to administer certain types of radiopharmaceuticals, citing the example of nuclear cardiology and stating that it "saved nuclear medicine in many respects." The commenter said that they especially supported creating tailored pathways because many nuclear medicine therapies could be obtained from a nuclear pharmacy as a unit dose and did not require manipulation of the product onsite. Later in the meeting the commenter clarified that they did not support allowing non-physicians to be granted AU status.

The next commenter, who identified as a health physicist and an RSO, echoed previous comments that they did not support granting AU status to non-physicians. The commenter pointed out that the AU was involved all aspects of the therapy including supervising the receipt of the therapy, patient assessment, overseeing administration, and follow-up. The commenter later went on to state that they also did not support teaming an authorized nuclear pharmacist with a limited AU to meet the T&E requirements. The commenter concluded by stating that the individual writing the directive needed to be a physician AU and the physician AU was ultimately responsible for the proper management of that radiopharmaceutical and the patient.

Another commenter stated their support for allowing nuclear medicine advance associates (NMAAs) to be considered for AU status and clarified that NMAAs were considered mid-level providers in the field of nuclear medicine. The commenter pointed out that NMAAs were technologists at one point but then go on to complete 2-3 years of additional schooling at the master's level and undergo a 24-month internship with a radiologist or nuclear medicine physician. The commenter stated that at the end of the program the NMAA has all the T&E currently required under the 700-hour alternate pathway. The commenter clarified that an NMAA, even with AU status, would still work under the supervision of a physician AU.

The last commenter identified as a board-certified nuclear pharmacist and said that they would not feel comfortable being an AU—but perhaps they could work in conjunction with a nuclear medicine department. The commenter encouraged the NRC and others to have an open-mind in terms of granting pharmacists "provider status," and noted that it would not be unprecedented (the commenter pointed out that some pharmacists have provider status for medical oncology). The commenter also suggested that the current relative value unit (RVU) model may be one reason for the potential shortage of AUs. The commenter stated that therapeutic AUs may be torn between reading images and having to spend 30 or more minutes with patients during therapy.

A complete accounting of the comments is contained in the meeting transcript, which is available in ADAMS at Accession No. ML19029B476.

Next Steps: The NRC staff is currently reviewing the written and transcribed comments receiving during the public comment period, which ended on January 29, 2019. The NRC staff will document its T&E requirements evaluation and recommendation in a report to for the Commission's consideration, which is planned to be issued 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 are available on the Regulations.gov T&E docket site: https://www.regulations.gov/docket?D=NRC-2018-0230.

ENCLOSURE:
As stated

C. Einberg

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ENCLOSURE:
As stated

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M. Ayoade, NMSS
J. Fisher, NMSS

ADAMS Accession Nos.: PKG ML19031C874; Meeting Summary ML19058A320, NRC Slide Presentation ML19011A462; Meeting Notice ML19015A162, Meeting Transcript ML19014A270

***via email**

OFFICE	NMSS/MSST/MSEB/PM	NMSS/MSST/MSEB/TL	NMSS/MSST/MSEB/BC
NAME	SLopas	LDimmick*	CEinberg* (CDimmick for)
DATE	02/12/19	02/22/19	0222/19
OFFICE	NMSS/MSST/MSEB/PM		
NAME	SLopas		
DATE	02/27/19		

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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)

January 22, 2019

Meeting Participants

Name	Affiliation (if applicable)
Jenna Abbott	State of Illinois
Jaime Barnes	Cook Children's Hospital
Mary Burkhart	State of Illinois
David Burpee	Bayer
Whitney Cox	State of Illinois
Scott Degenhardt	
Ariel Doucet	Virtua
Michele Panichi-Egberts	
Tina Getachew	American College of Radiology
Miguel de la Guardia	Cook Children's Hospital
Shaemus Gleason	Bayer
Alan Goldey	State of Maryland
Desmond Gordon	State of New York
Bennett Greenspan	
Ralph Lieto	
Cindi Luckett-Gilbert	
Samuel Mehr	Nebraska Cancer Specialists
Angela Morgan Hill (Hall)	State of Arkansas
James Salandro	Neal Gross Court Reporters
Rachel Semon	Advanced Accelerator Applications
Michael Stephens	State of Florida
John Suh	Cleveland Clinic
Cindy Tomlinson	American Society for Radiation Oncology
Andrew Zach	U.S. Senate Committee on Environment and Public Works
Maryann Ayoade	NRC/NMSS/MSST/MSEB
Jacqueline Cook	NRC/RIV/DNMS
Lisa Dimmick	NRC/NMSS/MSST/MSEB
Jennifer Fisher	NRC/NMSS/MSST/MSEB
Sara Forster	NRC/RIII/DNMS/MLB
Ian Irvin	NRC/NMSS/OGC
Sarah Lopas	NRC/NMSS/MSST/MSEB

ENCLOSURE