TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL: SUMMARY OF OUTREACH AND COORDINATION

This enclosure summarizes external stakeholder input and the U.S. Nuclear Regulatory Commission (NRC) staff's coordination with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the Agreement States during its evaluation of the training and experience (T&E) requirements for administration of radiopharmaceuticals under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.300, "Use of Unsealed Byproduct Material for Which a Written Directive Is Required." In summary, stakeholder views on T&E for radiopharmaceuticals vary widely and primarily align with each stakeholder's interests in either maintaining the status quo or revising the requirements in some manner.

Complete documentation of the staff's outreach efforts, which also included letters and e-mails, newsletter submissions, and conference attendance, detailed comment summaries, and commenter tables, is available in "Summary of Outreach and Comments" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19176A454).

Medical Community Feedback

The staff arranged for two public comment periods, including six public meetings, to gather stakeholder feedback. The first *Federal Register* notice (83 FR 54380; October 29, 2018) asked whether and how the NRC should tailor T&E, the appropriate content of tailored T&E requirements, and whether the NRC should consider other changes to the agency's T&E requirements. The second notice (84 FR 18874; May 2, 2019) asked for feedback on draft regulatory approaches. In total, the staff received approximately 197 written comment submissions, and 46 individuals provided oral comments during the public meetings.

Primarily citing the adequacy of the current regulations in protecting public health and safety, most comments expressed support for maintaining the NRC's existing T&E requirements (i.e., the status quo) and stated there was no evidence of a shortage of authorized users (AUs). These commenters represented the nuclear medicine and radiation oncology communities and their related medical specialty boards and professional societies, including the American College of Radiology, Society of Nuclear Medicine and Molecular Imaging, American College of Nuclear Medicine, American College of Radiation Oncology, American Osteopathic Board of Radiology, American Society for Radiation Oncology, American Association of Physicists in Medicine, American Brachytherapy Society, Health Physics Society, American Society of Radiologic Technologists, U.S. Oncology Network, and World Association of Radiopharmaceutical and Molecular Therapy. These groups were equally adamant in their opposition to any changes to the T&E requirements, primarily citing concerns about radiation safety, as well as the "dilution" and diminishment of the field of nuclear medicine.

The American Medical Association also submitted comments supporting the status quo and suggesting that the NRC work with interested medical specialty boards to integrate radiation safety training into their residency programs (ADAMS Accession No. ML19183A338). In a similar comment, a small group of nuclear medicine physicians suggested that the NRC should rely on the nuclear medicine specialty board to credential AUs and the agency should provide only "general guidance" on radiation safety requirements (ADAMS Accession Nos. ML19190A195 and ML19157A195).

The NRC received a smaller number of comments expressing support for tailoring the T&E requirements for certain radiopharmaceuticals. These comments came from the pharmaceutical industry,[1] the American Society of Hematology, urology and medical oncology physicians, and healthcare administrators. These groups advocated for a risk-informed approach to T&E based on drug safety profile and complexity of administration, and they recommended 80 hours of T&E for "unitized, patient-ready" doses of alpha or beta emitters. In their desire to use certain radiopharmaceuticals with less complex administration protocols, urology and medical oncology physicians stressed their expertise in treating the diseases for which these radiopharmaceuticals were developed as well as the importance of continuity and ease of care for patients. United Pharmacy Partners, Inc., and the National Rural Healthcare Association advocated partnering authorized nuclear pharmacists with tailored pathway AUs to increase both safety and patient access. Georgia Congressman Buddy Carter advocated for improving rural access to radiopharmaceuticals by considering authorized nuclear pharmacists for AU status (ADAMS Accession No. ML19018A194).

Agreement State Coordination

The NRC engaged the Agreement States through several letters informing them of the public comment periods and meetings, two government-to-government webinars, e-mails and teleconference coordination with the Organization of Agreement States (OAS) Executive Board, and updates to the States during the NRC/OAS/Conference of Radiation Control Program Directors (CRCPD) monthly teleconference. The staff also placed an article soliciting comments on the T&E evaluation in the CRCPD's monthly online newsletter (ADAMS Accession No. ML19177A101) and made a presentation on the NRC staff's T&E evaluation at the CRCPD's National Conference on Radiation Control in May 2019 and the OAS Annual Meeting in August 2019.

Generally, the Agreement States oppose any option that would create additional AU pathways or would otherwise complicate what are viewed as "already complex" T&E regulations. Most Agreement States find the existing AU pathways reasonable and accessible for physicians, and they do not see evidence of an AU shortage in their states. The CRCPD opposes any changes to the existing regulations and endorsed comments made by several of the nuclear medicine, medical physics, and radiology professional societies noted above (ADAMS Accession No. ML19031C710).

However, some Agreement States and the OAS Executive Board indicated that the NRC's regulation of T&E for AUs encroaches on the practice of medicine and that the NRC and the Agreement States could more effectively regulate medical use under 10 CFR 35.300 by focusing only on licensees' radiation safety programs and their procedures for ensuring that radiopharmaceuticals are administered in accordance with the written directive.[2] In its submission for the second comment period (ADAMS Accession No. ML19184A590), the OAS Executive Board commented that the NRC and Agreement States should no longer review and approve T&E for AUs; instead, licensees should rely on certification by medical specialty boards that physicians are medically competent to use radiopharmaceuticals.

[1] These industry commenters included the Council on Radionuclides and Radiopharmaceuticals, Bayer HealthCare, and Spectrum Pharmaceuticals.

[2] Comment submissions from the OAS and the States of Colorado, North Carolina, and Wisconsin are available in ADAMS (ADAMS Accession Nos. ML19030B764, ML19177A330, ML19170A073, and ML19184A593, respectively).

In its comments on the NRC staff's draft T&E Commission paper,[3] the OAS Executive Board restated its opposition to options that would require additional licensing resources or would further complicate the T&E regulations. The OAS expressed support for relying on NRC or Agreement State-recognized medical specialty boards to credential AUs (the staff's recommended rulemaking Option 3). The OAS stated the following:

> The Board's emphasis is on how the drug is being administered in accordance with a physician's prescription, and in accordance with radiation safety practices, not whether the physician is competent to make decisions on what drug to administer. That should be left to the medical specialty boards.

The OAS Executive Board also cited concerns about the status quo, including the administrative and technical reviewer burden of approving AUs with little evidence of safety value added and inappropriate supervision of non-AU individuals using radiopharmaceuticals,[4] suggesting that training requirements should emphasize handling, storage, and disposal by those who are actually administering the material.

Coordination with the Advisory Committee on the Medical Uses of Isotopes

In its draft report dated February 7, 2019 (ADAMS Accession No. ML19039A113), the ACMUI Subcommittee on T&E for All Modalities concluded the following: (1) there are no objective data to confirm a shortage of AUs for uses under 10 CFR 35.300, (2) the Subcommittee does not recommend creation of a new tailored AU pathway, and (3) if the NRC does pursue a new tailored AU pathway, candidates for this pathway must acquire all the basic knowledge topics contained in 10 CFR 35.390, "Training for Use of Unsealed Byproduct Material for which a Written Directive Is Required," satisfactorily complete an initial formal competency assessment, and complete formal periodic radiation safety competency reassessments to maintain tailored AU status. The ACMUI approved the Subcommittee's report, with one dissenting vote, during its public teleconference meeting on February 26, 2019.[5] The Subcommittee issued its final report on T&E for 10 CFR 35.300 uses on February 27, 2019 (ADAMS Accession No. ML19058A598). Enclosure 1 to the rulemaking plan SECY (ADAMS Accession No. ML19321E362) discusses the ACMUI's past efforts related to T&E for radiopharmaceuticals.

On October 6, 2019, the Subcommittee provided comments (ADAMS Accession No. ML19280D163) on the NRC staff's draft SECY paper, concluding that (1) the Subcommittee recommends maintaining the status quo, (2) if the NRC proceeds to grant AU status through NRC-recognized medical specialty board certification, the board certification recognition criteria should be equivalent to the requirements in 10 CFR 35.390, and (3) the Subcommittee recognizes the value of the alternate pathway and is willing to comprehensively review its requirements. The Subcommittee comments contained the dissenting view of one Subcommittee member, which stated that the NRC should shift its T&E regulatory framework towards the non-AU individuals most directly responsible for radiation safety (i.e., nuclear medicine technologists and radiation safety officers). The ACMUI approved the Subcommittee's

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[3] The draft T&E Commission paper was sent to the Agreement States for comment on August 12, 2019 (RCPD-19-011, nonpublic (ADAMS Accession No. ML19183A364)); OAS comments on the draft Commission paper are available in ADAMS (ADAMS Accession No. ML19290H493).

[4] Regulations for the receipt, possession, use, or transfer of byproduct material under the supervision of an AU are contained in 10 CFR 35.27, "Supervision."

[5] The meeting summary and transcript for the ACMUI's February 26, 2019, public teleconference are available (ADAMS Accession Nos. ML19072A259 and ML19308C362, respectively).

draft report with no changes during its public teleconference meeting on October 17, 2019.[6] The Subcommittee's final report is available (ADAMS Accession No. ML19296D256).

[6] The meeting summary and transcript for the ACMUI's October 17, 2019, public teleconference are available (ADAMS Accession Nos. ML19303A686 and ML19303A814), respectively.