POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette L. Vietti-Cook, Secretary

FROM: Commissioner Baran

SUBJECT: SECY-20-0005: Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)

Approved ____ **Disapproved** X **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** ____ **Attached** X **None** ____

Entered in "STARS"
Yes X
No ____

Jeffery M. Baran
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Commissioner Baran's Comments on SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material"

Under NRC's Part 35 regulations, to administer radiopharmaceuticals, a physician must be an "authorized user" approved by NRC or an Agreement State. There are two pathways for a physician to satisfy NRC's training and experience requirements and become an authorized user: (1) certification by one of the medical specialty boards recognized in the regulation, such as the American Board of Nuclear Medicine, American Board of Radiology, or American Osteopathic Board of Radiology; or (2) the "alternate pathway" of completing 700 hours of training and supervised work experience. This 700-hour option was established in 2002.

Over the past several years, NRC has been assessing how well this framework is working. Some stakeholders have argued that the agency's training and experience requirements are too stringent and have resulted in an insufficient number of authorized users and barriers to patient access to radiopharmaceuticals. These stakeholders have offered a range of suggestions, including establishing a limited-scope authorized user pathway tailored to particular types of radiopharmaceuticals.

In 2017, my colleagues and I thought it was important to examine these concerns and take a fresh look at NRC's authorized user training and experience requirements. The Commission directed the NRC staff to evaluate whether it made sense to establish tailored training and experience requirements for different categories of radiopharmaceuticals. In response, the staff sought stakeholder views through a questionnaire and consulted with the Organization of Agreement States. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) also formed a subcommittee to independently assess the issue and offer recommendations. Ultimately, there was broad agreement among the Agreement States, ACMUI, Conference of Radiation Control Program Directors, and most medical stakeholders that tailored requirements would be too complex and could erode radiological safety.

In this paper, the NRC staff proposes a rulemaking to eliminate the alternate pathway and leave only one pathway for a physician to become an authorized user: certification by a medical specialty board whose certification process meets NRC standards. Any medical specialty boards seeking NRC or Agreement State recognition (other than the current NRC-recognized boards) would be required to show that their training programs meet revised radiation safety training criteria established by NRC through the rulemaking. Under this approach, the 700-hour option would be dropped, and NRC and Agreement States would no longer review and approve the training and experience for authorized user applicants.

After reading the extensive public comments and letters, reviewing ACMUI's reports and recommendations, participating in Commission meetings addressing this topic, and talking with numerous knowledgeable stakeholders, including physicians, patient advocates, radiopharmaceutical developers, and state officials, I have concluded that NRC should maintain its existing training and experience requirements.

Many stakeholders offer persuasive arguments that the current training and experience framework is working effectively to ensure radiological safety and is not resulting in a shortage of authorized users to administer radiopharmaceuticals. As the NRC staff notes, a large number of commenters were concerned that "a change or reduction [in the training and experience requirements] could compromise proper training to deal with unusual occurrences or adverse radiological events" and worried about the "increased potential to compromise patient

and medical staff health and safety."[1] For example, the American College of Radiology (ACR) argued that the current training and experience requirements are valuable because "[s]afe and effective use of radiopharmaceuticals requires a thorough knowledge and understanding of the modality and experience with the various facets and potential toxicities and dangers to patients, staff, and the public."[2] ACR further noted that "[i]ssues such as spills, residual activity in tubing and syringes, unused material and care in handling … require knowledge and skills acquired through years of training and experience and a culture of safety among primary providers and staff."[3] Similarly, the American Medical Association (AMA) "believe[s] that to ensure patient safety and quality the NRC should maintain" the current requirements.[4] According to the AMA, the "current pathways for obtaining [authorized user] status under 10 CFR 35 are reasonable and accessible."[5] The organization states: "We have no evidence that there is a shortage of [authorized users] and have found no data to support a potential shortage."[6] The Conference of Radiation Control Program Directors agrees that "[l]essening the training and experience requirements could jeopardize the safety and effectiveness for these [radiopharmaceutical] treatments."[7] The ACMUI Training and Experience Subcommittee also found that "there are no objective data to support an [authorized user] shortage at the present time" and "strongly supports … maintaining the current and existing [authorized user] pathways."[8]

Moreover, because the staff's proposed approach would eliminate the 700-hour alternate pathway, it could actually reduce the number of future authorized users. As the staff acknowledges, its recommended "option relies on nonnuclear medicine and nonradiation oncology medical specialty boards to apply to the NRC or an Agreement States for recognition in order for new [authorized user] pathways to be realized."[9] Yet, establishing a radiation safety training program is resource intensive, and there is no indication that any additional medical specialty boards are interested in seeking this recognition. As the American Society for Radiation Oncology notes, "the alternate pathway offers flexibility and timely certification of new authorized users."[10] Dropping the alternate pathway without any assurance that new medical specialty boards would fill the gap could have negative unintended consequences.

The paper suggests that the current training and experience framework could be viewed as encroaching on the practice of medicine. I disagree. Ensuring that authorized users meet the training and experience requirements necessary for radiological safety does not insert NRC into the actual practice of medicine. The broad support among medical organizations for NRC's licensing role makes it clear that the medical community does not view the current framework as encroaching on the practice of medicine. For example, the American Society for Radiation Oncology believes that "NRC is the appropriate agency to regulate the [training and experience] of physicians for medical uses" of radiopharmaceuticals.[11] The AMA, ACR, Nuclear Medicine

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[1] SECY-20-0005, Enclosure 2 at 1.
[2] Letter from American College of Radiology (Jan. 29, 2019) at 5.
[3] *Id.* at 7.
[4] Letter from American Medical Association (July 1, 2019) at 1.
[5] *Id.*
[6] *Id.*
[7] Letter from Conference of Radiation Control Program Directors, Inc. (Jan. 30, 2019) at Comments 1.
[8] Advisory Committee on the Medical Uses of Isotopes, Training and Experience (T&E) for All Modalities Subcommittee, Final Report (Feb. 27, 2019) at 2, 5.
[9] SECY-20-0005 at 8.
[10] Letter from American Society for Radiation Oncology (Feb. 13, 2020) at 3.
[11] Letter from American Society for Radiation Oncology (July 2, 2019) at 9.

Technology Certification Board, American Association of Physicists in Medicine, American College of Nuclear Medicine, American College of Radiation Oncology, Nuclear Medicine Residents/Fellows Organization, and Society of Nuclear Medicine and Molecular Imaging agree that NRC's current framework is appropriate.[12]

Although I recognize that the Organization of Agreement States Executive Board views the training and experience verification process as time-consuming for NRC and Agreement States, I do not believe we should let workload considerations drive a decision to move away from an effective safety framework.

I also appreciate the interest among many stakeholders in having a regulatory framework that is well-suited to innovative radiopharmaceuticals. I support the NRC staff's separate proposal to update Part 35 to establish generally applicable, performance-based requirements for emerging medical technologies that would focus on the essential, safety-related elements necessary to ensure radiation safety for workers, patients, and the general public.

For these reasons, I approve maintaining the current training and experience requirements for authorized users (Option 1).

[12] *See, e.g.,* SECY-20-0005, Enclosure 2 at 1.