POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Hanson

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

Approved ____ **Disapproved** ✓ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** ____ **Attached** ✓ **None** ____

Christopher T. Hanson

Digitally signed by Christopher T. Hanson
Date: 2022.01.04 16:03:36 -05'00'

Entered in STARS
Yes x
No ____

Signature
Christopher T. Hanson

Date **01/04/2022**

Chairman Hanson's comments on SECY-20-0005: Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)

I commend the NRC staff for their thorough evaluation of training and experience requirements for Authorized Users and their insightful solutions to address stakeholder concerns and comments. The staff's paper is the culmination of extensive public stakeholder outreach and feedback, as well as consultation and coordination with the Advisory Committee on the Medical Uses of Isotopes and the Agreement States. The staff examined corresponding international regulations, related medical events, and the NRC Medical Use Policy Statement. The staff also considered the evolving landscape of emerging radiopharmaceutical therapies and found these therapies are increasingly patient-focused and inherently more complex. As such, the staff's evaluation transcends tailoring training and experience to a specific radiopharmaceutical to a more holistic assessment of training and experience.

I consider the radiation safety competency of Authorized Users to be one of the most important issues to ensure adequate protection of patients, health care workers, the public, and the environment. Adequately trained personnel are key to the safe use of radioactive material in medicine. The staff's recommended "specialty board only" pathway fundamentally changes the existing framework for physicians to become Authorized Users as well as agency licensing policy for reviewing Authorized User training and experience. Under the staff's recommended option, physicians would demonstrate they have achieved a high level of expertise in a specific area of medicine coupled with radiation safety protection competency necessary for physicians to supervise the medical use and administration of radioactive material. I find this overall approach intriguing and can appreciate the benefits, especially how the option could better position the agency for more effective and efficient regulatory decision making with respect to the expected increase in the number and complexity of emerging radiopharmaceuticals. However, I believe this option will yield unintended consequences.

I find this option, if only applied to radioactive material used in radionuclide therapy and diagnostic nuclear medicine, creates an unacceptable disparity for the Authorized User training and experience requirements among all the medical modalities in 10 CFR Part 35. For instance, the types of facilities that are authorized for radionuclide therapies might also perform manual brachytherapy or treatments with high dose rate remote afterloader units. Thus, revising the training and experience pathway and site licensing paradigms to apply to only some modalities in Part 35, but not all, creates discordant methods of compliance with respect to training and experience requirements for licensees that are authorized for multiple medical modalities under Part 35. I also find the core radiation safety concepts that were promulgated in the 2002 medical use regulations are still valid. The staff's recommended option does not describe the envisioned radiation safety criteria in detail. Without an understanding of how the criteria might differ from the current alternate pathway and without the staff's recommended option, which lacks stakeholder support, applying to all modalities, I do not approve the staff's recommended option. Instead, I approve Option 1, maintaining the status quo, with some enhancements, discussed in more detail below.

The Authorized User training and experience requirements are meant to ensure that physicians supervising medical uses of byproduct material have the base radiation safety knowledge and skills needed to adequately provide safe treatments. Successful completion of the NRC's training and experience requirements to become an Authorized User does not reflect on a

physician's medical competency related to the administration of radioactive material, but rather the physician's radiation safety competency. The NRC's current regulatory approach of authorizing the physicians responsible for supervising patient care is an appropriate and practical means of ensuring radiation safety during medical uses. Evidence of a burgeoning shortage of Authorized Users impacting patient access to radionuclide therapy caused by the current training and experience requirements is anecdotal at this time.

While I support maintaining the current regulatory framework for training and experience, this does not mean the knowledge topics and work experience requirements should never change. The practice of medicine will change unpredictably over the coming years. Novel uses of radioactive material in medicine will come and go. We can expect changes in the radionuclides, methodologies, and technologies. As a result, some aspects of the training and experience requirements, including continuing education, vendor training, and regulation review, will need to evolve.

As described in SECY-21-0013, "Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies," the staff will update knowledge topics and work experience requirements as necessary to incorporate emerging medical technologies into the corresponding subparts of Part 35. That rulemaking provides staff the opportunity to reconsider the full complement of training and experience requirements within the current paradigm—the knowledge topics under classroom, laboratory, and work experience, as well as casework and residency requirements. As part of that rulemaking, the staff should obtain stakeholder comments on the knowledge topics encompassing the safety related characteristics of emerging technologies required for Authorized Users to fulfill their radiation safety-related duties and supervision roles; the methods on how knowledge topics should be acquired; and consideration for continuing education, vendor training for new medical uses, and training on the NRC regulatory requirements.

I note that the staff's effort provided a regulatory solution for training and experience that is seemingly less complex that could improve upon regulatory clarity. I also observe that comments from stakeholders reveal general misunderstandings about the current training and experience requirements, including why training and experience is required for Authorized Users and how the criteria are applied, especially for uses under Subpart E, Unsealed Byproduct Material—Written Directive Required. Therefore, the staff should develop implementation guidance for training and experience requirements.

Lastly, to support the paradigm in the staff's recommended "specialty board only" option, staff intended to enhance oversight of the specialty board recognition process. The staff's specialty board process should be robust and ensure specialty board recognition criteria is being sustained. In accordance with staff procedure MSST-70-03 Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards, staff should complete its evaluation of whether each specialty board still satisfies the board recognition criteria and report its findings to the Commission within six months of the date of the Staff Requirements Memorandum.