POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette L. Vietti-Cook, Secretary

FROM: Commissioner Wright

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

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

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

David A. Wright
Digitally signed by David A. Wright
Date: 2022.01.19 11:59:50 -05'00'

SIGNATURE

January 19, 2022

DATE

Entered in STARS
Yes X
No ____

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

This paper covers a topic that has a long history and varied stakeholder perspectives and is personally of interest to me as a beneficiary of nuclear medicine. The NRC's regulations on the necessary training and experience (T&E) for radiation safety must keep pace with new medical uses of radioisotopes. Therefore, I appreciate the staff's innovative thinking in developing its recommendation to revise the framework for the recognition of authorized users (AU) of unsealed byproduct material. The staff proposes removing prescriptive T&E requirements and eliminating the need for NRC review and approval of AUs by requiring physicians be certified by NRC- or Agreement State-recognized medical specialty boards. The staff recommends increasing medical community involvement in determining the T&E requirements and in credentialling AUs so that T&E requirements better accommodate emerging medical technology and align with the NRC's Medical Policy Statement.[1] The staff's recommended approach would maintain oversight of T&E through recognized medical specialty boards while also achieving significant resource savings for the NRC and Agreement States.

Many aspects of the staff's recommendation resonate with my regulatory philosophy. The staff considered and accounted for various stakeholder perspectives, planned for advances in technology, recognized the NRC's role and mission, and developed an approach that would meet that mission in an effective and efficient manner. However, I share my colleagues' concern that this approach could have unintended consequences. In reviewing the paper, my focus was on patient access to nuclear medicine and the potential impacts of removing the alternate pathway and relying on additional specialty boards to seek recognition. My understanding is that no additional boards have expressed interest. Further, the cost of creating and maintaining a program for recognition may be cost prohibitive for specialty boards where the medical use of radioisotopes is more of a niche application. I am also concerned that this approach would eliminate a pathway to becoming an AU for foreign trained physicians and others who are not able to do so through board certification. For these reasons, elimination of the alternate pathway could have a real impact on patient access. While I considered modifying the staff's recommendation to retain the alternate pathway, I believe doing so would eliminate many of the proposal's benefits. Therefore, I do not approve the staff's recommended option.

Instead, I approve option 1 to maintain the status quo. While I support the status quo option, I do not support status quo thinking in this area. Instead, I believe some of the benefits of the staff's recommendation can be achieved by pursuing two of the Chairman's recommendations. Specifically, as part of the rulemaking approved in the staff requirements memorandum (SRM) for SECY-21-0013, the staff should reconsider the full complement of T&E requirements within the current paradigm and obtain stakeholder comments on the knowledge topics encompassing the safety related characteristics of emerging medical technologies. The staff should consider the knowledge topics required for AUs to fulfill their radiation safety-related duties and

[1] *See* Medical Use of Byproduct Material; Policy Statement, Revision, 65 Fed. Reg. 47654 (Aug. 3, 2000). The NRC's Medical Policy Statement says, in part, that the NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public; the NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions; and, in developing a specific regulatory approach, the NRC will consider industry and professional standards that define acceptable approaches of achieving radiation safety. *Id*. at 47655.

supervision roles; the methods on how knowledge topics should be acquired; consideration for continuing education, vendor training for new medical uses, and training on the NRC regulatory requirements. I also agree with the Chairman that the staff should complete an evaluation of whether each currently recognized specialty board still satisfies the board recognition criteria and should report its findings to the Commission within six months of the date of this SRM.