

POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Wright
SUBJECT: SECY-21-0013: Rulemaking Plan to Establish
Requirements for Rubidium-82 Generators and
Emerging Medical Technologies

Approved X Disapproved Abstain Not Participating

COMMENTS: Below Attached X None

Entered in STARS

Yes X

No

Signature

January 7, 2022

Date

Commissioner Wright's Comments on SECY-21-0013: Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies

I appreciate the staff's careful consideration of options to address the addition of calibration and dosage measurement requirements for rubidium-82 (Rb-82) generators and ways to make 10 C.F.R. Part 35 more flexible for emerging medical technologies (EMT). For the reasons described below, I approve the staff's recommended option 3 as it would improve the effectiveness and consistency of medical use licensing across the National Materials Program by modernizing 10 C.F.R. Part 35 to better accommodate existing and future EMTs.

I agree with the staff that longstanding reliance on temporary enforcement guidance is inconsistent with the NRC's Principles of Good Regulation. Therefore, I support rulemaking to address the fact that licensees using Rb-82 generators are not able to meet certain calibration and dosage measurement requirements in 10 C.F.R. § 35.60 and 10 C.F.R. § 35.63 because Rb-82 generators are fully automated. This rulemaking would eliminate existing compliance issues, provide a more efficient, clear, and reliable regulatory framework, and allow for public input.

I also agree with the staff's recommendation regarding well-established EMTs. Over the past 20 years, the NRC and Agreement States have licensed 14 EMTs and issued more than two dozen licensing guidance documents under 10 C.F.R. § 35.1000. Each EMT (i.e., vendor, model number, or use) is currently regulated on a case-by-case basis through license conditions that make prescriptive EMT licensing guidance legally binding. While this is a flexible way to review and license new EMTs, using this process for well-established EMTs can be resource intensive, raise compatibility requirement issues, and lead to inconsistent implementation. I agree with the staff that establishing risk-informed, performance-based, and technology-specific licensing requirements for commonly used EMTs will improve regulatory consistency and resolve compatibility issues.

Finally, I support the staff's proposal to more broadly examine 10 C.F.R. Part 35 to determine whether other outdated, prescriptive requirements could be revised to be more performance-based. The revised requirements would be more generic and focus on intended functions and outcomes rather than prescriptive requirements. I agree with the staff that these revisions would improve flexibility and enable licensing of all approved EMTs, updates to currently licensed EMTs, and better accommodate future EMTs.