

POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

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

Approved Disapproved Abstain Not Participating

COMMENTS: Below Attached None

Entered in STARS

Yes

No

Signature
Christopher T. Hanson

Date 11/01/2021

Chairman Hanson's comments on SECY-21-0013: Rulemaking Plan to Establish Requirement for Rubidium-82 Generators and Emerging Medical Technologies

I thank the staff for initiating this rulemaking plan to modernize 10 Code of Federal Regulations (CFR) Part 35. The staff's proposed rulemaking option would establish performance-based requirements for rubidium-82 generators and all current, well established, emerging medical technologies. The NRC anticipates there will be an increase in the number of emerging medical technologies licensed by the NRC, as the use of medical applications of radioisotopes continues to increase and new advancements in medical technologies are expected. I approve the staff's recommended option (Option 3) because this rulemaking will better position the agency to accommodate future emerging medical technologies and increase regulatory flexibility with less reliance on 10 CFR 35.1000.

The staff uses 10 CFR 35.1000 to efficiently evaluate and license emerging medical technologies that do not fit under the existing medical modality subsections in Part 35. For each emerging medical technology, the staff develops manufacturer-specific licensing guidance and updates the guidance to address changes in the technology as needed. Fourteen emerging medical technologies have been approved using 10 CFR 35.1000 since 2002. Staff has gained substantial operational experience with emerging medical technologies over the last 20 years. Some emerging medical technologies are more prevalent than others and are no longer considered "emergent." I agree with the staff that medical technologies that are no longer considered "emergent" can be moved out of 10 CFR 35.1000 and their regulations can be established elsewhere in Part 35.