POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Baran

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 ____

Jeffery M. Baran
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Date: 2021.10.15 13:08:08 -04'00'

Signature

10/15/21

Date

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

In this paper, the NRC staff requests approval to initiate a rulemaking to update the agency's Part 35 regulations governing the medical use of byproduct material. A rulemaking is necessary to address several issues.

First, Part 35 does not specifically address Rubidium-82 (Rb-82) generators, which produce an imaging radiopharmaceutical. Because the elution, measurement, and administration of Rb-82 are fully automated, licensees that use these generators cannot meet Part 35 instrument calibration and patient dosage measurement requirements that do not account for such automation. In lieu of appropriate regulatory requirements, NRC has relied on enforcement discretion in this area. But, as the staff explains, "longstanding reliance on temporary enforcement guidance to exercise enforcement discretion is inconsistent with NRC Enforcement Policy and is not a substitute for resolving the underlying technical issues associated with calibration and dosage measurement for Rb-82 generators" through rulemaking.[1]

Second, the current licensing process for emerging medical technologies is cumbersome. The process relies on detailed regulatory guidance that is specifically prepared for each individual device model, vendor, and use. The guidance becomes legally binding through license conditions rather than through regulation. This approach to licensing is time consuming and resource-intensive for NRC and Agreement States. In fact, NRC has needed to issue model-specific guidance documents on more than two dozen occasions.

Third, after nearly twenty years, the medical uses defined in part 35 are often "outdated or even obsolete."[2] The provisions are not well-suited to new technologies. Some existing medical technologies do not even fit neatly under the regulation. For example, modern gamma stereotactic radiosurgery (GSR) units "have been manufactured with engineering changes not addressed by Subpart H."[3] As a result, the staff expects that all installed GSR units will need to be licensed with model-specific guidance documents. Similarly, Yttrium-90 (Y-90) microspheres used for permanent implantation therapy have unique properties that prevent them from fitting under either Subpart E or Subpart F of the existing regulations.

To address these challenges, the NRC staff recommends updating 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 (Option 3). The revised regulation would also include performance-based requirements for Rb-82 generators, GSR units, and Y-90 microspheres.

I agree that this approach should effectively resolve the problems with the current regulation. Performance-based standards should eliminate the need to prepare case-by-case guidance documents for every new model, vendor, or use. They can also do a better job than the existing regulation of addressing both well-established and new medical technologies. For these reasons, this approach is supported by the Organization of Agreement States.[4] In my

[1] SECY-21-0013 at 8.
[2] *Id.* at 6.
[3] *Id.* at 4.
[4] *See* Letter from David Crowley, Chair, Organization of Agreement States to NRC (Nov. 20, 2020).

view, the only significant drawback of this option is that the staff anticipates that it will take about four years to complete the rulemaking. It could take even longer if the rulemaking ends up being more complex than expected.

Therefore, I approve the staff's recommended option. However, if the staff finds that the complexity of this approach would result in a timeframe substantially longer than the current estimate, the staff should notify the Commission and provide a recommendation about whether to proceed with a more targeted rulemaking to address only Rb-82 generators, GSR units, and Y-90 microspheres, as envisioned in Option 2.