

**POLICY ISSUE**  
**NOTATION VOTE**

**RESPONSE SHEET**

**TO:** Annette Vietti-Cook, Secretary  
**FROM:** Commissioner Caputo  
**SUBJECT:** SECY-19-0088 - Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423

Approved XX Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_ Not Participating \_\_\_\_\_

**COMMENTS:** Below XX Attached XX None \_\_\_\_\_

See attached.

Annie  
Caputo



Digitally signed by  
Annie Caputo  
Date: 2020.05.11  
15:13:20 -04'00'

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**Signature**

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**DATE**

**Entered in STARS**

Yes   X  

No \_\_\_\_\_

**Comments of Commissioner Caputo on SECY-19-0088:  
Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to  
Staff Requirements Memorandum M190423**

In SECY-19-0088, NRC staff address the Commission's previous concerns (as discussed in SRM-SECY-15-0040) that the medical use-related incidents and source security events being included in Abnormal Occurrence (AO) reports may not be significant from the standpoint of public health or safety.<sup>1</sup>

After reviewing the past five years of AO reports to Congress, these reports for both medical and source security AO criteria (Section 111.C. and Section I.C.1, respectively) have led to reporting of events with minimal or no impact to public health or safety. This is contrary to Section 208 of the Energy Reorganization Act of 1974, which defines an abnormal occurrence as "...an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety."

Realism in reporting both medical and source events is essential to effectively communicating the safety significance of these events. A timely revision to the AO criteria is needed and would more accurately inform Congress and the public of the types of events and the impacts that occur in these areas.

The most recent revisions to the medical AO criteria were completed in 2017. During this previous evaluation, the NRC staff, the Advisory Committee on the Medical Use of Isotopes (ACMUI), and the Agreement States were concerned that: "the previous medical AO criteria was overly conservative and some medical events captured by these criteria may not be significant from the standpoint of public health or safety."<sup>2</sup> The 2017 revision captured some of the recommended changes but did not adopt the requirement that the medical event result in: "unintended or unexpected permanent functional damage to an organ or physiological system, a significant unexpected adverse health effect, or death, as determined by an independent physician."<sup>3</sup>

In preparing SECY-19-0088, the NRC staff reviewed the lessons learned from the 2017 revision and the past 5 years of medical AO's. Of those 55 medical AO's, 47 met the AO reporting criteria but did not result in significant adverse health effects to the patient. The NRC also sought comments from ACMUI and the Agreement States who reaffirmed their previous positions on this issue.

Given the NRC staff's analyses and level of effort in developing SECY-19-0088, a limited review and subsequent proposal should be completed in the near term. I therefore approve staff's recommendation for Option 1, which would develop and propose to the Commission a limited revision to the AO criteria for only the medical event and source security areas. The staff's proposal should be provided to the Commission within six months.

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<sup>1</sup> Per Section 208 of the Energy Reorganization Act of 1974, the NRC is required to annually report abnormal occurrences to Congress. Energy Reorganization Act of 1974, as Amended § 208, 42 U.S.C. § 5848 (2017).

<sup>2</sup> SECY-19-0088: Sept. 16, 2019.

<sup>3</sup> Ibid.