

POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Baran

SUBJECT: SECY-19-0088 - Evaluation of Thresholds for
Reporting Abnormal Occurrences in Response to
SRM-M190423

Approved ____ Disapproved ☒ Abstain ____ Not Participating ____

COMMENTS: Below Attached ☒ None

Entered in "STARS"

Yes ☒

No


SIGNATURE

7/13/20

DATE

Commissioner Baran's Comments on SECY-19-0088, "Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423"

Section 208 of the Energy Reorganization Act of 1974 requires NRC to submit an annual report to Congress on abnormal occurrences, which the statute defines as unscheduled incidents or events that the Commission determines are significant from the standpoint of public health or safety. NRC first established criteria for determining what constitutes an abnormal occurrence in a 1977 policy statement. The Commission has periodically revised the criteria over the years, most recently in 2017.

In this paper, the NRC staff recommends revising the abnormal occurrences criteria related to (1) medical events and (2) stolen radioactive sources. The staff proposes to set a higher bar for what qualifies as an abnormal occurrence in these areas, which would result in fewer events being reported to Congress.

Although the staff does not offer specific revised language, the thrust of the staff's analysis is that only medical events that have the potential to cause significant adverse health effects to the patient should be reported as abnormal occurrences. I disagree. This would raise the bar too high and dramatically limit the information provided to Congress through the annual abnormal occurrence reports.

Events such as exposing the wrong patient to therapeutic levels of radiation or irradiating the wrong organ are preventable events that should not occur. If they do occur, it is appropriate to include them in the annual report to Congress. Requiring a medical error to also cause a significant adverse health effect or death before it would qualify as reportable to Congress would unnecessarily apply a standard higher than those currently applicable to reactors or fuel cycle facilities, where significant safety lapses are reported even if they do not cause actual harm to human health.

According to the staff, a "significant adverse health effects" standard would reduce the number of reported medical event abnormal occurrences over the last five years from 55 to 8. A standard of this kind, considered by the Commission but not adopted in the 2017 revision, would have screened out nearly all of the medical abnormal occurrences reported in fiscal years 2010 through 2013. It also likely would have screened out almost all of the 17 reported abnormal occurrences that took place at the VA Medical Center in Philadelphia from 2002 to 2008. An approach that would exclude cases such as these is clearly too restrictive.

Moreover, an approach that requires NRC or Agreement States to determine whether an erroneous dose resulted in a significant adverse health effect would increase the cost and complexity of the decision about whether an event constitutes an abnormal occurrence. We should not increase the costs for NRC and the Agreement States merely to reduce the number of medical events deemed abnormal occurrences or to avoid reporting such events to Congress. I do not support a proposed change that would expend additional agency resources in order to provide less information to Congress. After decades of issuing these annual reports to Congress, it would be a mistake to introduce new criteria that would drastically reduce the number of events reported. It would send the wrong signal to patients, licensees, Congress, and the public about the seriousness with which NRC takes these events.

For similar reasons, I do not support revising the abnormal occurrence criteria for stolen radioactive sources. Currently, if a Category 1 or Category 2 quantity of radioactive material is stolen, that event qualifies as an abnormal occurrence. The NRC staff suggests that it may not

be necessary to report these events to Congress if the radioactive source is quickly recovered. When a radioactive source that could pose a danger to the public is stolen, that is not a normal situation, even if the source is later recovered. In my view, NRC should continue to report such thefts as abnormal occurrences and simply provide Congress with all of the relevant information about any subsequent recovery.

Therefore, I disapprove revising the abnormal occurrence criteria for medical events and stolen radioactive sources and support the continued use of the 2017 criteria.