POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Hanson

SUBJECT: SECY-22-0014: Report to Congress on Abnormal Occurrences: Fiscal Year 2021

Approved ____ **Disapproved** XX **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** ____ **Attached** XX **None** ____

Christopher T. Hanson

Digitally signed by Christopher T. Hanson
Date: 2022.04.15 14:26:34 -04'00'

Signature
Christopher T. Hanson
Date: April 15, 2022

Entered in STARS
Yes x
No ____

Chairman Hanson's comments on SECY-22-0014:
Report to Congress on Abnormal Occurrences: Fiscal Year 2021

The NRC has a statutory obligation under Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438), to annually report to Congress significant health and safety incidents and events known as abnormal occurrences (AOs). The NRC's established policy on AOs reflects a range of health and safety concerns and applies to incidents and events involving a single individual, as well as those events having an overall impact on the general public. The NRC applies specific criteria to make an AO determination, and the criteria have been updated several times since their inception in 1977. Staff may also include in the report to Congress other events of interest (OEIs). These OEIs do not meet the specific AO criteria but may be perceived as significant by the public or Congress.

In meeting the intent and spirit of the law to report events and incidents that are significant from the standpoint of public health and safety, I believe that three events offered by staff as OEIs are misrepresented and meet the threshold to be reported as AOs. One event involved a safety significant deficiency in procedural controls and two others resulted in absorbed doses and health consequences comparable to those of reported AOs.

First, I disapprove designating Event OEI 21-2, the National Institute of Standards and Technology (NIST) test reactor event, as an "event of interest." While the actual radiological consequences remained within regulatory limits, the NIST event resulted in the violation of the Technical Specification (TS) fuel cladding safety limit and the partial melt of a single fuel element, representing a significant reduction of defense in-depth. This violation of a TS fuel safety limit marks the first of its kind in several decades in the United States.

The staff's year-long review has identified factors that contributed to the event, including inadequate fuel handling and reactor startup procedures, a culture of not adhering to procedures, and inadequate training of operators and supervisors. The staff further found broader safety culture issues at NIST including weaknesses in the leadership's commitment to safety. These findings implicate a serious safety significant deficiency in management or procedural controls. Therefore, the loss of fuel cladding integrity, together with the organizational weaknesses that contributed to the event, are of sufficient safety significance that the NIST event should be reported as an AO.

Next, I disapprove staff's designation of Events AS21-02 and OEI 21-01 as OEIs rather than AOs. Both events involve the mistaken administration of therapeutic quantities of iodine-131 instead of the intended diagnostic quantities of iodine-123. Further, both events resulted in an unintended dose above the NRC's dose threshold for a significant dose (10 Gy) and the same patient outcome—thyroid gland oblation. These two events highlight a gap in the current specific AO criteria for medical events in cases where a diagnostic treatment is intended but a therapeutic treatment is administered.

The written directive clause was added in the 2017 update to the AO criteria to better capture events involving significant doses beyond what was prescribed. As a result, medical events that trigger the current AO criteria are limited to procedures requiring a written directive that exceed 10 Gy to an organ or tissue beyond the expected dose prescribed in the written directive. The Commission is currently reviewing a proposed revision to the AO criteria presented in SECY-22-0009, "Proposed Limited Revision to Policy Statement on Criteria for Reporting Abnormal Occurrences" that would eliminate this clause.

Strict adherence to the terms of this criteria, as is the case with staff's classification of Events OEI 21-01 and AS21-02, leads to contradictory results. In OEI 21-01, an erroneous written

directive was prepared for the wrong treatment and radiopharmaceutical, and the patient was treated according to the erroneous written directive. But because a written directive was prepared and followed, the staff did not consider this event to meet the AO criteria despite the *significant dose to the patient beyond what was intended*. In Event AS21-02, a written directive was not required for the intended iodine-123 administration nor was a written directive created for the erroneous iodine-131 administration. Simply because a written directive was not required for the procedure, Event AS21-02 was not classified by the staff as an AO despite the *significant dose to the patient beyond what was intended*.

I emphasize the outcome in these two cases not to chastise the staff for appropriately following Commission policy, but to signal the need for the proposed revision of the AO criteria currently before the Commission and to underscore the differences between diagnostic and therapeutic procedures that should be considered as part of the revision. I believe it is appropriate and consistent with our statutory obligation to report these events as AOs in our annual report to Congress as we await revision of the criteria.

In consideration of the significance of the three events described above and my belief that they are most appropriately reported to Congress as AOs, I disapprove the draft FY 2021 AO Report to Congress. The staff should make edits to the report to characterize these events (AS21-02, OEI 21-01, and OEI 21-02) as AOs and return the report to the Commission for review within three weeks.