POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Brooke P. Clark, Secretary

FROM: Commissioner Baran

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

Approved ____ **Disapproved** X **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** ____ **Attached** X **None** ____

Entered in STARS
Yes X
No ____

Jeffery M. Baran
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Date: 2022.04.25 16:34:00 -04'00'

Signature

4/25/22

Date

Commissioner Baran's Comments on SECY-22-0014,
"Report to Congress on Abnormal Occurrences: Fiscal Year 2021"

The NRC is required by statute to report abnormal occurrences (AOs) to Congress every year. AOs are incidents and events that are deemed by NRC to be significant to public health or safety. In making AO determinations, the staff applies criteria established by the Commission. These criteria have been updated several times, and proposed changes are currently being considered by the Commission. The annual report to Congress may also include "other events of interest" that NRC deems significant and of high interest to the public and Congress yet not meeting any of the AO criteria.

For Fiscal Year 2021, the staff ultimately identified three incidents as "other events of interest." One of these was the event at the National Institute of Standards and Technology (NIST) Center for Neutron Research test reactor (OEI-21-02). NRC inspectors found that the NIST operators did not follow technical specifications for refueling and did not have adequate procedures for emergency response, refueling, or reactor startup. Moreover, NIST management did not provide the equipment, procedures, and training necessary to support safe operation, which led directly to a violation of the technical specification safety limit for fuel and ultimately to the partial melting of nuclear fuel. This scenario clearly meets AO criterion III.A.3: "A serious safety-significant deficiency in management or procedural controls." NRC's review also found that a lack of operator control of the refueling operations contributed to this event. This fits squarely within AO criterion III.A.2: "A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action." As a result, this event should be classified as an AO.

Two medical events identified as "other events of interest" (OEI-21-01 and AS-21-02) also appear to meet these two AO criteria. Both appear to involve significant deficiencies in management or procedural controls that resulted in significant unintended human health impacts. For one event, the NRC staff describes errors by a licensee that "resulted in the generation of an erroneous written directive," leading to a patient receiving a dose to the thyroid "approximately 9,000 times the dose that would have been administered by the diagnostic test requested by the physician."[1] The NRC's inspection revealed "numerous deficiencies in the licensee's safety program with respect to the receipt, documentation, and transmission of physician requests for patient treatment requiring a written directive."[2] In both cases, the patients were administered the wrong radiopharmaceutical and received a dose exceeding the expected amount by at least 10 Gy (1,000 rad), which is considered safety-significant by NRC. Each patient suffered a completely ablated thyroid gland. This means that the gland was effectively destroyed. One of the patients was "placed on a thyroid hormone replacement regimen and is expected to remain on this regimen for the remainder of their life."[3]

For these reasons, I disapprove the draft AO report. 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.

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[1] SECY-22-0014, Enclosure 1, at B-1.
[2] *Id.*
[3] *Id.* at 3.