POLICY ISSUE
(Notation Vote)

September 16, 2019 SECY-19-0088

FOR: The Commissioners

FROM: Margaret M. Doane
Executive Director for Operations

SUBJECT: EVALUATION OF THRESHOLDS FOR REPORTING ABNORMAL OCCURRENCES IN RESPONSE TO SRM-M190423

PURPOSE:

The purpose of this paper is to provide the Commission with the results of the U.S. Nuclear Regulatory Commission (NRC) staff's evaluation of whether the current abnormal occurrence (AO) criteria provide an appropriate threshold for determining if an event is significant from the standpoint of public health or safety or whether the criteria should be revised. This paper does not address any new commitments or resource implications.

SUMMARY:

The staff conducted an evaluation of the existing AO criteria and determined that the medical and source security AO criteria (Section III.C. and Section I.C.1, respectively) may capture events that are not significant from the standpoint of public health or safety. Therefore, the staff recommends that the Commission approve the additional evaluation and, if appropriate, development of revised medical event and source security AO criteria. Once complete, the NRC staff would send results and, if appropriate, the revised criteria to the Commission for approval. The staff's evaluation was based upon experience in the implementation of the criteria and health effects associated with medical AOs, as well as feedback from the NRC staff and input from the Organization of Agreement States (OAS) and the Advisory Committee on Medical Uses of Isotopes (ACMUI). In addition, the evaluation included a review of enforcement actions associated with medical AOs as an indicator of whether the medical AO criteria are appropriate.

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BACKGROUND:

The AO policy statement was developed to comply with Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438). Section 208 requires the agency to report AOs to Congress and make certain information concerning AOs publicly available. An AO is defined as an "unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety."

The NRC initially issued the AO criteria in a policy statement that the Commission published in the *Federal Register* on February 24, 1977 (42 FR 10950). The criteria was revised several times in subsequent years. The NRC published the most recent revision to the AO criteria in the *Federal Register* on October 2, 2017 (82 FR 45907), and the revised criteria (Enclosure 1) became effective on that date. The most recent AO report, NUREG-0090, Volume 41, "Report to Congress on Abnormal Occurrences Fiscal Year 2018," was published June 2019.

The NRC staff conducted an evaluation of the AO criteria in response to Staff Requirements Memorandum (SRM) SRM-M190423, "Briefing on Strategic Programmatic Overview of the Fuel Facilities and the Nuclear Materials Users Business Lines." That SRM required the staff to "submit a notation vote paper that evaluates whether the current [AO] criteria provide an appropriate threshold for determining if an incident or event is significant from the standpoint of public health and safety or whether the criteria should be revised."

DISCUSSION:

In response to SRM-M190423, the NRC staff considered lessons learned from implementation of the AO criteria that were established in 2017 and reviewed significant health effects associated with medical AOs over the past 5 years. In addition, while NRC enforcement and AO reporting are used for different purposes, the NRC staff evaluated how the NRC's Enforcement Policy dispositions violations associated with events which meet the medical event criteria to provide an indicator of how the agency determines the significance of these events in the enforcement context. Additionally, the NRC staff reassessed the deterministic and risk-informed AO criteria for Commercial Nuclear Power Plant Licensees, as the staff said it would in periodic assessments in SECY-15-0040. The staff's review leveraged the experience of the AO working group members, with a focus on obtaining insights that would support the current AO criteria or potential revisions to the criteria. In addition, staff considered the results from previous evaluations, such as the evaluation included in SECY-15-0040 and solicited input from OAS and the ACMUI.

The staff determined that most of the current AO criteria provide an appropriate threshold with respect to public health or safety. As discussed below, the staff identified that the medical events and source security criteria could be adjusted to ensure the AO criteria only capture those events that are significant from the standpoint of public health or safety. If the Commission approves the staff's recommendation to revise the AO criteria, the staff will work with OAS and the ACMUI and then provide a separate paper to the Commission with the revised criteria.

Medical Event Criteria

Criteria in Section III.C., "For Medical Licensees," requires reporting of medical events that meet specified dose thresholds and event criteria. During the NRC staff's previous evaluation described in SECY-15-0040, the staff recommended changes to the previous medical event criteria. The NRC staff, Agreement States, and ACMUI recommended these changes because they 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. In 2017, the new criteria adopted some of the recommended changes. Specifically, the dose threshold was changed from a simple 10 Gy dose threshold to a dose that exceeds, by 10 Gy, the expected dose to any other organ or tissue from the administration defined in the written directive. However, the new criteria did not adopt the recommendation that the criteria be changed to also require 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."

As part of SECY-15-0040, the ACMUI provided a report titled, "Final Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress," dated November 6, 2015 (Enclosure 2). In this report, the ACMUI expressed concern that the medical event AO criteria were overly conservative and tended to capture medical events that were not significant from the standpoint of public health or safety, and therefore, should not be considered as AOs. The ACMUI report concluded that, "The proposed AO criteria will most likely continue to mis-categorize future medical use related incidents and events as not meaningful or significant." The ACMUI also expressed concerns that the conservative nature of the medical event AO criteria resulted in an over-representation of medical events in the AO report, which could lead to the perception that there have been an inordinate number of AO events in medical uses as compared to other uses of radioactive materials. During a teleconference on July 24, 2019, the ACMUI reaffirmed its 2015 position and recommended that the medical event AO criteria be revised because they currently are not appropriate (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19239A096).

As part of the development of SECY-15-0040, the OAS provided a letter to the NRC dated October 28, 2013 (Enclosure 3). In its letter, the OAS did not support the NRC staff's draft revisions to the medical event AO criteria entirely, but did support the NRC staff's effort to set a "higher bar" for AOs as compared to the medical event reporting criteria in Title 10 of *the Code of Federal Regulations* (CFR) Part 35.3045 and effort to add the criterion that the medical event result in "unintended or unexpected permanent functional damage to an organ or physiological system." On July 2, 2019, OAS reaffirmed the position it took in its 2013 letter (ADAMS Accession No. ML19233A192).

The NRC staff evaluated the events that occurred in 2018 and determined that the change had little impact on reporting as all the events that would have been reported under the previous criteria were also reported under the new criteria. The NRC staff also reviewed the 55 medical event AOs that were reported in past 5 years and found that approximately 8 of those event reports noted that the event had the potential for causing significant adverse health effects to the patient. For this evaluation, the staff defined significant adverse health effects as early effects noted in the reports that were more significant than acute radiation skin complications like erythema. In 2014, one patient passed away from acute respiratory distress-like symptoms following one of these AOs. In this event, yttrium-90 microspheres shunted to the patient's lungs during the treatment of lesions in the liver. However, the cause of death was never determined to have been caused by the event. The other significant health effects included two ulcers following gastrointestinal shunting during yttrium-90 microsphere treatment of the liver, atrophy to additional liver volume following yttrium-90 microsphere treatment that traveled to the wrong side of the liver, two breast tissue wounds following high dose rate afterloader misalignment, increased risk of small necrosis of brain tissue following slight misalignment of gamma stereotactic radiosurgery of the brain, and increased risk of damage to the rectum and surrounding tissues following misplaced prostate brachytherapy seeds. The remaining 47 medical events met the AO criteria but, as determined by the licensee, did not cause significant adverse health effects to the patient.

Although most of these events were reported under the pre-2017 criteria, the majority would still have been reported under the 2017 criteria and demonstrate that the current AO criteria capture events that may not be significant from the standpoint of public health or safety.

In addition, the NRC staff reviewed the severity level assigned to violations associated with medical events that met the AO criteria. The working group reviewed the 2016 – 2018 AO reporting and determined that there were nine medical AOs that occurred at NRC-licensed facilities. Although 2016-2017 AOs were reported under the previous criteria, all these events met the current AO criteria. Agreement State events were not included in this review because Agreement States have their own enforcement policies. Of these nine NRC events, only four were associated with Severity Level III violations, and one of these violations was due to a failure to report an event rather than the event itself. The other events were either associated with Severity Level IV violations or no violations. This result provides an indicator that the significance of medical events is treated differently between enforcement and AO reporting, and therefore the medical event AO criteria may capture events that are not significant from the standpoint of public health or safety.

Based on this evaluation, the staff concluded that medical event AO criteria may capture events that are not significant from the standpoint of public health or safety. Therefore, the staff recommends revising the medical AO criteria.

Security Criteria for Category 1 or 2 Sources

Criteria in Section I.C., "Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach," requires reporting of theft of stolen radioactive material that meets or exceeds the thresholds listed in Appendix A, "Category 1 and Category 2 Radioactive Materials," 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," even if the source is quickly recovered and there is reasonable assurance that there was minimal exposure to the source. The NRC staff believes this may lead to reporting of events with minimal or no impact to public health or safety. For example, in September 2018, a vehicle containing an industrial radiography camera was stolen. The camera contained 3.996 terabecquerel (TBq) (108 Curie (Ci)) of iridium-192, which exceeds the threshold for a Category 2 quantity of radioactive material. The licensee immediately notified the police, who found the vehicle within 3 hours of the vehicle theft. The licensee responded and recovered the vehicle and determined that the industrial radiography camera was still locked in the back of the truck and that no tampering of the camera had occurred. Further there was no apparent radiological impact to the public or employees. Even though the source was recovered quickly and was not disturbed, this event was still reported as an AO in the 2018 AO report. Therefore, the staff believes that the current security criteria pertaining to theft does not provide the appropriate threshold for determining if an event involving the theft of Category 1 and Category 2 quantities of radioactive material is significant from the standpoint of public health or safety, and that this criterion should be revised.

Commercial Nuclear Power Plant Licensees

The working group evaluated whether the commercial nuclear power plant AO criteria (Criteria II, "Commercial Nuclear Power Plant Licensees") should be revised. As part of developing SECY-15-0040, the staff evaluated the deterministic and risk-informed AO criteria and determined that, while the timeliness of applying the risk-informed commercial nuclear power plant AO criteria had improved, the timeliness had not improved to the point where use of the deterministic AO criteria was no longer warranted. Staff committed to periodically evaluate the removal of these deterministic criteria in the future if application of risk-informed criteria were

found to produce applicable and timely results for the AO report. In response to SRM-M190423, the staff reassessed the deterministic and risk-informed AO criteria and continues to find that the use of the current deterministic AO criteria provide a necessary and appropriate supplement to the risk-informed AO criteria. The staff also finds that the thresholds for the risk-informed AO criteria remain appropriate.

In summary, the staff did not identify any proposed changes to the AO criteria for commercial nuclear power plants.

Options:

1) The staff would develop and propose to the Commission a limited revision to the AO criteria in the medical event and source security areas only. This would align the medical event and source security AO criteria with events that are significant from the standpoint of public health or safety.

2) Status quo. No revision to any of the AO criteria. The current AO criteria have been in effect for two years and only one full reporting cycle. This option would allow for staff to gather more information on the implementation of the criteria as updated in 2017. However, this option would not address the concerns staff described above in the medical and security AO criteria.

3) Staff would perform a comprehensive review of all the AO criteria from the standpoint of public health or safety similar to the one performed by the staff for SECY-15-0040. This evaluation would include a comparison of the AO criteria against all agency policies and the strategic plan. It would also include additional stakeholder outreach. While this option would result in a more detailed evaluation, the staff does not anticipate that the resources required to implement Option 3 would be justified since a comprehensive review of the criteria was completed 3 years ago.

RECOMMENDATIONS:

The staff recommends Option 1, that the staff pursue development of revised medical event and source security AO criteria. The staff recommends revising the AO criteria related to the theft of Category 1 and 2 sources (Criterian I.C.1, "Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach") to clearly delineate whether an incident is significant from the standpoint of public health or safety. The staff also recommends revising the medical event AO criteria (Criteria III.C, "Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects") to ensure that an appropriate threshold exists for reporting AO events to Congress that are significant from the standpoint of public health or safety. A breakdown of estimated resources is provided in Enclosure 4, "Resource Estimates."

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objection.

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Operations

Enclosures:
1. Abnormal Occurrence Criteria
2. Advisory Committee on Medical Uses of Isotopes Report, "Final Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress," dated November 6, 2015
3. Organization of Agreement States letter dated October 28, 2013
4. Resource Estimates (non-public)

EVALUATION OF THRESHOLDS FOR REPORTING ABNORMAL OCCURRENCES
DATED: September 16, 2019

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