POLICY ISSUE
(Notation Vote)

March 19, 2015 SECY-15-0040

FOR: The Commissioners

FROM: Mark A. Satorius **/RA/**
Executive Director for Operations

SUBJECT: PROPOSED REVISIONS TO POLICY STATEMENT ON REPORTING ABNORMAL OCCURRENCES CRITERIA

PURPOSE:

To request Commission approval to publish for public comment in the *Federal Register* a proposed revision to the Commission's Policy Statement for reporting abnormal occurrences (AO) to Congress. The proposed revision would enhance consistency with the U.S. Nuclear Regulatory Commission's (NRC) current guidance, regulations, and strategic plan.

SUMMARY:

The revised policy statement would: (1) revise some of the criteria used by the NRC and Agreement States for determining whether to consider an incident or event as an AO and (2) separate other events of interest from the AO criteria established by the NRC. The revisions are consistent with the fiscal year (FY) 2015 performance indicators that were approved by the Commission on September 15, 2014, in Staff Requirements Memorandum to SECY-14-0015.

BACKGROUND:

The Commission developed the AO policy statement to comply with Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438). Section 208 establishes the agency's statutory authority to identify and classify events. An AO is defined as an "unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety."

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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), after which the Commission made additional periodic revisions. The most recent revision to the AO criteria, provided in Enclosure 1, was published in the *Federal Register* on October 12, 2006 (71 FR 60198).

In May 2011, the Office of Nuclear Regulatory Research (RES) established a working group to review the existing criteria for reporting AOs and to determine whether any changes to the criteria were warranted. The working group included representatives from RES, Office of Nuclear Reactor Regulation, Office of Federal and State Materials and Environmental Management Programs, Office of Nuclear Material Safety and Safeguards (NMSS), Office of Nuclear Security and Incident Response, Office of New Reactors, and the NRC's four regional offices. In SECY-12-0032, "Report to Congress on Abnormal Occurrences: Fiscal Year 2011," dated February 25, 2012 (ADAMS Accession No. ML113260103), the staff informed the Commission that it would submit a SECY with proposed AO criteria for Commission approval in FY 2012.

The staff's proposed revisions to the AO medical event criteria (criteria III.C) were presented during the Advisory Committee on the Medical Use of Isotopes (ACMUI) meeting in September 2012. The ACMUI formed a subcommittee to review these revisions and provided its comments and proposed AO medical event criteria in a report (Enclosure 2). The full ACMUI accepted the subcommittee's report during an ACMUI meeting on April 15, 2013. The staff accepted the ACMUI's proposed AO medical event criteria in part and revised its proposed AO medical criteria accordingly. Enclosure 3 provides the staff's full response to the ACMUI report. In October 2013, the staff provided the proposed revised AO criteria to the Agreement States for review and comment. The staff received comments from four states and the Organization of Agreement States (OAS); the comments and staff's responses are summarized in Enclosure 4. The staff modified the proposed AO criteria in response to these comments.

DISCUSSION:

The staff proposes changes to the medical event criteria (criterion III.C) to ensure that only those events that are significant to public health or safety are reported as AOs. Additionally, the staff proposes major revisions to the following areas: addition of cyber security criteria, modification of security-related criteria based on Part 37 to Title 10 of the *Code of Federal Regulations* (10 CFR), and revision to the high-consequence hazard criteria for fuel cycle facilities. The staff also recommends restructuring the AO criteria to clearly delineate that incidents reported as "other events of interest" are not AOs, but do represent events that the Commission deems appropriate to report to Congress. Enclosure 5 shows the comparison of the current and proposed AO criteria and other events of interest.

The staff has reviewed the new NRC strategic plan in comparison with existing and proposed AO criteria and regulations. The staff determined that no changes to the existing AO criteria are needed to address the agency performance goal and indicator with respect to reactors under construction. The staff will report in Appendix A in the proposed new report on events concerning reactors under construction that involve the safe and secure use of radioactive

materials[1] and meet one or more AO criteria I.A through I.D, which pertain to all licensees. Events and occurrences at reactors under construction will be described in Appendix B in the proposed new report if they do not involve the safe and secure use of radiological materials or do not meet AO criteria, including AO criteria II.A through II.D for commercial nuclear power plants, but may nonetheless be perceived by Congress and the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area concerning reactors under construction. The staff's proposed approach is consistent with the performance goals and indicators approved by the Commission and past agency practice.

When NRC last published revised AO criteria in 2006, the Commission directed the staff to revisit the staff's proposal to delete the existing deterministic commercial nuclear power plant AO criteria (criteria II.A and II.B) if the timeliness of the risk-informed criteria was adequate. The staff reviewed the deterministic criteria during its evaluation of the current AO criteria and determined that, while the timeliness of the processes for risk-informed commercial nuclear power plant AO criteria has improved, there is a need to retain the deterministic commercial nuclear power plant AO criteria at this time. Therefore, the staff recommends keeping both deterministic and risk-informed criteria at this time. However, the staff recommends evaluating the removal of these deterministic criteria in the future if application of risk-informed criteria is able to produce applicable and timely results for the AO report.

The remaining discussion in this paper provides the major proposed changes to the AO criteria. In addition to these proposed changes, the staff intends to evaluate adding the phrase "common defense and security" in the introduction of the AO report and where appropriate in criterion I.C. The staff is not recommending the inclusion of "common defense and security" at this time. A complete description of all proposed changes, including minor and editorial changes, is included in Enclosure 6.

Medical Events

The staff proposes several changes to the criteria regarding events involving the medical use of radioactive materials in patients or human research subjects (criterion III.C). Many of the significant proposed changes are based upon recommendations from the ACMUI. The ACMUI was concerned that the current medical AO criteria were overly conservative and tended to capture medical events that were errors and may not be significant from the standpoint of public health and safety and, therefore, did not meet the threshold in the law to be considered as AOs.

The staff agrees with ACMUI's concern that the current AO criteria have resulted in reporting events that may not be significant from the standpoint of public health and safety. ACMUI also expressed concerns that the conservative nature of the current medical 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. Therefore, the staff proposes replacing the current criterion III.C with the revised criterion III.C shown in Enclosure 5. This proposed criterion would now require an AO to be a medical event that results in unintended or unexpected permanent functional

[1] Licensed radioactive materials may be used at a nuclear power reactor under construction for various purposes, such as to perform industrial radiography and calibration of gauges and other instruments.

damage to an organ or physiological system, a significant unexpected adverse health effect, or death, as determined by an independent physician. Under these new criteria, NRC will identify medical events that are significant from public health and safety perspective and warrant notification to Congress. The revision is consistent with Commission approved FY 2015 performance indicators.

In the proposed AO criteria, staff defines “independent physician” as a physician not on the licensee’s staff and who was not directly involved in the care of the patient. The staff recommends the use of an independent physician to avoid bias in the evaluation. A medical consultant used by the NRC or an Agreement State under the NRC medical consultant program described in NRC Inspection Manual Chapter 1360, “Use of Physician and Scientific Consultants in the Medical Consultant Program,” would be considered an independent physician (available at ADAMS Accession No. ML062720195). The staff recommends a physician make the determination of whether death or an unexpected health effect is an adverse effect from the medical event as the death or health effect could occur months, or years, following the treatment and may not be obvious to non-medically trained individuals whether the death or effect was linked to the medical event.

Currently, criterion III.C.1.(b) is a dose of greater than 10 Gy to an organ or tissue other than that described in criterion III.C.1.(a). Because many medical procedures have prescribed doses that are greater than 10 Gy to an organ or tissue, this criterion may be met without the medical event causing any excess dose to the organ or tissue, which may lead to reporting of events that are not significant from the standpoint of public health and safety. The staff recommends changing this criterion to include medical events that result in a dose that exceeds, by 10 Gy, the expected dose from the administration defined in the written directive. This recommendation would provide an additional screening criterion for medical events prior to having an independent physician evaluate medical events against the proposed criterion III.C.3.

In considering this proposed revision, the staff reviewed historical data to evaluate how many medical events would have been forwarded to a medical consultant for further evaluation had the proposed changes to the AO criteria been in place during FY 2010 through FY 2013. The staff concluded that had this approach been used in the past, approximately half of the AOs reported would have been forwarded to an independent physician for evaluation, while the other half would have been appropriately screened out as not needing further evaluation for AO purposes. The staff notes that most of the descriptions of AO events reported in FY 2010 through FY 2013 stated that no adverse health effects from radiation exposure were expected and, therefore, would likely not have been reported under the proposed criteria.

The proposed revisions to the regulations in 10 CFR Part 35 (79 FR 42410 (July 21, 2014)) related to the medical event reporting for permanent implant brachytherapy also focus on the public health and safety aspects. The proposed amendments to the regulations are expected to result in fewer incidents meeting the criteria for reporting as medical events. In addition, an incident must first be defined as a medical event under Part 35 in order to be considered as a medical AO. Therefore, both the proposed changes to the AO criteria and the proposed amendments to 10 CFR Part 35, if approved by the Commission, are expected to reduce the number of reported medical AOs.

Cyber Security

The staff proposes the addition of cyber security to criterion I.C.4 to align the AO criteria with the NRC strategic plan and performance measures. In addition, the staff proposes revising criterion I.C.4 to add protection against loss of licensed material and to revise language that addresses material control and accountability to improve clarity.

Part 37

The staff proposes revising criterion I.C to address the physical protection of byproduct material consistent with regulations codified in 10 CFR Part 37 and to better align with the strategic plan.

The staff proposes to remove references to Appendix P to 10 CFR Part 110 and the term "risk-significant radioactive sources," and replace those with a reference to the radioactive material thresholds listed in Appendix A of 10 CFR Part 37. Additionally, the staff proposes revising the reporting exclusion of criterion I.C.1 to improve clarity and to better align the AO criteria with 10 CFR Part 37.

The staff also proposes an additional footnote to the title of criterion I.C. Footnote 5 clarifies that the reporting of lost or stolen material is based upon the source activity of the radioactive material at the time the material was lost. It states that the NRC will indicate in the AO report to Congress, if the radioactive material has decayed to below the thresholds listed in Appendix A of 10 CFR Part 37 by the time of the report issuance. The radioactive material and thresholds listed in Appendix A of 10 CFR Part 37 are based on the Category 1 and Category 2 quantities of radioactive material listed in the International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources, which could pose a significant risk to individuals, society, and the environment. The staff believes that this added language would better inform Congress about the risk associated with the lost or stolen sources.

High-Consequence Hazard at Fuel Cycle Facilities

The staff proposes revising criterion III.B.1 to "Absence or failure of all safety controls (engineered and human) such that conditions were present for the occurrence of a high-consequence event involving an NRC-regulated hazard (radiological or chemical hazard)." The revision replaces "lethal" with "high-consequence." The word "lethal" is only defined within the NRC regulatory structure in terms of "lethal dose." It does not include chemical consequences, which are of concern for fuel cycle facilities, nor align with the risk-informed approach that applies to fuel cycle facilities. Experience with reported events at fuel cycle facilities indicates that AOs that fit the "lethal consequence" criterion are rare. Evaluation of fuel cycle events against the "lethal hazard" criterion requires subjective interpretation and thus may lead to inconsistent implementation of AO reporting. Revision of the AO criterion from a "lethal hazard" to a "high-consequence event" will make the criterion objective and risk-informed, and will align the criterion with the existing regulatory framework for fuel cycle facilities.

The proposed change also removes "security-related" from the criterion as security-related events are covered under section I.C of the AO criteria for all licensees, and its inclusion in I.C would be duplicative and unnecessary. Further, the proposed change replaces the language that relates to the presence of lethal hazard with language linked to the potential for the occurrence of a high-consequence event. This provides clarity to ensure that only those

conditions in which a potential event was imminent and significant are reported to Congress. Finally, the staff proposes the addition of footnote 14 to explain considerations for the review of fuel cycle events under this revised criterion III.B.1.

The totality of these clarifications will improve objectivity in determining if a given event meets the AO criteria. Staff will be able to assess the conditions in light of established performance requirements in 10 CFR 70.61, safety controls available to prevent or mitigate the event's consequences, and whether conditions were present for the event's occurrence. These principles are well-understood and defined within the regulatory framework for fuel cycle facilities. Revision of the criterion also aligns with other comparable criteria within the AO reporting requirements.

Other Events of Interest

The staff proposes to restructure the existing AO criteria by removing section IV, entitled "Other Events of Interest," from Appendix A and moving the guidelines to Appendix B as noted in Enclosure 5. Separating other events of interest from the AO criteria clearly indicates that events considered under this item are not AOs as they do not meet the AO criteria, and do represent events that the Commission deems appropriate to report to Congress.

RECOMMENDATION:

The staff recommends that the Commission approve for publication in the *Federal Register* the proposed revised policy statement (Enclosure 7) for a 90-day public comment period.

RESOURCES:

Resources for the use of independent physicians for medical event AO evaluations for both Agreement State and non-Agreement State events are expected to be approximately $50,000 annually. At present, there are 37 Agreement States and evaluations of Agreement States' medical events by independent physicians are expected to have minimal impact on the Agreement States because anticipated costs can be funded from existing NRC support to the Agreement States. Resources for FY 2016 and beyond for the use of independent physicians will be addressed in the Planning, Budgeting, and Performance Management process. No additional budgetary resources are expected for the other AO proposed criteria revisions.

COORDINATION:

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

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Enclosures:
1. Current Appendix A: Abnormal Occurrence Criteria and Guidelines for Other Events of Interest
2. ACMUI Report on Abnormal Occurrence Criteria for Medical Use
3. Staff Response to ACMUI Report on Abnormal Occurrence Criteria for Medical Use
4. Summary of Major Agreement State Comments and Staff Responses
5. Comparison of Current and Proposed Abnormal Occurrence Criteria
6. Summary of Proposed Changes to the Abnormal Occurrence Criteria
7. Draft *Federal Register* Notice