POLICY ISSUE
(Notation Vote)

February 3, 2017 SECY-17-0019

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: FINAL REVISION TO POLICY STATEMENT ON ABNORMAL OCCURRENCE REPORTING CRITERIA

PURPOSE:

To request Commission approval to publish in the *Federal Register* a final revision to the Commission's policy statement on reporting abnormal occurrences (AOs) to Congress (Enclosure 1). The draft final revisions would enhance consistency with the agency's current guidance, regulations, and strategic plan.

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 obligation to identify, classify, and report to Congress certain 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." The U.S. Nuclear Regulatory Commission (NRC) has issued several revisions since publishing the initial policy statement in 1977. The NRC issued the last revision in 2006.

In SECY-15-0040, "Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria," dated March 19, 2015, the staff proposed a draft revision to the AO criteria. In the staff requirements memorandum for SECY-15-0040, dated June 30, 2015, the Commission approved publication of the draft revision for public comment. In particular,

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the Commission directed the staff to seek public comment on screening all reports for exposures to an embryo/fetus or nursing child as AOs under Criterion I.A.2, related to the unintended radiation exposure of minors, versus screening reports required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3047, "Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child," for exposures to an embryo/fetus or nursing child resulting from treatment to a patient as an AO under Criterion III.C, related to medical events. The draft revision was published in the *Federal Register* on August 17, 2015 (80 FR 49177). The public comment period closed on November 16, 2015. The staff received comments from the State of Washington, the Commonwealth of Virginia, the Organization of Agreement States (OAS), and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). With the exception of a slight change in a footnote, the staff recommends the revised criteria as proposed.

DISCUSSION:

Consistent with the proposed revision in SECY-15-0040, the draft final policy statement (1) includes a change to the medical event criteria (Criterion III.C) to ensure that only events that are significant to public health or safety are reported as AOs, (2) adds cyber security criteria to align with the NRC strategic plan and performance measures, (3) adds criteria related to physical protection of byproduct material based on 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," and (4) revises the high-consequence hazard criteria for fuel cycle facilities. The proposed final policy statement also clarifies that incidents reported as "other events of interest" are not AOs, but do represent events that the Commission deems appropriate to report to Congress.

The draft final policy statement does not require changes to address the agency performance goal and indicator with respect to reactors under construction. Appendix A to the annual AO report will include any events concerning reactors under construction that involve the safe and secure use of radioactive materials[1] and meet one or more of AO Criteria I.A through I.D, which pertain to all licensees. The staff will describe these events in Appendix B to the AO report if the events do not involve the safe and secure use of radiological materials or do not involve AO Criteria II.A through II.D for commercial nuclear power plants. Members of Congress and the public may perceive these types of events to be of high health and safety significance, the events may have received significant media coverage, or the events may have caused the NRC to increase its attention to or oversight of a program area concerning reactors under construction. The proposed final policy statement is consistent with the proposed final 10 CFR Part 35, which is currently under Commission review in SECY-16-0080. This approach is consistent with past agency practice and the performance goals and indicators approved by the Commission.

Human Exposure to Radiation

The revised AO criteria in Criterion I.A, related to human exposure to radiation from licensed material includes the provision in Criterion I.A.3 that an independent physician evaluate the presence of permanent functional damage. This section 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 use of an independent physician is intended to avoid bias in the evaluation to determine whether permanent functional damage occurred as a result of exposure to radiation.

[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.

Medical Events

Criterion III.C.1.(b) in the proposed final revision includes one change to the criteria regarding events involving the medical use of radioactive materials in patients or human research subjects. The proposed final revision includes a criterion that an AO is a medical event that results in a dose that exceeds, by 10 gray (1000 rad), the expected dose in the written directive to an organ or tissue other than those described in Criterion III.C.1.(a). The staff made no changes in this criterion from the draft revision.

Cyber Security

The draft final revision adds cyber security to Criterion I.C.4 to align the AO criteria with the NRC strategic plan, performance measures, and requirements in 10 CFR part 73. Criterion I.C.4 also includes protection against the loss of licensed material and material control and accountability. The staff made minor editorial changes in this section from the proposed revision.

10 CFR Part 37

The draft final revision includes Criterion 1.C related to the physical protection of byproduct material and theft, diversion, or loss of licensed material; sabotage; or security breach. The proposed final revision is consistent with the regulations codified in 10 CFR Part 37 and aligns better with the strategic plan. The staff made no changes in this section from the proposed revision.

High-Consequence Hazard at Fuel Cycle Facilities

The draft final revision replaces “lethal” with “high-consequence” in Criterion III.B.1 because the word “lethal” is only defined within the NRC regulatory structure in terms of “lethal dose,” which does not include the chemical consequences of concern for fuel cycle facilities. Revision of the AO criterion from a “lethal hazard” to a “high-consequence event” makes the criterion objective and risk informed and aligns the criterion with the existing regulatory framework for fuel cycle facilities.

The draft final revision adds footnote 14 to explain considerations for the review of fuel cycle events under the revised Criterion III.B.1. These changes align the fuel cycle AO criteria with other comparable criteria within the AO reporting requirements. The staff made no changes in this section from the proposed revision.

Other Events of Interest

The draft final revision moved Criterion IV, related to other events of interest, from Appendix A to Appendix B, as shown in Enclosure 1 to this document. By distinguishing other events of interest from events that satisfy the AO criteria, the staff intends to clarify that these events do not meet the AO criteria and as such are not AOs, but they do represent events that the Commission deems appropriate to report to Congress. The staff made no changes in this section from the proposed revision.

Issues Raised by Agreement States

Enclosure 2 summarizes Agreement State and OAS comments and provides the staff's responses. The State of Washington commented on footnote 3 regarding the need for an "independent physician," stating that this physician should also be a qualified specialist in the relevant field. Criterion I.A.3 addresses this comment by stating that physicians deemed qualified by the NRC or an Agreement State takes into account all pertinent credentialing aspects of the individual, including specialty in the relevant field. Both the State of Washington and the Commonwealth of Virginia commented on Criterion I.A.2, stating that the reporting requirements and screenings for exposures to embryos/fetuses seemed redundant with current regulations in place under 10 CFR 35.3047. The Commonwealth of Virginia recommended completely removing the embryo/fetus reporting requirements under 10 CFR 35.3047 from the AO reporting criteria. All of the Commonwealth's other comments and recommendations were aimed at reducing perceived overlap in various sections of the reporting criteria and the current regulations under 10 CFR Part 35, "Medical Use of Byproduct Material." The NRC intends the AO criteria to identify those events that could have significant impacts to public health or safety and, therefore, warrant reporting to Congress. Reporting under 10 CFR 35.3047 is required only where an embryo/fetus was exposed to radiation as a result of a medical administration to a pregnant mother. Therefore, Criterion I.A.2 is necessary to capture all significant exposures to the embryo/fetus, providing for evaluation of the event in a broader industry context.

OAS had four comments. Two recommended changes, while the other two requested clarification or supported the revised language. OAS commented on Criterion I.A.2, stating that the threshold for an AO for a dose to an embryo/fetus is the same as the threshold for a medical event (i.e., 50 millisieverts (5 rem)), when in principle, the threshold for an AO should be higher than typical reporting criteria. OAS also recommended removing the provision that an independent physician review and determine cases of radiation exposure. OAS requested clarification on how the discussion on physical and cyber security in Criterion I.C.4 applies to material licensees. As further discussed in Enclosure 2, which contains the Agreement State comments and the NRC staff's responses to those comments, (1) 10 CFR 35.3047 only applies to medical administrations while Criterion I.A.2 is for exposure from any licensed material, (2) the staff recommends keeping the requirement for an "independent physician" as part of the review process for AOs to avoid any potential bias, and (3) Criterion I.C.4 is principally for licensees that possess more than a critical mass of special nuclear material and whose activities are included in a security plan required by 10 CFR Part 73, while Criterion I.C.1 is the principal criterion for capturing security incidents involving materials subject to 10 CFR Part 37 for materials licensees for consideration as AOs. The staff made no changes from the draft revision as a result of these comments.

Coordination with the Advisory Committee on the Medical Uses of Isotopes

The ACMUI submitted comments on the proposed AO policy statement in a letter dated November 6, 2015 (Agencywide Document Access and Management System Accession No. ML15356A087). Most of ACMUI's comments indicated agreement with the proposed revisions to the policy statement. However, ACMUI had three comments recommending changes to the AO criteria. The staff disagreed with two and partially agreed with one of these comments. The staff agreed to add "and human research subjects" to footnote 2 to Criterion 1, but it disagreed with excluding events reported under § 35.3047 from Criterion I.A.2. The staff disagreed with adding § 35.3047 to the footnote text because this would establish two different thresholds for reporting an AO involving exposure to an embryo/fetus; one for an embryo/fetus unintentionally exposed due to a medical

administration to a pregnant individual and one for an embryo/fetus exposed from all other sources of licensed material. Enclosures 3 and 4 include ACMUI's comments and the staff's responses to those comments, respectively.

RECOMMENDATION:

The staff recommends that the Commission adopt the draft final policy statement, and approve for publication in the *Federal Register* the enclosed notice (Enclosure 1).

RESOURCES:

The staff does not require additional budgetary resources for the AO 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.

/RA/

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Enclosures:
1. *Federal Register* Notice,
2. Summary of Comments from OAS, WDH, VDH on the Draft Revised Abnormal Occurrence Reporting Criteria and Staff Responses Recommendations on the Proposed Revision of the NRC Policy Statement on Reporting AOs to Congress
3. ACMUI Final Comments on Proposed Revision of the NRC Policy Statement on Reporting AOs to Congress, November 6, 2015
4. Staff's Response to ACMUI November 6, 2015, Recommendations on the Proposed Revision of the NRC Policy Statement on Reporting AOs to Congress

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