POLICY ISSUE
(Notation Vote)

February 1, 2022 SECY-22-0009

FOR: The Commissioners

FROM: Daniel H. Dorman
Executive Director for Operations

SUBJECT: PROPOSED LIMITED REVISION TO POLICY STATEMENT ON CRITERIA FOR REPORTING ABNORMAL OCCURRENCES

PURPOSE:

To request Commission approval to publish for public comment in the *Federal Register* (FR) a proposed limited revision to the Commission's policy statement on criteria for reporting abnormal occurrences (AOs) in the areas of medical use and source security. This paper does not address any new commitments or resource implications.

SUMMARY:

The NRC staff developed and is proposing revisions to the medical event and source security AO criteria to align the criteria with events that are significant from the standpoint of public health or safety. The proposed revisions to the medical event AO criteria remove redundancy, improve conformity with current regulatory requirements, reflect new developments in medical radiation treatments, and introduce a new medical consequence criterion. The proposed revisions to the source security AO criteria exclude those events that have no significant impact to public health or safety, such as an event involving a stolen vehicle where there was no intent to gain access to the radioactive material and where the radioactive material was recovered with no tampering or access to the radioactive material. The NRC staff is not recommending changes to reporting requirements imposed on licensees by Commission or Agreement State regulations, license conditions or technical specifications.

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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 U.S. Nuclear Regulatory Commission (NRC) initially issued AO criteria in a policy statement published in Volume 42 of the *Federal Register*, page 10950, on February 24, 1977 (42 FR 10950). The agency revised the criteria several times in subsequent years, publishing the most recent revision on October 2, 2017 (82 FR 45907). The current criteria (Enclosure 1) became effective on that date. The NRC published the most recent AO report, NUREG-0090, Volume 43, "Report to Congress on Abnormal Occurrences Fiscal Year 2020," in June 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21152A287), which were developed upon the criteria in Appendix A.

In SECY-19-0088, "Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423," the NRC staff reported the results of an evaluation of the existing AO criteria and determined that the medical event and source security AO criteria (Section III.C. and Section 1.C.1, respectively) may capture events that are not significant from the standpoint of public health or safety (ADAMS Accession No. ML19191A281). Based on this evaluation, the staff recommended that the Commission direct additional evaluation of and, if appropriate, development of revised medical event and source security AO criteria. The staff's evaluation was based upon its experience in the implementation of the medical event and source security AO criteria and its evaluation of health effects associated with medical event AOs, as well as feedback from the Organization of Agreement States (OAS) and the Advisory Committee on Medical Uses of Isotopes (ACMUI).

In the staff requirements memorandum (SRM) to SECY-19-0088, the Commission approved the NRC staff's recommendation to develop and propose to the Commission a limited revision to the medical event and source security AO criteria to align the criteria with events that are significant from the standpoint of public health or safety (ADAMS Accession No. ML20209A564). In September 2020, the Office of Nuclear Regulatory Research (RES) established a working group to further review the existing AO criteria and develop a proposal, for Commission consideration, to update the criteria for medical event and source security AOs. The working group included representatives from RES, the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Security and Incident Response, the NRC's four regional offices, and the Agreement States. In SECY-21-0023, "Report to Congress on Abnormal Occurrences: Fiscal Year 2020," dated March 1, 2021, (ADAMS Accession No. ML20343A247), the staff informed the Commission that it would submit a SECY with proposed revisions to AO criteria for Commission consideration in fiscal year (FY) 2022.

DISCUSSION:

Consistent with direction provided in the SRM-SECY-19-0088, the NRC staff developed limited proposed revisions to the medical event and source security AO criteria. The proposed changes to the medical event and source security AO criteria in Section III.C and Section I.C, respectively, ensure that only events that are significant to public health or safety are reported as AOs (Enclosure 2).

Medical Event Criteria

The NRC staff reviewed the current (implemented for FY 2018) medical event AO criteria and is proposing changes to establish medical event AO criteria that reflect both quantitative and qualitative considerations. The NRC staff is proposing to retain Criterion III.C.1 with refinements as a quantitative dose-based criterion that considers whether the medical event exceeds a certain dose. The NRC staff does not consider medical events such as underdoses and overdoses that fall below the doses specified in Criterion IIII.C.1 to be significant. If the medical event exceeds the dose prescribed in Criterion CIII.C.1, staff proposes use of a qualitative medical-consequence based criterion, the newly proposed Criterion III.C.2, which considers whether a radiation-induced patient injury is present. The medical event would have to meet both the quantitative and qualitative criteria to be considered an AO. Enclosure 3, "Proposed Changes to the Medical Event AO Criteria," provides a detailed description and rationale for the NRC staff's proposed changes to the medical event AO criteria.

In Enclosure 4, "Summary of Retrospective Review of Medical Events," staff identifies that a total of 546 medical events were reported between 2010 and 2020, but only about 22 percent (119) were determined to be dose-significant (above the current Criterion III.C.1 dose). The staff found that all events that met the AO reporting requirements under the pre-FY 2018 criteria continued to meet the reporting requirements under the current FY 2018 criteria, which are based on dose. Based on the staff's experience in the implementation of the previous AO criteria and preparation and issuance of AO reports, the staff recommends that the dose-based criterion III.C.1 be retained and used as a screening tool (step 1 in the proposed 2-step process) to identify those medical events that need to be further reviewed for public health and safety significance.

Advances in medical use of byproduct material result in the use of novel radionuclides, new administration procedures, new medical devices, and new treatment targets. As a result, the NRC staff is also proposing to refine criterion III.C.1 to take into consideration several advances in the use of byproduct material and regulatory updates including:

1) adding medical events that are being reported under both 35.3045 and specific license conditions,

2) reflecting developments in new medical radiation treatments that could result in expected doses to a major portion of the bone marrow, or lens of the eye, or to the gonads in excess of the current AO criteria,

3) addressing activity-based medical events to explicitly conform with current regulatory requirements, and

4) removing written directives as a necessary requirement for an AO.

In addition, the NRC staff recommends incorporation of a medical-consequence based qualitative criterion based on deterministic effects (as a new Section III.C.2 (or step 2 in the proposed 2-step process). Consistent with practices at the U.S. Food and Drug Administration and the Department of Health and Human Services' (HHS) for identifying adverse health effects, the NRC staff proposes a new medical-consequence AO criterion that would include events that result (or have a high likelihood of resulting) in a radiation-induced injury causing permanent impairment of bodily function or permanent damage to a body structure, or that need medical or surgical intervention to preclude permanent impairment of a bodily function or permanent

damage to a body structure (see Enclosure 3). The NRC staff asserts that this is equivalent to what is described by HHS as “impairment of a body function or damage to a body structure.,” or HHS “Grade 3 *severe* or *medically significant but not immediately life-threatening* adverse events.” The NRC staff also asserts that this proposed revised criterion adequately captures the subset of medical events that have public health or safety significance. The NRC staff finds that events that cause immediately life-threatening consequences or death (equivalent to HHS Grade 4 or Grade 5, respectively) have *serious* public health or safety significance and should always be reported as AOs. The staff continues to maintain that *mild or moderate* adverse effects (equivalent to HHS Grade 1 or Grade 2, respectively) should not be reported as AOs.

The staff evaluated the effectiveness and feasibility of using the recommended medical-consequence-based criteria to identify events that are significant from a public health or safety standpoint. The table in Enclosure 4 shows that 29 of the 119-total dose-significant AOs reported from medical events have a high likelihood of remaining AOs under the proposed changes to the AO criteria. An additional 12 medical events, which averages to 1-2 medical events per year, were “indeterminant” in terms of meeting the proposed qualitative medical-consequence based AO criteria. For the purposes of the study, medical events considered indeterminant would warrant follow-up questions for information to the licensee to understand the full scope the adverse health effect(s) under the proposed revised criteria. Thus, the range of total AOs under the proposed 2-step process is between 29 – 41. The staff also looked at the retrospective review information on the 29 medical events to see if the four aspects of the medical consequence criteria (i.e., radiation induced injury, high likelihood of radiation induced injury, permanent injury, and intervention to prevent permanent injury) would help to determine if a medical event meets the proposed AO criteria in a timely manner. The staff concluded that the patient-identified injuries (11 of the 29 medical events) delayed identifying unreported medical events but reduced the time after reporting the medical event to describe the extent of the injury. Further the staff concluded that the licensee’s identification of the high likelihood of a radiation induced injury based on the site receiving the unintended dose, the dose delivered to that site, and monitoring the patient helped identify if the criteria was met without long time delays. The staff concluded that the new criteria would have been effective in distinguishing events significant to public health or safety from other medical events and that in most cases, determination of whether an event meets the proposed criteria can be made in a timely manner and expects the same going forward.

The staff does not anticipate that the proposed revisions to the AO criteria will result in additional costs to Agreement States or licensees. Per 10 CFR 35.3045(c), licensees are required to identify “the effect, if any, on the individual(s) that received the administration” resulting in a reported medical event, and it is therefore the licensee’s responsibility to provide the regulator with information on the “effect on the patient.” This expectation is reflected in the OMB clearance for reporting and record-keeping requirements in 10 CFR Part 35. The staff is not proposing any changes to the medical event reporting criteria in 10 CFR 35.3045. However, it will be important for licensees to provide complete and accurate information to allow the NRC to make appropriate AO determinations. Potential AO cases where licensee-submitted information is missing or unclear will necessitate the Agreement State or the NRC to request the required information or additional clarification. This is a normal part of the current AO determination process. Because revised Criterion III.C.1 is being proposed as a screening tool, it will reduce the total number of medical events that would have to be evaluated under Criterion III.C.2. Based on findings from the staff’s retrospective review, the majority of the licensees reporting medical events that meet the current Criterion III.C.1 have historically provided the information staff would be needed to assess whether an event would be an AO under the proposed quantitative and qualitative criteria (as shown in the table in Enclosure 3,

107 out of 119 AOs did not require additional information to determine if they would have been AOs under the proposed revised criteria).

Security Criteria for Category 1 or 2 Sources

The staff proposes changes to the source security criteria to ensure that the AOs reported to Congress capture only those events that are significant to public health or safety. As discussed in SECY-19-0088, the current AO criteria in Section I.C require reporting of any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37, "Physical protection of Category 1 and Category 2 quantities of radioactive material," even if the sources are recovered and there is reasonable assurance that there is no risk to public health or safety. Under the current security criteria, an AO results when a radiography camera (which exceeds the threshold for Category 2 quantity of radioactive material) is stolen and recovered, even if there is reasonable assurance that there was no tampering with the radiography camera and where there was no intent to gain access to (or even knowledge of the presence of) the radioactive material. Events could also be reported as AOs under the current criteria if abandoned or diverted Category 1 or Category 2 sources are recovered with no apparent radiation risk to the public. The staff finds that these types of events do not pose a significant impact on public health or safety and do not warrant notification to Congress. To capture only events that are significant to public health or safety, the staff proposes changes to the source security criteria by revising AO Criterion I.C.1 to exclude events involving sources that are stolen, diverted, or abandoned when it is evident that there was no intent to gain access to the radioactive material, and the sources were recovered with little or no risk to public health or safety.

The staff reviewed historical data on source security events reported as AOs from FY 2010 through FY 2020 to gain insights on the potential revision to this reporting criterion. Only three AO events (documented in the FY 2011, 2018, and 2019 AO reports), all involving radiography cameras, met the current source security criteria during this 10-year period. After reviewing the reported events, the staff concluded that two of the three events would be reported as AOs under the proposed criteria. In the FY 2011 AO event, a radiography camera, along with associated equipment, was stolen from a radiography truck. Despite several attempts, the radiography camera was not recovered at the time of reporting to Congress. This incident posed a significant risk to public health or safety and would be reported to Congress as an AO under the proposed criteria. In the FY 2019 AO event, three radiography cameras were stolen, subsequently recovered, and returned to secure storage the day of the theft. However, in this case, there was evidence of malevolent intent in gaining access to the radioactive material, resulting in a potential risk to public health or safety. Therefore, this event would also be captured as an AO. In the FY 2018 AO event, law enforcement found a stolen vehicle containing a radiography camera within 3 hours of the theft, and the licensee determined that the radiography camera was locked in the back of the truck and no tampering had occurred. For this event, the staff concluded that there was no radiological impact to the public or employees; therefore, this type of event would not be reported as an AO under the proposed criteria.

In addition, AO Criterion I.C.2 includes only radiological sabotage as defined in 10 CFR 73.2, "Definitions," which is consistent with the regulations in 10 CFR Part 73, "Physical protection of plants and materials." The staff proposes adding a reference to the "sabotage" definition 10 CFR 37.5, "Definitions," as well to Criterion I.C.2 to better align with the regulations in 10 CFR Part 37 as it relates to Category 1 and Category 2 quantities of radioactive materials (Enclosure 2).

The staff does not anticipate that these proposed revisions will result in additional costs to Agreement states or licensees. This expectation is already accounted for in the reporting requirements of 10 CFR 37.57.

Licensee Reports

NRC and Agreement State licensees would continue to submit the required reports on a wide spectrum of events, including events that are not significant from the standpoint of public health and safety, but which provide data useful to the NRC and Agreement State regulators in monitoring operating experience. These reports, in turn, allow the NRC to follow up on events, identify deficiencies in the safe use of radioactive material, ensure that corrective actions are taken to prevent recurrence, and determine if other licensees might be experiencing the same or similar challenges. The NRC uses this information to assess trends or patterns, identify generic issues or concerns, and recognize any inadequacy or unreliability of specific equipment or procedures.

Comments by the Organization of Agreement States and Advisory Committee on the Medical Uses of Isotopes

The NRC staff provided the draft proposed revisions to the OAS on May 5, 2021, and to the ACMUI on March 17, 2021, for their review and comment.

The OAS Board generally supported the proposed revisions, but also offered additional comments and suggested text changes for the NRC's consideration. The OAS Board believes that the NRC 1980 policy exempting extravasations from being included in the definition of medical events keeps potentially significant extravasations from being reported as AOs. Until such time that the NRC rescinds the 1980 policy, the OAS Board believes this type of event must be captured in order to maintain acceptable practices and safety standards for patients. The OAS Board recommended specific revisions to the medical AO criteria that it believes will capture extravasations as AOs.

The NRC staff considered the OAS Board's recommendations and concluded that revisions of the AO criteria to capture extravasations as AOs would be outside the scope of the Commission's direction in SRM-SECY-19-0088 to make specific, limited changes to the medical AO criteria. The staff is currently reviewing a petition for rulemaking and considering whether significant extravasations should be reported as medical events and will provide a recommendation to the Commission in Spring 2022. The proposed medical event AO criteria is written to capture medical events with a broad spectrum of medical consequences. If extravasations are reported in the future as medical events, the proposed criteria will not need to be revised to capture future extravasation AOs. Under current procedures, if the NRC or an Agreement State becomes aware of an extravasation event that the NRC concludes would be of interest to Congress and the public, the NRC can include the event in the AO annual report under Appendix B, "Other Events of Interest".

The ACMUI AO subcommittee fully endorsed the proposed change to the medical AO criteria as noted in Enclosure 5. The full ACMUI committee voted unanimously to adopt the subcommittee report and recognized the dissenting opinion suggesting an even broader scope of revisions. The ACMUI fully supported the proposed changes to medical AO Criterion III.C and did not suggest any changes to the staff's recommendation or to the other AO criteria. The ACMUI reaffirmed an earlier request made by the ACMUI subcommittee for the NRC to provide a communication to be distributed to all NRC and Agreement State medical licensees to inform them of best practices in preparing a medical event report so that complete and accurate information is submitted in describing the event, root cause analysis of why the event occurred, and the medical effect on the individual(s). While this recommendation is outside the scope of this SECY paper, it is being addressed separately, and will be communicated with the public and licensee community appropriately.

The 2021 dissenting opinion proposed excluding events reported under 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child," from the AO Criterion in I.A.2. "Human Exposure to Radiation from Licensed Material." The individual proposed to include these events under the AO criterion in III.C., which would then make the medically related embryo/fetus AO reporting subject to a medical consequence criterion. This is similar to the position recommended by the ACMUI in its 2015 ACMUI AO criteria report. The 2015 ACMUI report, the ACMUI Patient Advocate's dissenting opinion, and the staff's rationale for not accepting this recommendation was provided in SECY-17-0019, "Final Revision to Policy Statement on Abnormal Occurrence Reporting Criteria" (ADAMS Accession No. ML16195A192).

The staff considered the dissenting opinion and continues to support its conclusions in SECY-17-0019. The staff concluded that there should be no difference in AO reporting for an embryo/fetus dose whether the source was a medically related exposure or exposure from another NRC-regulated radioactive material. Medically related embryo/fetus doses should continue to be reported under AO Criterion I.A. In 2002, the NRC intentionally set the reporting criterion for the embryo/fetus in 10 CFR 35.3047 to be the same as the reporting threshold of AO Criterion I.A.2. The staff considers this dose to the embryo/fetus to be significant from the standpoint of public health or safety. In addition, the staff observed that the dissenting opinion was included in the subcommittee's presentation to the full committee. When the full committee approved the report, it neither discussed nor recommended revising the proposed AO criteria to include the position expressed in the 2021 dissenting opinion. For these reasons, the NRC staff concluded that no revision was needed to the 2021 proposed AO criteria.

RECOMMENDATION:

The staff recommends that the Commission approve for publication in the *Federal Register* the proposed limited revisions to the criteria (Enclosure 6) for a 90-day public comment period.

COORDINATION:

The Office of the General Counsel reviewed this package and has no legal objection.

Signed by Dorman, Dan
on 02/01/22

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Enclosures:
1. Current Abnormal Occurrence Criteria
2. Comparison of Current and Proposed Abnormal Occurrence Criteria
3. Summary of Proposed Changes to the Medical Event Abnormal Occurrence Criteria
4. Summary of Retrospective Review of Medical Events
5. ACMUI Report on Abnormal Occurrence Criteria for Medical Use
6. Draft *Federal Register* notice

SUBJECT: SECY-21-XXXX PROPOSED LIMITED REVISION TO POLICY STATEMENT ON REPORTING ABNORMAL OCCURRENCES CRITERIA
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