

**U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Use of Isotopes**

Abnormal Occurrence Subcommittee

Final Report

June 1, 2021

Subcommittee Members:

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Subcommittee Charge:

During the March 30, 2020 Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, ACMUI Chairman, Dr. Darlene Metter, established an Abnormal Occurrence (AO) Subcommittee to (1) Define patient harm in AO; (2) Reassess the current AO criteria; (3) Define goals of AO criteria and reporting; (4) Evaluate whether the current AO criteria are appropriate regarding public health and safety; and (5) Comment on any NRC staff proposed AO changes. This subcommittee was delayed until July 27, 2020, following approval by the Commission for U.S. Nuclear Regulatory Commission (NRC) staff to develop and propose a limited revision to the AO criteria in the medical event area.

Background:

The NRC policy statement on AO criteria was developed to comply with Section 208 of the Energy Reorganization Act of 1974, as amended, and initially published in the Federal Register on February 24, 1977 (42 FR 10950)¹. The intent of the act is to keep Congress and the public informed of unscheduled incidents or events which the NRC considers significant from the standpoint of public health and safety. The policy reflects a range of health and safety concerns and applies to incidents and events involving a single individual, as well as those having overall impact on the general public. An AO is defined as “an unscheduled incident or event which the NRC determines to be significant from the standpoint of public health or safety”.

AOs are required to be reported annually to Congress, and that the discussion of each event must include (1) the date and place of each occurrence; (2) the nature and probable consequence of each occurrence; (3) the cause or causes of each; and (4) any action taken to prevent reoccurrence. The AO report is also widely disseminated to the public within 15 days of sending it to Congress.

The AO criteria has been revised several times, with the most recent revision to the medical AO criteria being published in the Federal Register on October 2, 2017 (82 FR 45907)².

In leading up to this revision, the NRC prepared its March 15, 2015 SECY-15-0040³ paper to inform the Commission that it was proposing revisions to the AO criteria. The ACMUI provided comments on the draft SECY Paper in its AO subcommittee report dated April 15, 2013⁴. The ACMUI recommended removing the applicability of AO criteria from section I.A.2. for

notifications of embryo/fetal exposures reported under 10 CFR 35.3047, and replacing the dose criteria in Section III.C. to:

1. Medical Event that, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State, results in one or more of the following:
 - a. Unintended or unexpected permanent functional damage to an organ.
 - b. Unintended or unexpected permanent functional damage to a physiological system.
 - c. A significant unexpected adverse health effect.
 - d. Death.
2. Notification under 10 CFR 35.3047 of an event involving an unintended dose to an embryo/fetus or a nursing child that results in a significant adverse health impact to the embryo/fetus or child, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State.

The NRC did not agree with the movement of the AO criteria for embryo/fetal exposures reported under 10 CFR 35.3047 to section III.C. However, the NRC kept the Medical Event and dose criteria in section III.C. and included the ACMUI recommendation for unintended or unexpected permanent functional damage to an organ or a physiological system; a significant unexpected adverse health effect; or death.

The Commission's June 30, 2015 SRM-15-0040⁵ approved publication of the draft revised AO criteria, however, the Commission removed the staff's (and ACMUI's) recommended text associated with unintended or unexpected permanent functional damage to an organ or a physiological system; a significant unexpected adverse health effect; or death.

The NRC published its proposed AO criteria for public comment in the Federal Register (30 FR 49177)⁶ August 17, 2015. The ACMUI provided comments in its AO subcommittee final report dated November 6, 2015⁷. This document recommended once more to move the reporting of AOs for embryo/fetus notifications reported under 10 CFR 35.3047 to section III.C. and to make it the same as the AO criteria for a Medical Event, and once more recommended no dose criteria in section III.C. for medical event AO's but replacing it with a criterion of unintended permanent functional damage to an organ or a physiological system as determined by an independent physician deemed qualified by NRC or an Agreement State. The NRC published the revised AO criteria on October 2, 2017 (82 FR 45907).

In response to a Staff Requirements Memorandum (SRM-M190423)⁸, the NRC conducted an evaluation of the AO criteria established in 2017 to determine 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 (SECY-19-0088)⁹. This evaluation included a review of significant health effects associated with medical AOs over the past 5 years and included the results from previous evaluations from SECY-15-0040 and solicited input from the Organization of Agreement States and the ACMUI. The NRC concluded that the medical event AO criteria may capture events that are not significant from the standpoint of public health or safety and recommended that a limited revision to the medical event AO criteria be developed. In a July 24, 2019 Teleconference Meeting¹⁰, the ACMUI concurred with the NRC staff's conclusion stating, "The current medical event abnormal occurrence criteria are not appropriate and need to be reviewed and revised." The Commission

approved the NRC recommendation to develop and propose a limited revision to the AO criteria in the medical event area on July 27, 2020¹¹.

NRC Proposed Revisions to Medical Event Abnormal Occurrence Criteria:

The following shows the current proposed changes from Enclosure 1 to the Medical Event AO criteria under Section III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events:

- C. Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects¹⁶
 - 1. A medical event, as defined in § 35.3045 or in a specific license (based on specific 10 CFR 35.1000 licensing guidance), which results in an unintended dose that:
 - (a) Is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal to or greater than 2.5 Gy (250 rad) to the gonads; or
 - (b) Exceeds, by 10 Gy (1,000 rad), the ~~expected dose~~ or dose that would have resulted from delivery of the prescribed dose, prescribed dosage or prescribed activity to any other organ or tissue from the administration ~~defined in the written directive~~; and
 - 2. A medical event, as defined in § 35.3045 or in a specific license (based on specific 10 CFR 35.1000 licensing guidance), ~~which involves that results or has high probability of resulting in:~~
 - (a) ~~A dose or dosage that is at least 50 percent greater than that prescribed~~ Radiation induced injury causing permanent impairment of bodily function or permanent damage to a body structure¹⁷, or
 - (b) Radiation induced injury in which medical or surgical intervention is needed to preclude permanent impairment of a bodily function or permanent damage to a body structure¹⁷.
~~A prescribed dose or dosage that:~~
 - (i) ~~Uses the wrong radiopharmaceutical or unsealed byproduct material; or~~
 - (ii) ~~Is delivered by the wrong route of administration; or~~
 - (iii) ~~Is delivered to the wrong treatment site; or~~
 - (iv) ~~Is delivered by the wrong treatment mode; or~~
 - (v) ~~Is from a leaking source or sources; or~~
 - (vi) ~~Is delivered to the wrong individual or human research subject.~~

¹⁷ NRC will use dose and medical consequence information from the licensee, inspections, physicians (referring, licensee, or consultant physicians), other professionals (e.g., medical physicist, radiation biologist), and other resources to make its AO determination.

Enclosure 2 provides a summary and explanation for each of the proposed changes to the Medical Event AO criteria.

Enclosure 3 provides a table showing the number of medical Abnormal Occurrence (AO) events reported to Congress by Fiscal Year (FY) from 2010 through 2020. It also includes the number of medical events reported to the NRC per FY, number that resulted in pre-2018 AO criteria, number under the revised 2018 criteria, and the number that had a high possibility of meeting the proposed medical-consequence AO criteria.

Discussion:

The ACMUI has repeatedly discussed concerns with NRC Staff that medical use incidents and events being included in AO reports may not be significant from the standpoint of public health or safety. The ACMUI has been concerned that the medical AO criteria is overly conservative and tends to capture medical events that are known risks for the procedure, and not significant from the standpoint of public health or safety. The ACMUI has also expressed concerns that the conservative nature of the current medical AO criteria has resulted in an over-representation of medical events in the AO report to Congress, which has led to the perception that medical use licensees have more significant radiation safety incidents than non-medical users of radioactive material. Since previous revision of the AO criteria, over 95% of the AOs reported to Congress are medical use related from which the majority did not expect any adverse health effects to the patient. AOs should have a reporting threshold such that only those events considered significant from the standpoint of public health or safety are reported to Congress. As previously stated, and endorsed by the ACMUI, a medical event AO should result in patient harm such as unintended or unexpected permanent functional damage to an organ or physiological system, a significant unexpected adverse health effect, or death.⁹

The subcommittee believes that the goal of AO reporting is to elevate significant events to the level of Congressional and Public attention so that they gain the appropriate consideration and resources for mitigation and corrective action necessary to prevent future similar occurrences. Reporting of events that are not significant with respect to public health or safety is inconsistent with the statutory threshold for what constitutes an AO and inappropriately introduces confusion as to the significance of the event. It is important to note that revising the medical AO reporting criteria will not adversely influence public health and safety. Regulatory reporting requirements of medical events currently applicable to NRC and Agreement State licensees remain in place. Therefore, licensees will continue to submit required reports on a broader range of medical events, and NRC and Agreement States will continue to monitor these events, identify trends, and evaluate performance and corrective actions.

The current NRC proposed changes establish a two-step criterion for Medical Events to be reported as an AO. The first would be to exceed some level of a tissue/organ dose threshold, and the second would be to result in some type of radiation induced patient injury. Both conditions must be met to be considered an AO. This would address the concerns from the regulatory community to have a discrete dose metric to eliminate potential AOs below this threshold, and the concerns from the ACMUI (and others) to have some measurement of significant patient harm that decides if the event is an AO. The dose threshold levels are essentially the same as in the current AO criteria, with the addition of the condition that it is an unexpected dose in excess of that intended from the prescribed dose, dosage, or activity. The radiation induced injury criteria are deterministic effects that either result or have a high probability of resulting in permanent impairment of bodily function or permanent damage to a

body structure, or in which medical or surgical intervention is needed to preclude permanent impairment of a bodily function or permanent damage to a body structure.

The NRC has the responsibility to determine whether both the dose and radiation induced injury criteria are met, and when medical events are determined to be AOs. The NRC will make this determination based on dose and medical consequence information provided by the licensee, inspections, physicians (referring, licensee, or independent physicians), other health care professionals (including medical physicist and radiation biologists), and other resources. While the current Medical Event reporting requires a brief description of the event; why the event occurred; the effect, if any, on the individual(s) who received the administration; and what actions, if any, have been taken or are planned to prevent recurrence; it will be especially important for licensees to provide complete and accurate information to allow the NRC to make an appropriate AO determination.

From the data in Enclosure 3, "Retrospective Review of the Medical Events reported to NRC between 2010 and 2020 and to Congress as AOs", there have been an average of 12 medical AOs reported to Congress each year. The table shows that there was essentially no difference in determining the medical events reported as AOs before 2017 and determining if they were AOs based on the 2018 criteria. However, the newly proposed AO criteria would reduce this number to an average of 3 or 4 medical AOs reported to Congress each year. Based on this review, the newly proposed medical AO criteria will better identify those medical events that are significant from a public health or safety perspective and eliminate reporting of those medical events with little or no adverse health consequence.

Subcommittee Recommendations:

1. The Subcommittee fully supports the proposed changes to the medical AO criteria as outlined in Enclosure 1.
2. The Subcommittee recommends that some type of communication be prepared for distribution 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 provided in describing the event, root cause analysis on why the event occurred, and the medical effect on the individual(s). This same recommendation was also previously made by the ACMUI Subcommittee on the Appropriateness of Medical Event Reporting¹².

References:

1. Federal Register, 10950, February 24, 1977, Vol. 42, No. 37, Nuclear Regulatory Commission, Policy Statement on Abnormal Occurrence Criteria
2. Federal Register, 45907, October 2, 2017, Vol. 82, No. 189, Nuclear Regulatory Commission, Revised Policy Statement on Abnormal Occurrence Criteria
3. NRC SECY-15-0040, Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria, March 19, 2015
4. ACMUI, Report on Abnormal Occurrence Criteria for Medical Use, April 15, 2013
5. NRC SRM-15-0040, Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria, June 30, 2015

6. Federal Register, 49177, August 17, 2015, Vol. 80, No. 158, Nuclear Regulatory Commission, Abnormal Occurrence Reports – Proposed Revision to Policy Statement; Request for Comments
7. ACMUI, Final Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress, November 6, 2015
8. NRC SRM-M190423, Briefing on Strategic Programmatic Overview of the Fuel Facilities and the Nuclear Materials Users Business Lines, May 8, 2019
9. NRC SECY-19-0088 Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423, September 16, 2019
10. ACMUI Teleconference, Meeting Summary, July 24, 2019
11. NRC SRM-19-0088, Staff Requirements - SECY-19-0088 - Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423, July 27, 2020
12. ACMUI Subcommittee on the Appropriateness of Medical Event Reporting, Draft Report, August 28, 2019

The ACMUI unanimously approved this report, and the recommendations provided within, during its public teleconference meeting on May 27, 2021.

**Respectfully submitted, June 1, 2021
Abnormal Occurrence Subcommittee
Advisory Committee on the Medical Use of Isotopes
U.S. Nuclear Regulatory Commission**

Dissenting Opinion:

One member of the current AO subcommittee has a different perspective on reports of embryo/fetal events reported under 10 CFR 35.3047 being included in AO criterion I.A.2. with a dose threshold of 50 mSv. While this criterion was not part of the current NRC proposed changes, it was previously addressed in the two prior ACMUI AO subcommittee reports. This subcommittee member supports the previous AO subcommittees' position that medical-related events reported under 35.3047 be screened under AO Criteria III.C. since the event exposure was due to the medical use of radioactive material. It is inappropriate to judge any medical related exposures under AO criterion I.A. (Human Exposure to Radiation from Licensed Material) due to the relatively low dose threshold criterion. It is also inconsistent with the goal of the AO criteria and the current NRC proposed revisions to have a threshold level set that is not significant with respect to health or safety. The AO criteria should be a high reporting threshold so that only those events considered significant from the standpoint of public health or safety and result in measurable harm are reported to Congress. Embryo/fetal exposures of 50 mSv would not result in any deterministic effects and have an exceedingly small potential increased risk for stochastic effects. The current low dose threshold criterion for an unintended dose to an embryo/fetus will continue to result in several reported AOs each year from radiopharmaceutical therapy patients unknowingly being pregnant at the time of their therapy. The argument that there should not be 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, ignores that there are already two different regulatory reporting thresholds for the embryo/fetus, one in 35.3047 for medical use and the other in 20.2203(a)(2)(iv) for general radiation protection. This subcommittee member supports excluding events reported under 35.3047 from the AO criteria in I.A.2. and including these events under AO criteria in III.C. which will result in unintended radiation induced injury causing permanent impairment of bodily function or permanent damage to a body structure.

Respectfully submitted,
Michael Sheetz