

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC–2023-0075]

Abnormal Occurrence Reporting

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a limited revision to its policy statement on reporting abnormal occurrences (AOs) to Congress. The revised policy statement provides more specific language to the medical event criteria to better identify those incidents and events that the Commission considers significant from the standpoint of public health or safety. The revised AO criteria contain additional language to add clarity, helping to delineate abnormal occurrence events from nonreportable events which may have been reviewed under the previous criteria.

DATES: The policy statement is effective on **[INSERT DATE XX DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID NRC–2023-0075 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC–2023-0075. Address questions about NRC dockets to Dawn

Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Rigel Flora, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-3890; e-mail: Rigel.Flora@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438), defines an AO as an unscheduled incident or event that the NRC determines to

be significant from the standpoint of public health or safety. ~~The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually.~~ As required by Section 208, the discussion for each event includes the date and place, the nature and probable consequences, the cause or causes, and the action taken to prevent recurrence. The Commission must also widely disseminate the AO report to the public within 15 days of publishing the AO report to Congress. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually.

Abnormal Occurrence Reporting

The Commission ~~has~~ developed the AO policy statement to comply with Section 208 of the Energy Reorganization Act of 1974, as amended. The annual AO report is developed based upon the criteria in the AO policy statement. The AO report keeps Congress and the public informed of unscheduled incidents or events that the Commission considers significant from the standpoint of public health or safety. This policy addresses a range of health or safety concerns and applies to incidents and events involving a single individual, as well as those having an overall impact on the general public. The AO criteria set out in the policy use a reporting threshold so that only those events considered significant from the standpoint of public health or safety are reported to Congress.

Licensee Reports

The changes to the general policy statement do not change the reporting requirements for licensees in ~~NRC Commission~~ or Agreement State regulations, license conditions, or technical specifications. The licensees will continue to submit required reports on a wide range of events, including instrument malfunctions and deviations from

normal operating procedures that may not be significant from the standpoint of the public health or safety but provide data useful to the ~~NRC Commission~~ in monitoring operating trends of licensed facilities and in comparing the actual performance of these facilities with their design and/or licensing basis.

II. Opportunity for Public Participation

The NRC is revising the AO criteria for medical events to improve conformance with current regulatory requirements and reflect new developments in medical radiation treatments. In developing the revised AO criteria, the NRC staff consulted with experts in the reactor and nuclear material areas, including the Advisory Committee on the Medical Uses of Isotopes (ACMUI), and coordinated with Agreement States. The NRC staff undertook this effort to ensure events that have the potential for significant health or safety consequences are properly identified and reported to Congress.

The NRC staff provided multiple opportunities for public participation. Staff shared the preliminary proposed changes with the prepared an Organization of Agreement States (OAS) ~~letter highlighting the proposed changes and inviting for~~ comments. Several coordination meetings were held with ACMUI providing updates on the process and allowing opportunity for comments. Additionally, the proposed AO criteria ~~was~~ were published in the *Federal Register* (FR) on May 19, 2023 (88 FR 32144), for a 90-day public comment period. No comments were received.

III. Coordination with NRC Agreement States

The NRC coordinated with the Agreement States throughout the development of this final policy statement. On May 5, 2021, the NRC provided a preliminary proposed

policy statement to the Agreement States for their review and comment. The OAS ~~Organization of Agreement States~~ Executive Board (Board) provided ~~one letter in response with their~~ comments dated July 26, 2021 (ADAMS Accession No. ML22335A582). The NRC staff did not make any changes in response to the comments.

While ~~the comments provided by~~ the Board ~~were was~~ generally supportive of the 2021 preliminary proposed changes, it suggested edits to the AO criteria that would be inclusive of nuclear medicine extravasations, which are currently excluded from medical event reporting requirements~~there were suggestions to edit the criteria to capture extravasations for reporting~~. The NRC staff considered the Board's recommendations and concluded that revision of the AO criteria to capture extravasations is outside the scope of the Commission's direction to make limited changes to the medical AO criteria in the policy statement on AO reporting. However, the NRC staff submitted SECY-24-0067, Proposed Rule: Reporting Nuclear Medicine Injection Extravasations as Medical Events (ADAMS Accession Package No. ML24016A290) on August 13, 2024, to the Commission for its consideration. The proposed rule would amend the regulations in Title 10 of the Code of Federal Regulations (10 CFR) Part 35, "Medical Use of Byproduct Material," to require reporting of certain nuclear medicine injection extravasations as medical events.~~Making such changes would go against the NRC 1980 policy exempting extravasations from being included in the definition of medical events. Additionally, the staff believes that if an extravasation was deemed to be of importance or interest to Congress and the public, it could be included in Appendix B: Other Events of Interest.~~

IV. Coordination with the Advisory Committee on the Medical Uses of Isotopes

The ACMUI submitted comments on the preliminary proposed ~~AO~~-policy statement in a final report dated June 1, 2021 (ADAMS Accession No. ML21227A001).

These comments concerned the reporting of events that the ACMUI may not find to be significant for public health or safety. The ACMUI recommended that criteria in Section III.C “For Medical Licensees” be adjusted to remove dose-based criteria and instead focus on radiation induced injuries, significant adverse health effects, or death. In response to SRM-SECY-22-0009 (ADAMS Accession Package No. ML23088A089), NRC staff ~~was directed to~~ retained ed previous Section III.C criteria (ADAMS Accession No. ML12166A196) and ~~thus~~ did not make any changes in response to ACMUI's ~~the~~ recommendation. The final ACMUI comment concerned moving reporting of embryo/fetal exposure from Section I.A “Human Exposure to Radiation from Licensed Material” to Section III.C. The NRC staff did not make any changes in response to this comment.

V. Congressional Review Act

This policy statement is not a rule as defined in the Congressional Review Act (5 U.S.C. 801-808).

Dated: [INSERT DATE].

For the Nuclear Regulatory Commission.

Carrie M. Safford,
Secretary of the Commission.

Attachment – Abnormal Occurrence Statement of Policy

APPENDIX A

ABNORMAL OCCURRENCE CRITERIA

ABNORMAL OCCURRENCE GENERAL STATEMENT OF POLICY

The U.S. Nuclear Regulatory Commission (NRC) will apply the following policy in determining whether an incident or event at a facility or involving an activity that is licensed or otherwise regulated by the Commission or an Agreement State is an abnormal occurrence (AO):¹

An incident or event is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event has a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:

- (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission or Agreement State;
- (2) Major degradation of essential safety-related equipment;
- (3) Major deficiencies in design, construction, use of, or management controls for, facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement State; or
- (4) Substantiated case of actual loss, theft, or diversion of risk-significant radioactive material licensed by or otherwise regulated by the Commission or Agreement State.

Abnormal Occurrence Criteria

¹ Events reported to the NRC by Agreement States that reach the threshold for reporting as AOs will be reported as such by the Commission.

The following presents the criteria, by types of events, used to determine which events will be considered for reporting as AOs.

I. All Licensees²

A. Human Exposure to Radiation from Licensed Material

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in:
 - (a) An annual total effective dose equivalent (TEDE) of 250 millisieverts (mSv) (25 rem) or more;
 - (b) An annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more;
 - (c) An annual dose equivalent to the lens of the eye of 1 Sievert (Sv) (100 rem) or more;
 - (d) An annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more;
 - (e) A committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or
 - (f) An annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.
2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem)

² Medical patients and human research subjects are excluded from consideration under these criteria, and these criteria do not apply to medical events defined in § 35.3045 of Title 10 of the Code of *Federal Regulations* (10 CFR), "Report and notification of a medical event," which are considered in AO Criteria III.C.

or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by an independent physician³ deemed qualified by the NRC or Agreement State.

B. Discharge or Dispersal of Radioactive Material from Its Intended Place of Confinement

The release of radioactive material to an unrestricted area in concentrations that, if averaged over a period of 24 hours, exceed 5,000 times the values specified in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20, "Standards for protection against radiation," unless the licensee has demonstrated compliance with § 20.1301, "Dose limits for individual members of the public," using § 20.1302(b)(1) or § 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

C. Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security

³ "Independent physician" is defined as a physician not on the licensee's staff and who was not involved in the care of the patient involved.

Breach⁴⁵⁶

1. 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." Excluded from reporting under this criterion are those events involving sources that are lost or abandoned under the following conditions: sources that have been lost and for which a reasonable attempt at recovery has been made without success, or irretrievable well logging sources as defined in § 39.2, "Definitions." These sources are only excluded if there is reasonable assurance that the doses from these sources have not exceeded, and will not exceed, the reporting thresholds specified in AO Criteria I.A.1 and I.A.2 and the agency has determined that the risk of theft or diversion is acceptably low.
2. An act that results in radiological sabotage as defined in § 37.5 and

⁴Information pertaining to certain incidents may either be classified or under consideration for classification because of national security implications.

Classified information will be withheld when formally reporting these incidents in accordance with Executive Order 13526, "Classified National Security Information," as amended (75 FR 707; January 5, 2010), or any predecessor or successor order to require protection against unauthorized disclosures. Any classified details about these incidents would be available to Congress upon request, under appropriate security arrangements.

⁵ Information pertaining to certain incidents may be Safeguards Information as defined in § 73.2 because of safety and security implications. The AO report would withhold specific Safeguards Information in accordance with Section 147 of the Atomic Energy Act of 1954, as amended. Any safeguards details regarding these incidents would be available to Congress upon request, under appropriate security arrangements.

⁶ Reporting lost or stolen material is based on the activity of the source at the time the radioactive material was known to be lost or stolen. If, by the time the AO report is due to Congress, the radioactive material has decayed below the thresholds listed in Appendix A to 10 CFR Part 37, the report will clarify that the radioactive material has decayed below the thresholds.

§ 73.2.

3. Any substantiated⁷ case of actual theft, diversion, or loss of a formula quantity of special nuclear material,⁸ or an inventory discrepancy of a formula quantity of special nuclear material that is judged to be caused by theft or diversion.
4. Any substantial breakdown⁹ of physical security, cyber security, or material control and accountability programs that significantly weakens the protection against loss, theft, diversion, or sabotage.
5. Any significant unauthorized disclosures (loss, theft, and/or deliberate disclosure) of classified information that harms national security or of Safeguards Information that threatens public health or safety.

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D. Initiation of High-Level NRC Team Inspection¹⁰

II. Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of a license technical specification (TS) (§ 50.36(c)).
2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

⁷ "Substantiated" means a situation in which there is an indication of loss, theft, or unlawful diversion, such as an allegation of diversion, report of lost or stolen material, or other indication of loss of material control or accountability that cannot be refuted following an investigation, and requires further action on the part of the agency or other proper authorities.

⁸ "Formula quantity of special nuclear material" is defined in § 70.4, "Definitions."

⁹ A substantial breakdown is defined as a red finding under the Reactor Oversight Process (ROP) in the physical security inspection program or any plant or facility determined to have overall unacceptable performance.

¹⁰ This item addresses the initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program" (ADAMS Accession No. ML13175A294), or initiation of any accident review groups, as described in MD 8.9, "Accident Investigation" (ADAMS Accession No. ML13319A133).

3. **Loss** of plant capability to perform essential safety functions so that a release of radioactive materials that could result in exceeding the dose limits of 10 CFR Part 100, "Reactor site criteria," or five times the dose limits of General Design Criteria (GDC) 19, "Control Room," in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50, "Domestic licensing of production and utilization facilities," could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

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B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report or TS that requires immediate remedial action.
2. Personnel error or procedural deficiencies that result in the loss of plant capability to perform essential safety functions such that a release of radioactive materials exceeding the dose limits of 10 CFR Part 100 or five times the dose limits of GDC 19 in Appendix A to 10 CFR Part 50, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any operating reactor events or conditions evaluated by the NRC ROP to be the result of or associated with licensee performance issues of high safety significance.¹¹

¹¹ The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process" (ADAMS Accession No. ML17347B670), green is used for very low safety significance, white is used for low to moderate safety significance,

- D. Any operating reactor events or conditions evaluated by the NRC Accident Sequence Precursor (ASP) program to have a conditional core damage probability (CCDP) or change in core damage probability (Δ CDP) of greater than or equal to 1×10^{-3} .¹²
- E. Any operating reactor plants that are determined to have overall unacceptable performance or are in a shutdown condition as a result of significant performance problems and/or operational event(s).¹³
- III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events
- A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal
1. An accidental criticality.
 2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.
 3. A serious safety-significant deficiency in management or procedural controls.

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yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered AOs.

¹² Results from the NRC Accident Sequence Precursor program are used to monitor agency performance against the agency's strategic safety goal (e.g., ensure the safe use of radioactive materials) and objectives (e.g., prevent and mitigate accidents and ensure radiation safety). A precursor event with a CCDP or Δ CDP of greater than or equal to 1×10^{-3} is used as a performance indicator for the strategic safety goal by determining that there have been no significant precursors of a nuclear reactor accident and that there have been no more than one significant adverse trend in industry safety performance.

¹³ Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program" (ADAMS Accession No. ML19256A191), or under NRC IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns" (ADAMS Accession No. ML17116A273). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

B. Fuel Cycle Facilities¹⁴

1. 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).¹⁵
2. An NRC-ordered safety-related or security-related immediate remedial action.

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 conditions of a license¹⁷, which results in an unintended dose:
 - (a) That 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

¹⁴ Criterion III.A also applies to fuel cycle facilities.

¹⁵ High-consequence events for facilities licensed under 10 CFR Part 70, "Domestic licensing of special nuclear material," are those that could seriously harm the worker or a member of the public in accordance with § 70.61, "Performance requirements." The integrated safety analysis conducted and maintained by the licensee or applicant of 10 CFR Part 70 fuel cycle facilities identifies such hazards and the safety controls (§ 70.62(c)) applied to meet the performance requirements in accordance with § 70.61(b) through (d). Fuel cycle facilities licensed under 10 CFR Part 40, "Domestic licensing of source material," or certified under 10 CFR Part 76, "Certification of gaseous diffusion plants," have licensing basis documents that describe facility specific hazards, consequences, and those controls used to prevent or mitigate the consequences of such accidents. For these facilities, a high-consequence event would be a release that has the potential to cause acute radiological or chemical exposures to a worker or a member of the public similar to that defined in Appendix A to Chapter 3, Section A.2, of NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications—Final Report," issued June 2015, under "Consequence Category 3 (High Consequences)" (ADAMS Accession No. ML15176A258).

¹⁶ Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.

or greater than 2.5 Gy (250 rad) to the gonads; or

- (b) To any other organ or tissue from the administration that exceeds, by 10 Gy (1,000 rad), the intended dose or the dose that would have resulted from delivery of the prescribed dose, prescribed dosage, or prescribed activity; **and**

and

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3.2. A medical event, as defined in § 35.3045 or in conditions of a license¹⁷

- a. **A** dose or dosage that is at least 50 percent greater than that prescribed, or
- b. 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.

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¹⁷ "In conditions of a license" means either the specific 35.1000 medical criterion can be written out in a license condition, or a license condition can incorporate a commitment to use the applicable criteria.