[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0176]

Abnormal Occurrence Reports

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy revision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a revision to its policy statement on reporting abnormal occurrences (AOs) to Congress. The revised policy statement adds more specific criteria for determining those incidents and events that the Commission considers significant from the standpoint of public health or safety for reporting to Congress and the public, and makes the policy consistent with recent changes to NRC regulations. The revised AO criteria contain more discrete reporting thresholds, making them easier to implement and ensuring more consistent reporting.

DATES: This revision to the policy statement is effective on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID **NRC-2015-0176** when contacting the NRC about the availability of information regarding this action. You may obtain publicly-available information related to this action using any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID **NRC-2015-0176**. Address questions about NRC dockets to Carol Gallagher;

telephone: 301-415-3463; e-mail: Carol.Gallagher@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 http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then 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, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. For the convenience of the reader, the ADAMS Accession numbers are provided in a table in Section VIII, "Availability of Documents," of this document.

- **The NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Tanya Palmateer Oxenberg, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-2437; e-mail: Tanya.Oxenberg@nrc.gov.

SUPPLEMENTARY INFORMATION:

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I. Background

Section 208, "Abnormal Occurrence Reports," of the Energy Reorganization Act of 1974, as amended (Pub. L. 93-438) (the Act), 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 (Pub. L. 104-66) requires that AOs be reported to Congress annually. As required by Section 208 ~~of the Act~~, the discussion for each reported 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.

Abnormal Occurrence Reporting

The Commission has developed the AO policy statement to comply with Section 208 of the Energy Reorganization Act. The intent of the Act is to keep Congress and the public informed of unscheduled incidents or events that the Commission considers significant from the standpoint of public health or safety. The policy reflects a range of health and safety concerns and applies both to incidents and events involving a single individual and to those having an overall impact on the general public. The AO criteria use a high 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 policy statement do not change the reporting requirements for NRC licensees in Commission regulations, license conditions, or technical specifications. The NRC 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 public health or safety but that provide data useful to the Commission in monitoring the 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

To develop the revised AO criteria, the NRC staff evaluated several AO approaches and 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 that it was properly identifying those events that have the potential for significant health or safety consequences are reported to Congress.

After an evaluation, the NRC staff incorporated several comments provided by the States and ACMUI into the draft revision in SECY-15-0040, "Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria," dated March 19, 2015 (ADAMS Accession No. ML12166A091). The proposed AO policy statement that was published for comment included the Commission's subsequent direction in the staff requirements memorandum (SRM) for SECY-15-0040, dated June 30, 2015 (ADAMS Accession No. ML15181A030). The proposed AO criteria was published in the *Federal Register* (FR) on August 17, 2015 (80 FR 49177), for a 90-day public comment period.

The NRC received three comment letters on the proposed AO criteria published in the FR from the Organization of Agreement States (OAS) (ADAMS Accession No. ML16209A194), Washington State Department of Health (WDH) (ADAMS Accession No. ML16209A199), and the Commonwealth of Virginia Department of Health (VDH) (ADAMS Accession No. ML16209A196). Each letter contained multiple comments. In summary, the comments asked the NRC to (1) revise and/or remove the dose threshold for reporting AO events to Congress on unintended exposures to an adult and a minor or an embryo/fetus, (2) add "medical physicist" or revise "independent physician" in the requirement to obtain the determination of an independent physician, (3) remove the requirements for "irretrievable well logging sources," (4) clarify the applicability of the "substantial breakdown" provision in Criterion I.C.4 to materials licensees, and (5) remove or modify Criterion III.C medical events.

III. Coordination with NRC Agreement States

The NRC coordinated with the Agreement States throughout the development of this final policy statement. In October 2013, the NRC provided a preliminary proposed policy statement to the Agreement States for their review and comment. The Agreement States provided comments on the preliminary proposed policy statement. Several comments resulted in revisions to the proposed AO criteria. A summary of the Agreement State comments and the NRC staff responses to those comments are available at ADAMS Accession No. ML14346A274.

The NRC received comment letters on the proposed AO criteria, which was published in the FR on August 17, 2015 (80 FR 49177). The NRC received comments from OAS, WDH, and VDH. Each letter contained multiple comments. The NRC staff analyzed and categorized these comments according to the AO criterion to which they apply. A summary of the Agreement

States' comments and the NRC staff responses to the comments are available in ADAMS under Accession No. ML16209A049. The staff did not ~~incorporate~~ make any changes in response to the comments.

The AO criteria are designed to identify those events that could signal a potential public health or safety issue and evaluate events in a broad industrywide perspective. In response to comments regarding the requirement that an independent physician determine whether permanent functional damage occurred, the NRC staff did not agree to add "authorized medical physicist" because medical physicists are neither qualified nor credentialed to make a medical determination that unintended permanent functional damage to an organ or a physiological system has occurred. The criterion requires a determination by an independent physician "deemed qualified by the NRC or Agreement State," which takes into account all pertinent credentialing aspects of the individual, including specialty in the relevant field.

The staff disagreed with removing or modifying requirements for "irretrievable well logging sources" and Criterion III.C medical events. The staff disagreed with modifying the criterion regarding "irretrievable well logging sources" as NRC and Agreement State regulations require the licensee to evaluate the potential threat to public health or safety from an abandoned irretrievable source. This evaluation and dose assessment would be used as a basis to evaluate these events as potential AOs for irretrievable well logging sources. ~~The staff disagreed with modifying Criterion III.C.~~ The NRC previously added Criterion III.C for medical AO because the Commission considered misadministrations to be a concern. The current criteria are based on doses that would likely have a significant potential for resulting in permanent deterministic effects.

In response to a comment that requested clarification of the applicability of the "substantial breakdown" provision in criterion ~~1~~I.C.4 to materials licensees, the staff explained that this criterion is principally for licensees that possess special nuclear material and whose activities are included in a security plan required by 10 CFR Part 73. Criterion ~~1~~I.C.1 is the

principal criterion for security incidents involving materials subject to 10 CFR Part 37 for NRC or Agreement State radioactive materials licensee events to determine if an AO has occurred.

IV. 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 (ADAMS Accession No. ML15356A087). These comments concerned the reporting of incidents and events related to medical use that the ACMUI found may not be significant for public health or safety. The NRC prepared a response to the ACMUI recommendations (ADAMS Accession No. ML16209A061). 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 ~~NRC~~ staff disagreed with two comments and partially agreed with one comment. 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 also 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.

V. Congressional Review Act

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

VI. Availability of Documents

The documents identified in the following table are available as indicated.

DATE	DOCUMENT	ADAMS ACCESSION NO./FR CITATION
3/19/2015	SECY-15-0040, Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria	ML12166A091
6/30/2015	Staff Requirements – SECY-15-0040 – Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria	ML15181A030
8/17/2015	Proposed revision to policy statement issued for a 90 day public comment period.	80 FR 49177
11/16/2015	OAS letter to NRC, RE: Opportunity to Comment on Proposed Revision to Abnormal Occurrence Policy Statement	ML16209A194
11/17/2015	State of Washington Comment for Docket ID NRC-2015-0176 Abnormal Occurrence Criteria Revision	ML16209A199
11/12/2015	Virginia Comments on Abnormal Occurrence (AO) Reporting Revision	ML16209A196
3/19/2015	Summary of Major Agreement State Comments and Staff Response	ML14346A274
7/08/2016	Summary of Organization of Agreement State (OAS), State of Washington, and Commonwealth of Virginia Comments and Staff Response	ML16209A049
11/6/2015	Final ACMUI Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress	ML15356A087
10/09/2015	Meeting Summary, ACMUI Meeting, October 8–9, 2015	ML15294A461
8/08/2016	Staff's Response to the Advisory Committee on the Medical Uses of Isotopes' November 6, 2015, Recommendations to Final Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress	ML16209A061
6/24/2014	Management Directive 8.3, "NRC Incident Investigation Program."	ML13175A294
4/11/2014	Management Directive 8.9, "Accident Investigation."	ML13319A133
10/03/2010	Management Directive 8.13, "Reactor Oversight Process," DT-10-14	ML101400045
12/23/2015	Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program"	ML15317A147
12/15/2006	IMC 350, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns"	ML063400076

6/30/2015	NUREG-1520 Rev. 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," Final Report.	ML15176A258

The final policy statement is attached.

Dated at Rockville, Maryland, this_____day of_____, 2017~~6~~.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Statement of Policy

General Statement of Policy on the Implementation of

Section 208 of the Energy Reorganization Act of 1974, as Amended

Applicability

Implementation of Section 208, “Abnormal Occurrence Reports,” of the Energy Reorganization Act of 1974, as amended, involves the conduct of Commission business and does not impose requirements on licensees or certified facilities. The reports cover certain unscheduled incidents or events related to the manufacture, construction, or operation of a facility or the conduct of an activity subject to the requirements of Parts 20, 30 through 37, 39, 40, 50, 61, 70, 71, 72, or 76 of Title 10 of the *Code of Federal Regulations* (10 CFR).

Agreement States provide information to the U.S. Nuclear Regulatory Commission (NRC) on incidents and events involving nuclear materials in those States. Agreement States

are those States that have entered into formal agreements with the NRC, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (AEA) (Pub. L. 83-703), to regulate certain quantities of AEA material at facilities located within their borders. ~~The NRC also publishes e~~Events reported by Agreement States that reach the threshold for reporting as abnormal occurrences (AOs) are also published in the "Report to Congress on Abnormal Occurrences."

Abnormal Occurrence General Statement of Policy

The Commission 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 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 States;

(2) Major degradation of essential safety-related equipment;

(3) Major deficiencies in design, construction, or use of, or management controls for, facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement States; 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 States.

Appendix A to this policy statement sets forth the criteria for determining whether an

[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.

incident or event is as an AO.

Commission Dissemination of Abnormal Occurrence Information

The Commission widely disseminates AO reports to the public. The Commission submits an annual report~~s~~ to Congress on AOs ~~that occur~~ at or ~~are~~ associated with any facility or activity that is licensed or otherwise regulated by the NRC. This report ~~gives~~ provides the date, place, nature, and probable consequences of each AO; the cause or causes of each AO; and any action taken by the licensee to prevent recurrence.

Appendix A: Abnormal Occurrence Criteria

An incident or event is considered an abnormal occurrence (AO) if it involves a major reduction in the degree of protection of public health or safety. This type of 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 States;

(2) Major degradation of essential safety-related equipment;

(3) Major deficiencies in design, construction, or use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement States; 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 States.

Abnormal Occurrence Criteria.

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

I. All Licensees.[2]

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

[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.

age) resulting in an annual TEDE of 50 mSv (5 rem) 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 physician[3] deemed qualified by the U.S. Nuclear Regulatory Commission (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~~s~~ 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 10 CFR 20.1301, "Dose limits for individual members of the public," using 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

C. Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach.[4,5,6]

[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.

[4] Information 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 10 CFR 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 ~~to~~ 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.

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 10 CFR 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 10 CFR 73.2, "Definitions."

3. Any substantiated[7] 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[8] that is judged to be caused by theft or diversion.

4. Any substantial breakdown[9] 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.

[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 10 CFR 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.

D. Initiation of High-Level NRC Team Inspection.[10]

II. Commercial Nuclear Power Plant Licensees.

A. Malfunction of Facility, Structures, or Equipment.

1. Exceeding a safety limit of a license technical specification (TS) (10 CFR 50.36(c)).

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

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).

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 ~~could result~~ 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

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

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]

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 (ΔCDP) of greater than or equal to $1x10^{-3}$.[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.

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[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. ML101400045), green is used for very low safety significance, white is used for low to moderate safety significance, 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 ASP 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 ΔCDP of greater than or equal to $1x10^{-3}$ 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. ML15317A147), or under NRC IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns" (ADAMS Accession No. ML063400076). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

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.

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 Facilities.[14]

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 Subjects.[16]

1. A medical event, as defined in 10 CFR 35.3045, which results in a 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

[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 10 CFR 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 (10 CFR 70.62(c)) applied to meet the performance requirements in accordance with 10 CFR 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.

(b) Exceeds, by 10 Gy (1,000 rad), the expected dose to any other organ or tissue from the administration defined in the written directive; and

2. A medical event, as defined in 10 CFR 35.3045, which involves:

(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.

Appendix B: Other Events of Interest

This appendix discusses other events of interest that do not meet the criteria for abnormal occurrences (AOs) in Appendix A to this policy statement. The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as "Other Events of Interest." Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health or safety significance, have received significant media coverage, or have caused the U.S. Nuclear Regulatory Commission to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.