UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 30, 2015

SECRETARY

# COMMISSION VOTING RECORD

DECISION ITEM: SECY-15-0040

TITLE: PROPOSED REVISIONS TO POLICY STATEMENT ON REPORTING ABNORMAL OCCURRENCES CRITERIA

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 30, 2015.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Rochelle C. Bavol

Rochelle C. Bavol
Acting Secretary of the Commission

Enclosures:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Burns
Commissioner Svinicki
Commissioner Ostendorff
Commissioner Baran
OGC
EDO
PDR

## VOTING SUMMARY - SECY-15-0040

## RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|---|---|---|---|---|---|---|
| CHRM. BURNS | X | X | | | X | 6/1/15 |
| COMR. SVINICKI | X | | | | X | 6/10/15 |
| COMR. OSTENDORFF | X | | | | X | 5/28/15 |
| COMR. BARAN | X (in part) | | | | X | 5/14/15 |

# NOTATION VOTE

## RESPONSE SHEET

**TO:** Annette Vietti-Cook, Secretary

**FROM:** Chairman Burns

**SUBJECT:** SECY-15-0040: Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria

**Approved** XX **Disapproved** XX **Abstain** _____

**Not Participating** _____

**COMMENTS:** **Below** XX **Attached** XX **None** ___

I approve, in part, and disapprove, in part, for publication in the *Federal Register* for public comment the proposed revised Abnormal Occurrences Statement of Policy, subject to the attached edits. I agree with Commissioner Baran that the addition of proposed criterion III.C.3 would raise the bar too high for identifying abnormal occurrences. Therefore, I disapprove the staff's proposal to add criterion III.C.3. I find that the staff's proposed revision to criterion III.C.1.(b), in combination with the criteria in III.C.2, is sufficient to address the staff's concern that events that are not "significant from the standpoint of public health or safety" are being reported as abnormal occurrences.

**SIGNATURE**

1 June 2015
**DATE**

**Entered on "STARS" Yes** x **No** ___

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.

*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 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 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 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 and safety are reported to Congress.

~~*Licensee Reports*~~

~~This general policy statement will not change the reporting requirements for NRC licensees in Commission regulations, license conditions, or technical specifications (TS). NRC licensees will continue to submit required reports on a wide range of events, including instrument malfunctions and deviations from normal operating procedures that are not significant from the standpoint of the public health and safety but provide data useful to the Commission in monitoring operating trends of licensed facilities and in comparing the actual performance of these facilities with their design and/or licensing basis.~~

*Applicability*

Implementation of Section 208 of the Energy Reorganization Act of 1974, as amended, "Abnormal Occurrence Reports," 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 conduct of an activity subject to the requirements of parts 20, 30 through 37, 39, 40, 50, 61, 70, 71, 72 or 76 of Chapter I, Title 10, Code of Federal Regulations (10 CFR).

Agreement States provide information to the NRC on incidents and events involving applicable nuclear materials in their States. Events reported by Agreements States that reach the threshold for reporting as AOs are also published in the "Report to Congress on Abnormal Occurrences."

*Proposed Revisions*

The NRC is proposing revisions to the AO criteria to focus the criteria on~~clarify reporting criteria regarding which~~ events that are significant from the standpoint of public health and safety, particularly with respect to medical events. ~~In addition, t~~The proposed revisions ~~is~~ would also make the criteria consistent with the NRC's "Strategic Plan for Fiscal Year (FY) 2014–2018" (NUREG-1614, Volume 6, issued August 2014) and new NRC requirements in 10 CFR Part 37, "Physical protection of category 1 and category 2 quantities of radioactive material." ~~Additionally, extensive revision to the criterion for reporting medical events as AOs is being proposed.~~ Further, the NRC proposes to amend the AO criteria to separate "Other Events of Interest" from the AO criteria to clearly delineate that events considered "Other Events of Interest" are not AOs, but do represent significant events that the Commission deems

appropriate to report to Congress. Finally, restructuring and minor editorial changes are proposed to some sections for clarity.

The NRC is requesting public comments on this policy statement at this time.

*Licensee Reports*

The~~is~~ proposed changes to the general policy statement will~~ould~~ not change the reporting requirements for NRC licensees in Commission regulations, license conditions, or technical specifications ~~(TS)~~. NRC licensees will continue to submit required reports on a wide range of events, including instrument malfunctions and deviations from normal operating procedures that are not significant from the standpoint of the public health and safety but provide data useful to the Commission in monitoring operating trends of licensed facilities and in comparing the actual performance of these facilities with their design and/or licensing basis.

## III. Paperwork Reduction Act.

This policy statement does not contain information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

## Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting documents displays a currently valid Office of Management and Budget control number.

## IV. Abnormal Occurrence 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 ~~will be~~is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event ~~would have~~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, 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~~.

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The criteria for determining whether to consider an incident or event for reporting as an AO are set forth in Appendix A of this policy statement.

*Commission Dissemination of Abnormal Occurrence Information*

The Commission widely disseminates the AO reports to the public. The Commission will submit an annual report to Congress on AOs that occur at or are associated with any facility or activity that is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as

[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.

amended, or the Energy Reorganization Act of 1974, as amended. This report gives the date, place, nature and probable consequences of each AO, the cause or causes of each AO, and any action taken to prevent recurrence.

## Appendix A: Abnormal Occurrence Criteria

An accident or event ~~will be~~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 ~~would have~~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, 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*[3]

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in:

(a) ~~an adult (any individual 18 years of age or older) resulting in~~ an annual total effective dose equivalent (TEDE) of 250 millisievert (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 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) 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[4] deemed qualified by the NRC or Agreement State.

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[2] ~~Medical patients are excluded from consideration under this criterion.~~

[3] These criteria do not apply to medical events defined in 10 CFR 35.3045 and included in AO Criteria III.C. "Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects."

[4] Independent physician is defined to be a physician not on the licensee's staff and who was not involved in the care of the patient involved.

~~4. These criteria do not apply to medical events defined in 10 CFR 35.3045 and included in AO Criteria III.C. "Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects."~~

**Comment [SGB1]:** Move to footnote.

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 Title 10 of the Code of Federal Regulations (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*[5,6,7]

1. Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A of 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

[5] Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details about these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[6] Because of increased terrorist activities worldwide, the AO report would withhold specific safeguards information. Safeguards information is defined in 10 CFR 73.2. Any safeguards details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[7] 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 of 10 CFR Part 37, the report will clarify that the radioactive material has decayed below the thresholds.

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 ~~do~~ 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[8] case of actual theft, diversion, or loss of a formula quantity of special nuclear material[9] or an inventory discrepancy of a formula quantity of special nuclear material[7] that is judged to be caused by theft or diversion.

4. Any substantial breakdown[10] 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) of classified information that harms national security or safeguards information that threatens public health and safety.

*D. Initiation of High-Level NRC Team Inspection.*[11]

**II. Commercial Nuclear Power Plant Licensees**

*A. Malfunction of Facility, Structures, or Equipment*

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

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[8] "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.

[9] Formula quantity of special nuclear material is defined in 10 CFR 70.4, "Definitions."

[10] 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.

[11] This item addresses initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any accident review groups, as described in MD 8.9, "Accident Investigation."

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, which could result in exceeding the dose limits of 10 CFR Part 100, "Reactor Site Criteria," or 5 times the dose limits of General Design Criteria (GDC) 19 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 loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 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 Reactor Oversight Process (ROP) to be the result of or associated with licensee performance issues of high safety significance ~~of licensee performance~~.*[12]

[12] The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process," 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.

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 $1x10^{-3}$.*[13]

*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).*[14]

**III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events**

*A. Events Involving Design, Analysis, Construction, Testing, ~~or~~ Operation, Transport, Use, or Disposal ~~of Licensed Facilities or Regulated Materials~~*

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.

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*[13]

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[13] 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.

[14] 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" or under the NRC IMC 0305, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

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).[14]

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*[15]

1. A medical event, as defined in 10 CFR 35.3045 ~~and~~ , which results in a dose that:

(a) is equal to or greater than 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or

(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 ~~Represents~~ involves~~either~~:

(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

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[13] Criterion III.A also applies to Fuel Cycle Facilities.

[14] The integrated safety analysis (ISA) 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) to (d). Safety controls may include items relied on for safety designated in accordance with 10 CFR 70.61 (e) as well as other controls available to prevent or mitigate the consequences of an event. High-consequence events should be considered as those that could seriously harm the worker or a member of the public in accordance with 10 CFR 70.61. Fuel cycle facilities licensed under 10 CFR Part 40 or certified ~~under 10 CFR Part 40 or~~ under 10 CFR Part 76 have licensing basis documents which describe facility specific hazards, consequences, and those controls utilized to prevent or mitigate the consequences of such accidents. For these facilities, an AO 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 a high-consequence event, as defined in NUREG-1520, Revision 1, Appendix A to Chapter 3, Section A.2, under "Consequence Category 3 (High Consequences)."

[15] Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.

(vi) is delivered to the wrong individual or human research subject.~~; and~~

~~3. Results in one or more of the following, as determined by an independent physician(s)[2] deemed qualified by NRC or an Agreement State:~~

~~(a) unintended or unexpected permanent functional damage to an organ or physiological system;~~

~~(b) a significant unexpected adverse health effect; or~~

~~(c) death.~~

**Appendix B: Other Events of Interest**

This appendix discusses other events of interest that do not meet the AO criteria in Appendix A. 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 and safety significance, have received significant media coverage, or have caused the NRC 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.

Dated at Rockville, Maryland, this day of 2015

For the Nuclear Regulatory Commission

Annette Vietti-Cook,
Secretary of the Commission.

# NOTATION VOTE

## RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-15-0040: Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___

SIGNATURE

06/10/15
DATE

Entered on "STARS" Yes ✓ No ___

**Commissioner Svinicki's Comments on SECY-15-0040**
**Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria**

I approve for publication in the *Federal Register* the proposed revised policy statement (Enclosure 7 to SECY-15-0040), subject to the attached edits.

I regretfully observe that the staff's proposed revision of criterion III.C.3 does not appear to have garnered the support of a Commission majority. I agree wholeheartedly with the NRC staff and the Advisory Committee on the Medical Uses of Isotopes that reporting medical events each year to the Congress that have not resulted, and are not forecast to result, in any significant adverse effect or permanent medical harm is inappropriate. As I have reviewed these reports, year to year, during my service on this Commission – noting that most of the descriptions of abnormal occurrence events reported by this agency conclude with a statement to the effect that "no adverse health effects from the misadministration of radiation are expected" – I can only imagine the anguish created for patients and families knowing that their medical treatments are labeled "abnormal" by a Federal government agency and yet their medical care providers conclude that no harm will follow. This is made all the more confusing when the policy statement clearly states that the criteria "use a high reporting threshold so that *only those events considered significant from the standpoint of public health and safety* are reported." (emphasis added) Clearly this circumstance should be corrected. The staff's proposed revision to this criterion would have moved in that direction. I hope the staff and the advisory committee will continue to bring thought and attention to this issue, in spite of the Commission's action here.

Kristine L. Svinicki 06/10/15

[7590-01-P]

**NUCLEAR REGULATORY COMMISION**

**[NRC-~~2014~~2015-0XXX]**

**Abnormal Occurrence Reports**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed revision to policy statement; request for comments.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is proposing revisions to its policy statement on reporting abnormal occurrences (AO) to Congress. The proposed revisions would amend and restructure the criteria used by the NRC and Agreement States for determining whether to consider an incident or event as an AO. The proposed amendments to the policy statement would ensure consistency with current NRC guidance and regulations. The NRC is requesting public comments on this policy statement at this time.

**DATES:** Submit comments by **[INSERT DATE 90 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID **<INSERT: NRC-20YY-XXXX>**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical

questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Office of Administration, Mail Stop: 3WFN-06-A44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** Katie Tapp, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-251-7520; e-mail: Katherine.Tapp@nrc.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Obtaining Information and Submitting Comments.

A. Obtaining Information.

Please refer to Docket ID **<INSERT:** NRC-20YY-XXXX> 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 Web Site:** Go to http://www.regulations.gov and search for Docket ID **<INSERT:** NRC-20YY-XXXX>.

- **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.

- **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.

B. Submitting Comments.

Please include Docket ID **<INSERT:** NRC-20YY-XXXX> in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## II. 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.

*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 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 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 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 and safety are reported to Congress.

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*Applicability*

Implementation of Section 208 of the Energy Reorganization Act of 1974, as amended, "Abnormal Occurrence Reports," 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 conduct of an activity subject to the requirements of parts 20, 30 through 37, 39, 40, 50, 61, 70, 71, 72 or 76 of Chapter I, Title 10, Code of Federal Regulations (10 CFR).

Agreement States provide information to the NRC on incidents and events involving applicable nuclear materials in their 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 (AEA) (Public Law 83 703), to regulate certain quantities of AEA material at facilities located within their borders. Events reported by Agreements States that reach the threshold for reporting as AOs are also published in the "Report to Congress on Abnormal Occurrences."

*Proposed Revisions*

The NRC is proposing revisions to the AO criteria to clarify ~~reporting~~ the criteria ~~regarding~~for determining ~~which~~ events that are significant from the standpoint of public health and safety and should therefore be considered AOs. In addition, the revision is consistent with the NRC's "Strategic Plan for Fiscal Year (FY) 2014–2018" (NUREG-1614, Volume 6, issued August 2014) and new NRC requirements in 10 CFR Part 37, "Physical protection of category 1 and category 2 quantities of radioactive material." Additionally, ~~extensive~~ revision to the criterion for reporting medical events as AOs is being proposed. Further, the NRC proposes to amend the AO criteria to separate "Other Events of Interest" from the AO criteria to clearly

delineate that events considered "Other Events of Interest" are not AOs, but do represent significant events that the Commission deems appropriate to report to Congress. Finally, restructuring and minor editorial changes are proposed to some sections for clarity.

The NRC is requesting public comments on this policy statement at this time.

*Licensee Reports*

Thi~~s~~e proposed changes to the general policy statement will not change the reporting requirements for NRC licensees in Commission regulations, license conditions, or technical specifications (TS). NRC licensees will continue to submit required reports on a wide range of events, including instrument malfunctions and deviations from normal operating procedures that ~~are~~may not be significant from the standpoint of the public health and safety but provide data useful to the Commission in monitoring operating trends of licensed facilities and in comparing the actual performance of these facilities with their design and/or licensing basis.

## III. Paperwork Reduction Act.

This policy statement does not contain information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

## Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting documents displays a currently valid Office of Management and Budget control number.

## IV. Abnormal Occurrence 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.

An incident or event ~~will be~~is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event ~~would have~~ 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, 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.

The criteria for determining whether to consider an incident or event for reporting as an AO are set forth in Appendix A of this policy statement.

*Commission Dissemination of Abnormal Occurrence Information*

The Commission widely disseminates the AO reports to the public. The Commission will submit an annual report to Congress on AOs that occur at or are associated with any facility or activity that is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. This report gives the date,

place, nature, and probable consequences of each AO; the cause or causes of each AO; and any action taken to prevent recurrence.

## Appendix A: Abnormal Occurrence Criteria

An accident or event will be 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 would have 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, 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[1]

### *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 adult (any individual 18 years of age or older) resulting in~~ an annual total effective dose equivalent (TEDE) of 250 millisievert (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 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) 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[2] deemed qualified by the NRC or Agreement State.

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[1] ~~Medical patients are excluded from consideration under this criterion~~These criteria do not apply to medical events defined in 10 CFR 35.3045 and included in AO Criteria III.C. "Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects."

[2] Independent physician is defined to be a physician not on the licensee's staff and who was not involved in the care of the patient involved.

~~4. These criteria do not apply to medical events defined in 10 CFR 35.3045 and included in AO Criteria III.C. "Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects~~."

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, exceeds 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 Title 10 of the Code of Federal Regulations (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*[3,4,5]

1. Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A of 10 CFR Part 37, "Physical protection of category 1 and category 2 quantities of radioactive material." Excluded from reporting under

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[3] Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with ~~Section 208 of the Energy Reorganization Act of 1974, as amended~~E.O. 13526, as amended, or any predecessor or successor order to require protection against unauthorized disclosures. Any classified details about these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[4] ~~Because of increased terrorist activities worldwide,~~ Information pertaining to certain incidents may be Safeguards Information as defined in 10 CFR 73.2 because of safety or security implications. ~~t~~The AO report would withhold specific safeguards information in accordance with Section 147 of the Atomic Energy Act of 1954, as amended. ~~Safeguards information is defined in 10 CFR 73.2~~. Any safeguards details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[5] 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 of 10 CFR Part 37, the report will clarify that the radioactive material has decayed below the thresholds.

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 the doses from these sources do 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[6] case of actual theft, diversion, or loss of a formula quantity of special nuclear material[7] or an inventory discrepancy of a formula quantity of special nuclear material[7] that is judged to be caused by theft or diversion.

4. Any substantial breakdown[8] 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) of classified information that harms national security or safeguards information that threatens public health and safety.

*D. Initiation of High-Level NRC Team Inspection.*[9]

## II. Commercial Nuclear Power Plant Licensees

*A. Malfunction of Facility, Structures, or Equipment*

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

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[6] "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.

[7] Formula quantity of special nuclear material is defined in 10 CFR 70.4, "Definitions."

[8] 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.

[9] This item addresses initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any accident review groups, as described in MD 8.9, "Accident Investigation."

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, which could result in exceeding the dose limits of 10 CFR Part 100, "Reactor Site Criteria," or 5 times the dose limits of General Design Criteria (GDC) 19 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 loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 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 Reactor Oversight Process (ROP) to be the result of or associated with licensee performance issues and of high safety significance ~~of licensee performance~~.*[10]

[10] The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process," 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.

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 $1x10^{-3}$.*[11]

*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).*[12]

**III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events**

*A. Events Involving Design, Analysis, Construction, Testing,* ~~*or*~~ *Operation, Transport, Use, or Disposal* ~~*of Licensed Facilities or Regulated Materials*~~

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.

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*[13]

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[11] 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.

[12] 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" or under the NRC IMC 0305, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

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).[14]

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*[15]

1. A medical event, as defined in 10 CFR 35.3045, ~~and~~which results in a dose that:

(a) is equal to or greater than 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or

(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 ~~Represents~~ involves either:

(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

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[13] Criterion III.A also applies to Fuel Cycle Facilities.

[14] High-consequence events for facilities licensed under 10 CFR Part 70 are~~should be considered as~~ those that could seriously harm the worker or a member of the public in accordance with 10 CFR 70.61. The integrated safety analysis (ISA) 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) to (d). ~~Safety controls may include items relied on for safety designated in accordance with 10 CFR 70.61 (e) as well as other controls available to prevent or mitigate the consequences of an event. High-consequence events should be considered as those that could seriously harm the worker or a member of the public in accordance with 10 CFR 70.61.~~ Fuel cycle facilities licensed ~~or certified~~ under 10 CFR Part 40 or certified under 10 CFR Part 76 have licensing basis documents ~~which~~ that describe facility specific hazards, consequences, and those controls utilized to prevent or mitigate the consequences of such accidents. For these facilities, a ~~n AO~~ 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 ~~a high-consequence event, as~~ that defined in NUREG-1520, Revision 1, Appendix A to Chapter 3, Section A.2, under "Consequence Category 3 (High Consequences)."

[15] Criteria III.A.2, III.A.3, and III.A.4 also apply to events involving the medical use of radioactive materials~~medical licensees~~.

(vi) is delivered to the wrong individual or human research subject; and

3. Results in one or more of the following, as determined by an independent physician(s)[2] deemed qualified by NRC or an Agreement State:

(a) unintended or unexpected permanent functional damage to an organ or physiological system;

(b) a significant unexpected adverse health effect; or

(c) death.

## Appendix B: Other Events of Interest

This appendix discusses other events of interest that do not meet the AO criteria in Appendix A. 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 and safety significance, have received significant media coverage, or have caused the NRC 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.

Dated at Rockville, Maryland, this day of 2015

For the Nuclear Regulatory Commission

Annette Vietti-Cook,
Secretary of the Commission.

# NOTATION VOTE

## RESPONSE SHEET

**TO:** Annette Vietti-Cook, Secretary

**FROM:** Commissioner Ostendorff

**SUBJECT:** SECY-15-0040: Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria

**Approved** _X_ **Disapproved** _____ **Abstain** _____

**Not Participating** _____

**COMMENTS:** **Below** _X_ **Attached** _X_ **None** ___

I approve the staff's recommendation to publish for public comment in the *Federal Register* a proposed revision to the Commission's Policy Statement for reporting Abnormal Occurrences to Congress, subject to the comments below and the edits attached.

I see the protection of an embryo/fetus from licensed activities differently than the protection afforded when a patient receives a medical treatment. The practitioner and licensee take appropriate precautions (in this case requiring a pregnancy test) and counsel the patient on the effects of the treatment on an embryo/fetus or nursing child. I find, similar to the cases that occur after a patient has been released after I-131 treatment, it is through no fault of the licensee that an embryo/fetus or nursing child receives a dose due to patient intervention. The Advisory Committee on Medical Uses of Isotopes recommended that events reported under 10 CFR 35.3047 be screened under III.C, Medical Use criteria. There may be unintended consequences of using the Medical Use criteria. However, I do not think that it is reasonable for the NRC to offer less protection to the embryo/fetus or nursing child of a patient than that afforded the embryo/fetus of a declared pregnant worker. Therefore, in the *Federal Register* Notice the staff should specifically seek public comment on screening all reports for exposures to embryo/fetus or nursing child as an Abnormal Occurrence under I.A-2., unintended radiation exposure, versus screening reports required by 10 CFR 35.3047 for exposures to embryo/fetus or nursing child resulting from treatment to a patient as an Abnormal Occurrence under III.C, Medical Use criteria.

_____
**SIGNATURE**

5/28/15
_____
**DATE**

**Entered on "STARS" Yes** _x_ **No** ___

[7590-01-P]

**NUCLEAR REGULATORY COMMISION**

**[NRC-2014-0XXX]**

**Abnormal Occurrence Reports**

DRAFT

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed revision to policy statement; request for comments.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is proposing revisions to its policy statement on reporting abnormal occurrences (AO) to Congress. The proposed revisions would amend and restructure the criteria used by the NRC and Agreement States for determining whether to consider an incident or event as an AO. The proposed amendments to the policy statement would ensure consistency with current NRC guidance and regulations. The NRC is requesting public comments on this policy statement at this time.

**DATES:** Submit comments by **[INSERT DATE 90 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID **<INSERT:** NRC-20YY-XXXX>. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical

questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Office of Administration, Mail Stop: 3WFN-06-A44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** Katie Tapp, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-251-7520; e-mail: Katherine.Tapp@nrc.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Obtaining Information and Submitting Comments.

A. Obtaining Information.

Please refer to Docket ID **<INSERT:** NRC-20YY-XXXX> 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 Web Site:** Go to http://www.regulations.gov and search for Docket ID **<INSERT:** NRC-20YY-XXXX>.
- **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.

- **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.

B. Submitting Comments.

Please include Docket ID **<INSERT:** NRC-20YY-XXXX> in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## II. 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.

*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 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 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 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 and safety are reported to Congress.

*Licensee Reports*

This general policy statement will not change the reporting requirements for NRC licensees in Commission regulations, license conditions, or technical specifications (TS). NRC licensees will continue to submit required reports on a wide range of events, including instrument malfunctions and deviations from normal operating procedures that are not significant from the standpoint of the public health and safety but provide data useful to the Commission in monitoring operating trends of licensed facilities and in comparing the actual performance of these facilities with their design and/or licensing basis.

*Applicability*

Implementation of Section 208 of the Energy Reorganization Act of 1974, as amended, "Abnormal Occurrence Reports," 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 conduct of an activity subject to the requirements of parts 20, 30 through 37, 39, 40, 50, 61, 70, 71, 72 or 76 of Chapter I, Title 10, Code of Federal Regulations (10 CFR).

Agreement States provide information to the NRC on incidents and events involving applicable nuclear materials in their States. Events reported by Agreements States that reach the threshold for reporting as AOs are also published in the "Report to Congress on Abnormal Occurrences."

*Proposed Revisions*

The NRC is proposing revisions to the AO criteria to clarify reporting criteria regarding which events are significant from the standpoint of public health and safety. In addition, the revision is consistent with the NRC's "Strategic Plan for Fiscal Year (FY) 2014–2018" (NUREG-1614, Volume 6, issued August 2014) and new NRC requirements in 10 CFR Part 37, "Physical protection of category 1 and category 2 quantities of radioactive material." Additionally, extensive revision to the criterion for reporting medical events as AOs is being proposed. Further, the NRC proposes to amend the AO criteria to separate "Other Events of Interest" from the AO criteria to clearly delineate that events considered "Other Events of Interest" are not AOs, but do represent significant events that the Commission deems

appropriate to report to Congress. Finally, restructuring and minor editorial changes are proposed to some sections for clarity.

The NRC is requesting public comments on this policy statement at this time.

## III. Paperwork Reduction Act.

This policy statement does not contain information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

### Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting documents displays a currently valid Office of Management and Budget control number.

## IV. Abnormal Occurrence 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.

An incident or event will be considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event would have 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, 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.

**Comment [TEB1]:** Edit spacing

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The criteria for determining whether to consider an incident or event for reporting as an AO are set forth in Appendix A of this policy statement.

*Commission Dissemination of Abnormal Occurrence Information*

The Commission widely disseminates the AO reports to the public. The Commission will submit an annual report to Congress on AOs that occur at or are associated with any facility or activity that is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. This report gives the date, place, nature and probable consequences of each AO, the cause or causes of each AO, and any action taken to prevent recurrence.

## Appendix A: Abnormal Occurrence Criteria

An accident or event will be 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 would have 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;

~~(2)~~(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 States; or

~~(3)~~(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.

**Comment [TEB2]:** Pagination issue

## 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[1]

**Comment [TEB3]:** Footnote redundant w Criteria 4

*A. Human Exposure to Radiation from Licensed Material*

1. Any unintended radiation exposure to:

(a) an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (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 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

[1] ~~Medical patients are excluded from consideration under this criterion.~~

(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) 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[2] deemed qualified by the NRC or Agreement State.

4. These criteria do not apply to medical events defined in 10 CFR 35.3045 and included in AO Criteria III.C. "Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects."

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, exceeds 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 Title 10 of the Code of Federal Regulations (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.

[2] Independent physician is defined to be a physician not on the licensee's staff and who was not involved in the care of the patient involved.

*C. Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach*[3,4,5]

1. Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A of 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 the doses from these sources do 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[6] case of actual theft, diversion, or loss of a formula quantity of special nuclear material[7] or an inventory discrepancy of a formula quantity of special nuclear material[7] that is judged to be caused by theft or diversion.

4. Any substantial breakdown[8] of physical security, cyber security, or material control and accountability programs that significantly weakens the protection against loss, theft, diversion, or sabotage.

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[3] Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details about these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[4] Because of increased terrorist activities worldwide, the AO report would withhold specific safeguards information. Safeguards information is defined in 10 CFR 73.2. Any safeguards details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

[5] 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 of 10 CFR Part 37, the report will clarify that the radioactive material has decayed below the thresholds.

[6] "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 cannot be refuted following an investigation; and requires further action on the part of the Agency or other proper authorities.

[7] Formula quantity of special nuclear material is defined in 10 CFR 70.4, "Definitions."

[8] 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.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that threatens public health and safety.

*D. Initiation of High-Level NRC Team Inspection.*[9]

**II. Commercial Nuclear Power Plant Licensees**

*A. Malfunction of Facility, Structures, or Equipment*

1. Exceeding a safety limit of 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, which could result in exceeding the dose limits of 10 CFR Part 100, "Reactor Site Criteria," or 5 times the dose limits of General Design Criteria (GDC) 19 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 loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result

[9] This item addresses initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any accident review groups, as described in MD 8.9, "Accident Investigation."

in exceeding the dose limits of 10 CFR Part 100 or 5 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 Reactor Oversight Process (ROP) to be of high safety significance of licensee performance.*[10]

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 $1x10^{-3}$.*[11]

*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).*[12]

**III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events**

*A. Events Involving Design, Analysis, Construction, Testing, or Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials*

1. An accidental criticality.

[10] The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process," 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.

[11] 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.

[12] 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" or under the NRC IMC 0305, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns." 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*[13]

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).[14]

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*[15]

1. A medical event as defined in 10 CFR 35.3045 and 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 or greater than 2.5 Gy (250 rad) to the gonads; or

(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

**Comment [TEB4]:** Spell out first use of Gray

[13] Criterion III.A also applies to Fuel Cycle Facilities.

[14] The integrated safety analysis (ISA) 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) to (d). Safety controls may include items relied on for safety designated in accordance with 10 CFR 70.61 (e) as well as other controls available to prevent or mitigate the consequences of an event. High-consequence events should be considered as those that could seriously harm the worker or a member of the public in accordance with 10 CFR 70.61. Fuel cycle facilities licensed or certified under 10 CFR Part 40 or 10 CFR Part 76 have licensing basis documents which describe facility specific hazards, consequences, and those controls utilized to prevent or mitigate the consequences of such accidents. For these facilities, an AO 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 a high-consequence event, as defined in NUREG-1520, Revision 1, Appendix A to Chapter 3, Section A.2, under "Consequence Category 3 (High Consequences)."

[15] Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.

2. Represents either:

(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; and

3. Results in one or more of the following, as determined by an independent physician(s)[2] deemed qualified by NRC or an Agreement State:

(a) unintended or unexpected permanent functional damage to an organ or physiological system;

(b) a significant unexpected adverse health effect; or

(c) death.

## Appendix B: Other Events of Interest

This appendix discusses other events of interest that do not meet the AO criteria in Appendix A. 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 and safety significance, have received significant media coverage, or have caused the

NRC 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.

Dated at Rockville, Maryland, this day of 2015

For the Nuclear Regulatory Commission

Annette Vietti-Cook,
Secretary of the Commission.

# NOTATION VOTE

## RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Baran

SUBJECT: SECY-15-0040: Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria

Approved XX (In part) Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

5/14/15

DATE

Entered on "STARS" Yes XX No ___

**Commissioner Baran's Comments on SECY-15-0040, "Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria"**

Section 208 of the Energy Reorganization Act of 1974 requires NRC to submit an annual report to Congress on abnormal occurrences, which are defined as unscheduled incidents or events that the Commission determines are significant from the standpoint of public health or safety. NRC first established criteria for determining what constitutes an abnormal occurrence in a 1977 policy statement. The Commission has periodically revised the criteria over the years, most recently in 2006.

In this SECY paper, the NRC staff recommends publication of proposed changes to the policy statement on abnormal occurrence reports for public comment. Most of the proposed revisions provide useful clarifications to the abnormal occurrence criteria or update the criteria to better reflect current regulatory requirements.

There also are two recommended changes to the criteria related to events involving the medical use of radioactive materials. Currently, there are two criteria that a medical event must meet before it is considered an abnormal occurrence that must be reported to Congress. One criterion limits abnormal occurrences by setting a threshold on the size of the dose and the other requires an error in administration, such as a dose that is 50 percent greater than prescribed, using the wrong radiopharmaceutical, or delivering it to the wrong treatment site.

The staff recommends two changes to the medical event criteria. First, it would modify the dose criterion to change the threshold for a dose to an organ or tissue other than bone marrow, the gonads, or the lens of the eye from the existing 10 gray to a dose exceeding the expected dose to such an organ or tissue as defined in the written directive by 10 gray or more. As prescribed therapeutic doses typically exceed 10 gray, I agree that it makes sense to modify the criterion to limit abnormal occurrences to cases in which the actual dose exceeds the expected dose by 10 gray rather than having every dose that exceeds 10 gray meet the criterion.

The second proposal is to add a third medical event criterion, which would require that an independent physician determine that the erroneous dose resulted in permanent functional damage to an organ, a significant adverse health effect, or death. In my view, this raises the bar too high and would dramatically limit the information provided to Congress through the annual abnormal occurrence reports.

I appreciate the staff's interest in reflecting the experience gained in the evaluation of medical events over the past 17 years since this reporting requirement began. However, events such as exposing the wrong patient to therapeutic levels of radiation or irradiating the wrong organ are preventable events that should not occur. If they do occur, it is appropriate to include them in the annual report to Congress. Changing the dose criterion as proposed by the staff is sufficient to screen out events of lesser safety significance. Requiring a medical error to also cause a significant adverse health effect or death before it would qualify as reportable to Congress would unnecessarily apply a standard higher than those currently applicable to reactors or fuel cycle facilities, where significant safety lapses are reported even if they do not cause actual harm to human health.

According to the staff, the proposed medical abnormal occurrence reporting criteria would screen out nearly all of the medical abnormal occurrences reported in fiscal years 2010 through 2013. The revised criteria likely would have eliminated almost all of the reported

abnormal occurrences that took place at the VA Medical Center in Philadelphia in 2008. Using the current criteria, of the 97 medical events found at that VA facility, 17 were considered abnormal occurrences. Under the proposed revised criteria, the NRC staff believes that only one or two would have met the abnormal occurrence criteria for medical events. Criteria that would exclude cases such as these are simply too restrictive.

Changing the criteria to require NRC or Agreement States to consult with an independent physician to determine whether an erroneous dose resulted in a significant unexpected adverse health effect would increase the cost and complexity of the decision about whether an event constitutes an abnormal occurrence. We should not increase the costs for NRC and the Agreement States merely to reduce the number of medical events deemed abnormal occurrences and thus reported to Congress. I do not support a proposed change that would expend additional agency resources in order to provide less information to Congress. After decades of issuing these annual reports to Congress, it would be a mistake to introduce new criteria that would drastically reduce the number of events reported. It would send the wrong signal to patients, licensees, Congress, and the public about the seriousness with which NRC takes these events.

Therefore, I approve for publication in the Federal Register for public comment the proposed revised policy statement, with the exception of the new proposed criterion III.C.3.

As an alternative approach, the staff should consider revising the structure of the annual report to more readily distinguish those medical abnormal occurrences with expected health consequences from those that do not have such consequences.