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

October 23, 2006

ALL AGREEMENT AND NON-AGREEMENT STATES

ISSUANCE OF REVISED POLICY STATEMENT ON ABNORMAL OCCURRENCE CRITERIA (FSME-06-095)

On October 5, 2006, the U.S. Nuclear Regulatory Commission (NRC) approved the revised Abnormal Occurrence Criteria. The revised policy statement (enclosed) was published on October 12, 2006, in the *Federal Register* (71 FR 60198), and can be accessed at http://www.gpoaccess.gov/fr/. A *Federal Register* notice was issued soliciting public comments (71 FR 10568). The comment period ended May 30, 2006, and no public comments were received. However, the Office of Nuclear Security and Incident Response (NSIR) requested minor clarifications, which were incorporated.

The Commission uses the abnormal occurrence (AO) criteria for selecting AOs for the annual report to Congress as required by Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438). Section 208 of the Act defines an AO as an unscheduled incident or event which the NRC determines to be significant from the standpoint of public health or safety. The AO criteria have been amended to ensure that they are consistent with the NRC's Strategic Plan for Fiscal Years (FY) 2004–2009 and the NRC rulemaking on Title 10, Part 35, of the Code of Federal Regulations (10 CFR Part 35), "Medical Use of Byproduct Material." Additionally, risk-informed criteria based on the NRC Accident Sequence Precursor (ASP) Program and Reactor Oversight Process (ROP) have been added for selecting abnormal occurrences at commercial nuclear power plants for the report to Congress. The ASP program assesses the risk significance of issues and events. The ROP is a risk-informed, tiered approach to ensuring the safety of nuclear power plants. Events occurring after September 30, 2006, will be evaluated using the 2006 revised AO criteria.

The previous criteria for determining an AO and the guidelines for "Other Events of Interest" were stated in an NRC policy statement published in the *Federal Register* on December 19, 1996 (61 FR 67072). That policy statement was revised to include criteria for gaseous diffusion plants and was published in the *Federal Register* on April 17, 1997 (62 FR 18820).

/RA/
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Enclosure:
As stated

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U.S. NUCLEAR REGULATORY COMMISSION

ABNORMAL OCCURRENCE REPORTS: IMPLEMENTATION OF SECTION 208 OF THE ENERGY REORGANIZATION ACT OF 1974; REVISED POLICY STATEMENT

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Issuance of Revised Policy Statement on Abnormal Occurrence Criteria.

SUMMARY: This policy statement presents the revised abnormal occurrence (AO) criteria the Commission uses for selecting AO's for the annual report to Congress as required by Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438). Section 208 of the act defines an AO as an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The AO criteria have been amended to ensure that the criteria are consistent with the NRC's Strategic Plan for Fiscal Year (FY) 2004–2009 and the NRC rulemaking on Title 10, Part 35, of the Code of Federal Regulations (10 CFR Part 35), "Medical Use of Byproduct Material." Additionally, risk-informed criteria based on the NRC Accident Sequence Precursor (ASP) Program and Reactor Oversight Process (ROP) have been added for selecting abnormal occurrences at commercial nuclear power plants for the report to Congress. The ASP program assesses the risk significance of issues and events. The ROP is a risk-informed, tiered approach to ensuring the safety of nuclear power plants. The ROP is a process for collecting information about licensee performance, assessing the safety significance of the information, taking appropriate actions, and ensuring that licensees correct deficiencies. Some sections of

the AO criteria have been restructured. The restructuring accommodates the changes in the criteria and minimizes duplication.

EFFECTIVE DATE: All revisions included in this publication are complete and accurate as of September 21, 2006.

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SUPPLEMENTARY INFORMATION:

I. Background

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (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. Section 208 requires that the discussion of each event include 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 sending it to Congress.

Abnormal Occurrence Reporting

The AO policy statement has been developed 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 which 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 overall impact on the general public. The AO criteria results in reports to Congress only for those events considered significant from the standpoint of public health and safety.

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 at licensed facilities and in comparing the actual performance of the 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 36, 39, 40, 50, 61, 70, 71, 72 or 76 of Chapter I of Title 10 of the 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."

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 is an AO.

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 or otherwise regulated by the Commission,

(2) major degradation of essential safety-related equipment, or

(3) major deficiencies in the design, construction, or use of management controls for facilities or radioactive material.

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 AO Information

The Commission widely disseminates the AO reports to the public. The Commission submits an annual report to Congress on AOs at or associated with any facility or activity which 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 actions taken to prevent recurrence.

Appendix A: Abnormal Occurrence Criteria

The following criteria are used to determine whether to consider events for reporting as AOs:

I. For All Licensees

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 an annual total effective dose equivalent (TEDE) of 250 mSv (25 rem) or more; or 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; or an annual dose equivalent to the lens of the eye of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more; or a committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or 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 a physician.

B. Discharge or dispersal of radioactive material from its intended place of confinement which results in the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with § 20.1301 using § 20.1302(b)(1) or § 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach[1,2]

1. Any unrecovered lost, stolen, or abandoned sources that exceed the values listed in Appendix P to Part 110, "High Risk Radioactive Material, Category 2." Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.

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1 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 ERA of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

2 Due to increased terrorist activities worldwide, the AO report would not disclose specific classified information and sensitive information, the details of which are considered useful to a potential terrorist. Classified information is defined as information that would harm national security if disclosed in an unauthorized manner.

2. A substantiated[3] case of actual theft or diversion of licensed, risk-significant radioactive sources or a formula quantity[4] of special nuclear material; or act that results in radiological sabotage[5].

3. Any substantiated[3] loss of a formula quantity[4] of special nuclear material or a substantiated[3] inventory discrepancy of a formula quantity[4] of special nuclear material that is judged to be caused by theft or diversion or by a substantial breakdown[6] of the accountability system.

4. Any substantial breakdown[6] of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against 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 harms the public health and safety.

D. Initiation of High-Level NRC Team Inspections.[7]

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

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3 "Substantiated" means a situation where an indication of loss, theft, or unlawful diversion such as: an allegation of diversion, report of lost or stolen material, statistical processing difference, 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.

4 A formula quantity of special nuclear material is defined in 10 CFR 70.4.

5 Radiological sabotage is defined in 10 CFR 73.2.

6 A substantial breakdown is defined as a red finding in the security inspection program, or any plant or facility determined to have overall unacceptable performance, or in a shutdown condition (inimical to the effective functioning of the nation's critical infrastructure) as a result of significant performance problems and/or operational events.

7 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."

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 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, 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 (SAR) 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 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any reactor events or conditions that are determined to be of high safety significance.[8]

D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s).[9]

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 of Licensed Facilities or Regulated Materials

1. An accidental criticality [10 CFR 70.52(a)].

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. For Fuel Cycle Facilities

1. Absence or failure of all safety-related or security-related controls (engineered and human) for an NRC-regulated lethal hazard (radiological or chemical) while the lethal hazard is present.

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8 The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC Management Directive 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 Abnormal Occurrences. Additionally, Criterion II.C also includes any events or conditions evaluated by the NRC ASP program to have a conditional core damage probability (CCDP) or change in core damage probability (ΔCDP) of greater than $1x10^{-3}$.

9 Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

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

C. For Medical Licensees

A medical event that:

1. Results in a dose that is

a. equal to or greater than 1Gy (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. equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and

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.

IV. Other Events of Interest

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.

[5 U.S.C. 552(a)]

Dated at Rockville, Maryland, this 5th day of October 2006.

For the U.S. Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission.