

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

July 16, 1997

MEMORANDUM TO: S. J. Collins, Director, NRR

- C. J. Paperiello, Director, NMSS
- A. C. Thadani, Director, RES
- K. D. Cyr, General Counsel, OGC
- J. Lieberman, Director, OE
- G. P. Caputo, Director, OI
- W. M. Beecher, Director, OPA
- R. L. Bangart, Director, OSP
- H. J. Miller, Regional Administrator, RI
- L. A. Reyes, Regional Administrator, RII
- A. B. Beach, Regional Administrator, RIII
- E. W. Merschoff, Regional Administrator, RIV
- H. T. Bell, Inspector General, OIG

FROM:

Denwood F. Ross, Jr., Director Office for Analysis and Evaluation of Operational Data

SUBJECT: REVISED MANAGEMENT DIRECTIVE 8.1, ABNORMAL OCCURRENCE REPORTING PROCEDURE

Attached for your concurrence is a draft revision of Management Directive (MD) 8.1, Abnormal Occurrence Reporting Procedure. The draft incorporates comments which were received during informal review of a previous draft, which was conducted via your abnormal occurrence (AO) coordinators. (Your AO coordinators are listed below for reference.) Your concurrence is requested by July 30, 1997.

Attachment: As stated

cc: AO Coordinators:

T. J. Carter, NRR R. L. O'Connell, NMSS P. K. Holahan, NMSS M. A. Satorius, OE J. L. Telford, RES R. L. Fonner, OGC P. M. Larkins, OSP J. M. Johansen, RI S. J. Vias, RII C. M. Hosey, RII B. L. Burgess, RIII T. J. Kozak, RIII C. A. Hackney, RIV F. R. Huey, RIV

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Volume 8, Licensee Oversight Programs Abnormal Occurrence Reporting Procedure Directive 8.1

Policy

(8.1-01)

It is the policy of the United States Nuclear Regulatory Commission to establish procedures to ensure that abnormal occurrences (AOs) are identified and reported to Congress in compliance with Section 208 of the Energy Reorganization Act of 1974 and the Federal Reports Elimination and Sunset Act of 1995. (011)

These procedures pertain to events that occurred at facilities licensed, certificated, or otherwise regulated by NRC (i.e., nuclear power plants, fuel cycle facilities and nuclear byproduct material users in industrial, medical, and academic applications). They do not affect the Commission's rules, regulations, or other requirements applicable to NRC licensees or certificate holders. These other requirements are stated in the *Code of Federal Regulations*, the technical specifications, the license, or the certificate. The procedures within this directive and handbook do not impose additional requirements on licensees or certificate holders and they do not affect the Commission's agreements with the Agreement States, as authorized by Section 274 of the Atomic Energy Act of 1954, as amended. (012)

Objectives

(8.1-02)

- To establish a procedure for the review, selection, and processing of reported events for submittal to the Commission as potential AOs and other events of interest, for annually publishing the AO report to Congress, and for making the information publicly available after the AO report is sent to Congress. (021)
- To ensure that the reporting process is properly coordinated and in compliance with statutory requirements and the requirements of the Commission. (022)
- To ensure that the annual AO report to Congress is prepared by NRC staff, approved by the Commission, and submitted to Congress via forwarding letters signed by the Chairman. (023)

Organizational Responsibilities and Delegations of Authority (8.1-03)

Chairman

(031)

Submits the annual AO report to Congress via forwarding letters to the President of the Senate and the Speaker of the House.

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Commission

(032)

- Makes final determinations of AOs and other events of interest. (a)
- Grants final approval of the annual AO report to Congress. (b)

Director, Office of Congressional Affairs (OCA)

(033)

- Assigns an AO coordinator and an alternate to represent the office for matters pertaining to the AO reporting process. Identifies these individuals to the Office for Analysis and Evaluation of Operational Data (AEOD). (a)
- Notifies AEOD of incidents or events that are receiving widespread congressional interest. (b)
- Provides comments and concurrence to AEOD on potential AOs and other events of interest. (c)
- Notifies AEOD when the annual AO report has been delivered to Congress. (d)

General Counsel, Office of the General Counsel (OGC) (034)

- Assigns an AO coordinator and an alternate to represent the office for matters pertaining to the AO reporting process. Identifies these individuals to AEOD. (a)
- Provides comments and concurrence to AEOD on proposed AOs and other events of interest. (b)

Director, Office of Public Affairs (OPA)

(035)

- Assigns an AO coordinator and an alternate to represent the office for matters pertaining to the reporting process. Identifies these individuals to the AEOD. (a)
- Provides comments and concurrence to AEOD on potential AOs and other events of interest. (b)

Executive Director for Operations (EDO)

(036)

 Reviews staff recommendations of potential AOs and other events of interest. Resolves staff disagreements, if any, and forwards recommendations to the Commission for final determination. (a)

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- Ensures that arrangements are made for any required informal or formal Commission briefings. (b)
- Ensures that Commission comments on staff recommendations are resolved. (c)

Deputy Executive Director for Regulatory Effectiveness (DEDE) (037)

- Works with the Deputy Executive Director for Regulatory Programs to resolve staff disagreements, if any, before the staff's recommended potential AOs and the other events of interest are forwarded to the EDO. (a)
- Forwards to the EDO the staff's recommended potential AOs and other events of interest. (b)

Deputy Executive Director for Regulatory Programs (DEDR) (038)

Works with the DEDE to resolve staff disagreements, if any, before the staff's recommended potential AOs and other events of interest are forwarded to the EDO.

Director, Office for Analysis and Evaluation of Operational Data (AEOD)

(039)

- Establishes internal procedures to cnsure expeditious processing of reportable items (see Part II of Handbook 8.1 for AO criteria and guidelines.) (a)
- Assigns an AO coordinator and an alternate to represent AEOD on matters pertaining to the reporting of AOs and other events of interest. (b)
- Coordinates events proposed by AEOD, the other offices, and the regions for reporting as AOs and other events of interest and ensures that all reportable events receive a security review. (c)
- Makes the final determination of the recommended potential AOs and other events of interest that the staff will submit to the EDO. (d)
- Prepares the AO report to Congress using the procedure given in Part I(c) of Handbook 8.1(e).
- Proposes and coordinates changes to the AO reporting criteria, reporting procedures, and guidelines for selecting other events of interest with other offices, the regions, and the Commission, as necessary. (f)

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Office Directors of Nuclear Reactor Regulation (NRR) and Nuclear Material Safety and Safeguards (NMSS) and the Regional Administrators

(0310)

- Establish internal procedures for their respective office or region for the expeditious review, identification, and processing of potential AOs and other events of interest. (a)
- Assign an AO coordinator and an alternate to represent the office or region on matters pertaining to potential AOs and other events of interest. Identify these individuals to AEOD. (b)
- Provide assistance to AEOD during evaluation of potential AOs, including Commission briefings or responses to Commission questions. (c)

Director, Office of State Programs (OSP)

(0311)

- Assigns an AO coordinator and an alternate to represent the office for matters pertaining to potential AOs and other events of interest. Identifies these individuals to AEOD. (a)
- Establishes internal procedures to ensure that the write-ups received from the Agreement States for AOs and other events of interest, as well as information received on other reported events, are made available for review by the cognizant NRC offices. (b)
- Asks the Agreement States to prepare write-ups for AOs and other events of interest, when AEOD requests the information. (c)

Proposing Events for Evaluation as Potential AOs or Changes to the AO Reporting Procedure

(8.1-04)

- Any individual, NRC office, other government agency, licensee, certificate holder, or member of the public may propose an event to any NRC organizational unit for evaluation as a potential AO. Any such event, together with the reasons why it does or does not appear to meet the AO criteria, should then be submitted to AEOD for evaluation and processing. (a)
- Any individual, NRC office, other government agency, licensee, certificate holder, or member of the public may contact AEOD and recommend changes in the AO reporting program, evaluation and determination procedures, or method of dissemination to the public or Congress. (b)

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Applicability

(8.1-05)

The policy and guidance in this directive and handbook apply to all NRC employees.

Handbook

(8.1-06)

Handbook 8.1 contains information on the review, selection, and processing of potential AOs and the AO criteria and guidelines for other events of interest.

References

(8.1-07)

Atomic Energy Act of 1954, Section 274, as amended (42 U.S.C. 2011 et seq.).

Code of Federal Regulations, Title 10, "Energy."

Energy Reorganization Act of 1974, Section 208, Pub. L. 93-438 (42 U.S.C. 5848).

Federal Register, Vol. 62, No. 74, U.S. Government Printing Office, April 17, 1997.

Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104-66).

"Report to Congress on Abnormal Occurrences, Fiscal Year 1996," NUREG-0090, Vol. 19.

Staff Requirements Memorandum to SECY-96-193, "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Final Policy," November 7, 1996.

----to SECY-97-029, "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Revision to Policy Statement," March 17, 1997.

Part I

Review, Selection, and Processing of Potential AOs

Review of Reported Events (A)

The Offices of Nuclear Reactor Regulation (NRR) and Nuclear Material Safety and Safeguards (NMSS), the Office for Analysis and Evaluation of Operational Data (AEOD), and the regional offices review reported events to identify candidate potential abnormal occurrences (AOs). The Office of State Programs (OSP) makes information on Agreement State events available for review. (1)

Within NRC, the word "event" means either something that actually happened (an event) or something that may happen (a condition). Potential AOs are selected using the AO criteria contained in Part II of this handbook, and may involve either an event or a condition. (2)

The documents reviewed include licensee event reports submitted in accordance with 10 CFR 50.73, event notifications submitted in accordance with 10 CFR 50.72, regional morning reports, regional preliminary notifications, NRC inspection reports, and Agreement State event reports. (3)

NRR has primary responsibility for the review and identification of nuclear reactor events for potential AOs and NMSS has primary responsibility for the review and identification of nuclear material events, each using its own internal procedures. The regional offices review both nuclear reactor events and nuclear material events using their internal procedures. (4)

AEOD performs an independent review of both reactor events and nuclear material events. (5)

Select Potential AOs and Prepare Write-Ups (B)

When sufficient information is available, the technical basis for each candidate potential AO is discussed at the AO-coordinator level to determine if it meets the AO reporting criteria. (1)

The regional offices prepare write-ups for events within their respective regions that they believe are potential AOs. NRR and NMSS will prepare write-ups for potential AOs if their organization is most cognizant. The write-ups must contain the AO reporting criteria and satisfy the reporting requirements of Section 208 of the Energy Reorganization Act of 1974. (2)

Potential AO write-ups prepared by the regional offices, NRR, and NMSS are submitted to AEOD and forwarded to the NRC Public Document Room (PDR). The following

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statement should be included in the memorandum forwarding the potential AO write-ups to AEOD and the PDR: (3)

The Nuclear Regulatory Commission (NRC) staff has identified the attached event as a potential abnormal occurrence (AO), and it may be included in the AO report that the NRC prepares annually to inform Congress of events reported by NRC and Agreement State licensees which the Commission has determined are significant to public health and safety.

AEOD sends quarterly requests for AO event assessments and write-ups to the cognizant NRC offices. The informal requests for the first three quarters of the fiscal year are approved by the responsible AEOD manager. The formal request for the entire fiscal year, which includes the fourth-quarter request, is approved by the responsible AEOD division director. The requests include examples of the short write-ups required. (4)

Potential AO write-ups voluntarily submitted by the Agreement States are placed in the PDR upon receipt by NRC via the Regulatory Information Distribution System. NRC staff subsequently review these write-ups to determine if they are potential AOs. (5)

Formal disagreements about potential AOs or AO write-ups are resolved through the AO coordinators and, when necessary, at the management level. AEOD makes the final determination of the recommended potential AOs and other events of interest that staff will submit to the Executive Director for Operations (EDO). If an impasse is encountered, AEOD will submit supporting documentation and an AEOD recommendation to the EDO for resolution. (6)

Process Potential AOs (C)

AEOD reviews and revises the proposed AO write-ups, as required, for the AO report. (OSP may submit revised write-ups to the applicable Agreement State for review.) AEOD then prepares the draft-for-comment AO report and submits the report to the cognizant NRC offices for review. The body of the AO report contains the AO write-ups; Appendix A to the report contains the AO criteria, Appendix B updates previously reported AOs, and Appendix C provides other events of interest. (1)

AEOD coordinates resolution of comments received from the cognizant NRC offices and regions, and prepares a draft of the AO report for submittal to the EDO. (2)

The EDO submits the AO report to the Commission via the Secretary of the Commission (SECY). The Commission receives the AO report as a SECY-numbered document and subsequently reviews the report. The Commission submits its approval of the AO report, along with any comments that it may have, to AEOD via a staff requirements memorandum (SRM). (3)

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AEOD incorporates the Commission's comments as stated in the SRM, has the AO report printed, prepares a *Federal Register* notice (FRN) announcing its publication, and prepares the Chairman's letters forwarding the AO report to Congress. (NRC does not publish Agreement State AOs in the FRN.) The Chairman sends one letter to the President of the Senate and another identical letter to the Speaker of the House. (4)

AEOD submits the AO report, the FRN, and the Chairman's letters to SECY. It also submits 25 advance copies of the report to the Office of Congressional Affairs. After the AO report has been delivered to Congress, AEOD authorizes the release of the report to the public. (5)

Guidance for Preparing AO Write-Ups (D)

General (1)

Each AO write-up should be a clear, concise, and accurate report of what happened, as required by Section 208. (a)

Do not cite references in the write-ups. (b)

Format for Write-Ups (2)

First Paragraph - State the AO criteria for the event by citing the appropriate section of Appendix A of the AO report, which contains all of the criteria. (a)

Begin Second Paragraph "Date and Place" - with information following, as required by Section 208. (b)

Begin Third Paragraph "Nature and Probable Consequences" - (c)

Briefly explain what happened and what were the consequences, as required by Section 208. This part may include several paragraphs. (i)

Next Marked Paragraph "Cause or Causes" - (d)

Briefly explain what caused the event, as required by Section 208.

Stand-Alone Heading "Action(s) Taken to Prevent Recurrence" - (e)

Briefly explain what actions were taken to prevent recurrence, as required by Section 208, by--

- "Licensee" (i)
- "NRC" (ii)

 For Agreement States, briefly explain what actions were taken to prevent recurrence by the Agreement State and the Agreement State license. (iii)

Last Paragraph - All AOs should be closed out at the time of reporting for the purpose of the AO report, so long as Section 208 reporting requirements are met. However, the AO will be kept open if there is a reasonable expectation that currently unavailable information will be obtained shortly. Also, if significant new information becomes available for a closed AO at a later date, the AO will be reopened, the new information will be reported under "Update of Previously Reported Abnormal Occurrences" (Appendix B), and the AO will again be closed out for the purpose of the AO report. (f)

Appendix C - The requirements for reporting "Other Events of Interest" (Appendix-C items) were given by the Commission in SECY-96-193. SECY-96-193 states that--(g)

The Commission may determine that events other than AOs may be of interest to Congress and the public and be included in an appendix to the AO report as 'Other Events of Interest.' Guidelines for events to be included in the AO report for this purpose are items that may possibly be perceived by the public to be of health or safety significance. Such items would not involve a major reduction in the level of protection provided for public health or safety; therefore, they would not be reported as abnormal occurrences. An example is an event where upon final evaluation by an NRC Incident Investigation Team, or an Agreement State equivalent response, a determination is made that the event does not meet the criteria for an abnormal occurrence.

Examples of Write-Ups (3)

Two examples of acceptable AO write-ups are shown below using the revised AO criteria that became effective on April 17, 1997 (62 FR 18820).

96-2 Containment-Bypass Leakage via Disconnected Hydrogen-Monitor Lines at Braidwood Units 1 and 2

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion II.A.2) of this report notes that a serious degradation of the primary containment boundary can be considered an AO.

Date and Place - February 15, 1995; Braidwood Unit 2, a Westinghousedesigned pressurized water nuclear reactor plant, operated by Commonwealth Edison Company and located about 38.6 kilometers (24 miles) south southwest of Joliet, Illinois.

Nature and Probable Consequences - On November 9, 1994, the licensee completed a containment integrated leak rate test (ILRT). For this test, the 6.35-millimeter (0.25-inch) containment penetration hydrogen sensing lines for trains "A" and "B" were disconnected and a balloon placed on the end to identify any leakage. The procedure did not specify whether to disconnect the sensing line

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inside the hydrogen monitor cabinet or outside. The operators who lined up the test disconnected the lines inside the cabinet. The licensee's investigation concluded that when other operators restored the system from the test, they observed the exterior sensing lines and assumed that the lines were reconnected. Therefore, the sensing lines remained disconnected inside the cabinet.

On January 31, 1995, the operations department wrote a problem identification report to identify a growing difference in the hydrogen readings on the "A" and "B" trains which are taken during each shift. On February 15, 1995, during troubleshooting, the "A" train lines were found to be disconnected, approximately 3 months after being disconnected. Surveillance tests performed on December 11, 1994, and January 25, 1995, provided opportunities to detect the deficiency with the "A" train but were missed. It could not be conclusively determined when the "B" train was restored. Two maintenance workers had a recollection of discovering balloons on the sensing lines in a hydrogen monitoring cabinet in late 1994. Maintenance records indicate these individuals worked on the "B" train on December 20, 1994. However, computer and operator logs for the "B" train appear to have been accurately reading containment hydrogen following the ILFIT.

The hydrogen monitors are normally isolated. However, during a loss of coolant accident, the Emergency Operating Procedures direct the operators to put them into service to monitor containment hydrogen concentration. This would create an unfiltered release path from the containment to the auxiliary building. The licensee calculated that, under worst case conditions using guidance from NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," regulatory dose limits could be exceeded within approximately 3 hours. NRC review found the licensees calculations to be conservative.

There are area radiation monitors near the hydrogen monitors. These area radiation monitors alarm in the control room and the alarm response procedures call for notification of Radiation Protection personnel to survey the area. Additionally, there are radiation monitors in the auxiliary building exhaust that would assist the operators in identifying the leak. The containment bypass flow path could be isolated remotely from the control room and it appears credible that the leak could be isolated prior to exceeding regulatory limits.

Cause or Causes - The cause of this event was a procedural deficiency in that the ILRT procedure did not provide adequate guidance on where the containment penetration hydrogen sensing lines should be disconnected. Additionally, the operator tasked with reconnecting the containment penetration hydrogen sensing lines, after the ILRT was completed, did not display a guestioning attitude when he found that the lines appeared to be reconnected.

Actions Taken to Prevent Recurrence

Licensee - Corrective actions included revision of ILRT line up and restoration sheets to provide adequate guidance on where disconnections and connections are to be performed. Additionally, a General Information Notice was issued to all site personnel highlighting the human performance problems identified from this event.

NRC - Escalated enforcement was exercised on this issue and the licensee was assessed a \$100,000 civil penalty. Information Notice 96-13, "Potential Containment Leak Paths Through Hydrogen Analyzers," was issued to alert other licensees to this event.

This event is closed for the purpose of this report.

96-5 Medical Brachytherapy Misadministration at Harper Hospital in Detroit, Michigan

The following information pertaining to this event is also being reported concurrently in the *Fedoral Register*. Appendix A (see Part IV, "For Medical Licensees") of this report states that a medical misadministration that results in a dose that is equal to cr greater than 1 gray (100 rad) to the lens of the eye and is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place - November 24, 1995; Harper Hospital; Detroit, Michigan.

Nature and Probable Consequences - A patient was being treated with a strontium-90 eye applicator for pterygium (a growth over the eye which causes gradual blindness). The patient was prescribed three 800-centigray (800 rad) treatments lasting 30 seconds each. Each of the treatments was to be administered to the medial side of the left eye. However, the second treatment was mistakenly administered to the lateral side of the left eye. The physician realized the error and immediately treated the correct side with the prescribed dose.

The patient was notified of the misadministration and given a written report. The patient's referring physician was notified. An NRC medical consultant evaluated the effects of the misadministration and concurred with the licensee that the patient was not expected to suffer any adverse health effects.

Cause or Causes - The patient's chart was upside down and the treating physician incorrectly interpreted the sketch of the left eye on the diagram that specified the treatment site. (The diagram was part of the written directive for treatment using the strontium-90 eye applicator; however, it did not show the nose, top of the page, or bottom of the page.) Also, the second treatment was administered by a different physician and physicist than the first treatment.

Actions Taken To Prevent Recurrence

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Licensee - The licensee revised the diagram so that it shows the nose, thereby making it obvious which is the left eye and which is the right eye.

NRC - NRC conducted a special safety inspection. A Notice of Violation was issued for failing to ensure that the administration was in accordance with the written directive. Since the inspection showed that actions had been taken to correct the violation and to prevent recurrence, no reply to the violation was required.

This event is closed for the purpose of this report.

Part II

Abnormal Occurrence Criteria and Guidelines for Other Events of Interest

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 requires that AOs be reported to Congress on an annual basis (see "Report to Congress on Abnormal Occurrences, Fiscal Year 1996," NUREG-0090, Vol. 19). (A)

The criteria for determining an AO were published in the *Federal Register* on April 17, 1997 (62 FR 18820). (B)

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. This type of incident or event would have a moderate or more severe impact on the public health or safety and could include, but need not be limited to the following: (C)

- Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
- (2) Major degradation of essential safety-related equipment; or
- (3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

The new AO criteria are stated below. The criteria for fuel cycle facilities (Section III of the new AO criteria stated below) that are applicable to licensees and certificate holders, such as the gaseous diffusion plants (GDPs). However, other criteria that reference "licensees," "licensed facility," or "licensed material" also may be applied to events at facilities of certified holders. (D)

Abnormal Occurrence Criteria (Appendix A, 62 FR 18822)

Criteria by types of events used to determine which incidents or events will be considered for reporting as AOs are as follows:

- 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 millisievert (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 or tissue other than the lens of the eye, bone marrow and the gonads, of 2500 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, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 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.
 - 1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 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).
 - 2. Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material; (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47; or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).

Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.³

- 1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A, values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A2 or 0.01 times the A, values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. 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 during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.
- 2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
- 3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.
- 4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.
- D. Other Events (i.e., those concerning design, analysis, construction, testing, operation, use, or disposal of licensed facilities or regulated materials).
 - 1. An accidental criticality [10 CFR 70.52(a)].
 - A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

C.

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 regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

- 3. A serious deficiency in management or procedural controls in major areas.
- 4. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.
- II. For Commercial Nuclear Power Plant Licensees.
 - A. Malfunction of Facility, Structures, or Equipment.
 - 1. Exceeding a safety limit of license technical specification (TS) [§50.36(c)].
 - 2. Serious degradation of fuel integrity, primary coolant pressure houndary, 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 Inadeguacy.
 - 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 system).
- III. For Fuel Cycle Facilities.
 - 1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.
 - 2. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.

- 3. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.
- IV. For Medical Licensees.

A medical misadministration that:

- (a) Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, <u>or</u> (2) equal to or greater than 10 Gy (1000 rad) to any other organ; and
- (b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive <u>or</u> (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical,⁴ 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(s).

Guidelines for "Other Events of Interest."

The Commission may determine that events other than AOs may be of interest to Congress and the public and be included in an Appendix to the AO report as "Other Events of Interest." Guidelines for events to be included in the AO report for this purpose are items that may possibly be perceived by the public to be of health or safety significance. Such items would not involve a major reduction in the level of protection provided for public health or safety; therefore, they would not be reported as abnormal occurrences. An example is an event where upon final evaluation by an NRC Incident Investigation Team, or an Agreement State equivalent response, a determination is made that the event does not meet the criteria for an abnormal occurrence.

⁴ The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.