U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

TN: DT-01-08

To:	NRC Management Directives Custodians
Subject:	Transmittal of Directive 8.1, "Abnormal Occurrence Reporting Procedure"
Purpose:	Directive and Handbook 8.1 have been updated to reflect the current abnormal occurrence process. Change bars do not appear in Management Directive 8.1 because, except for the italicized "Abnormal Occurrence Criteria" of Part II of the handbook, 80 percent of the material has been revised.
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Abnormal Occurrence Reporting Procedure

Directive 8.1

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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 or otherwise regulated by NRC and Agreement States (i.e., nuclear power plants, fuel cycle facilities, and material licensees). They do not affect the rules, regulations, or other requirements applicable to NRC or Agreement State 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)

Agreement States provide information to NRC on all reportable material events as a matter of compatibility. Agreement States file reports for all reportable events following guidance contained in the Office of State and Tribal Programs Procedure SA-300, Reporting Material Events. Subsequently, following guidance in

Policy
(8.1-01) (continued)

SA-300, the Agreement State staff voluntarily prepares and submits to the NRC draft AO writeups for the subset of those reportable events that were identified as proposed AOs. (013)

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 the annual publishing of 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 the 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. (a)

Organizational Responsibilities and Delegations of Authority
(8.1-03) (continued)

Chairman
(031) (continued)

- Approves AO criteria proposed by the staff. (b)

The Commission
(032)

- Makes final determinations of AOs and other events of interest. (a)
- Grants final approval of the annual AO report to Congress. (b)
- Approves AO criteria proposed by the staff. (c)

Executive Director for Operations (EDO)
(033)

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

Director, Office of Congressional Affairs (OCA)
(034)

- Assigns an AO coordinator to represent the office on matters pertaining to the AO reporting process. Identifies

Organizational Responsibilities and Delegations of Authority
(8.1-03) (continued)

Director, Office of Congressional Affairs (OCA)
(034) (continued)

these individuals to the Office of Nuclear Regulatory Research (RES). (a)

- Notifies RES of incidents or events that are receiving widespread congressional interest. (b)

- Provides comments and concurrence to RES on potential AOs and other events of interest. (c)

- Notifies RES when the annual AO report has been delivered to Congress. (d)

General Counsel, Office of the General Counsel (OGC)
(035)

- Assigns an AO coordinator to represent the office on matters pertaining to the AO reporting process. Identifies these individuals to RES. (a)

- Provides comments and concurrence to RES on proposed AOs and other events of interest. (b)

Director, Office of Nuclear Regulatory Research (RES)
(036)

- Implements this directive to ensure expeditious processing of reportable items (see Part II of Handbook 8.1 for AO criteria and guidelines). (a)

Organizational Responsibilities and Delegations of Authority
(8.1-03) (continued)

Director, Office of Nuclear Regulatory Research (RES)
(036) (continued)

- Assigns an AO coordinator to represent RES on matters pertaining to the reporting of AOs and other events of interest. (b)

- Coordinates events proposed by RES, the other offices, and the regions for reporting as AOs and other events of interest and ensures that all reportable events undergo 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)

- 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)

- Coordinates with the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of State and Tribal Programs (STP), and the Agreement States on written descriptions for potential AOs and other events of interest. (g)

Organizational Responsibilities and Delegations of Authority
(8.1-03) (continued)

Directors of the Offices of Nuclear Reactor Regulation (NRR) and Nuclear Material Safety and Safeguards (NMSS) and the Regional Administrators
(037)

- Establish internal written 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 to represent the office or region on matters pertaining to potential AOs and other events of interest. Identify these individuals to RES. (b)

- Coordinate with RES and STP on written descriptions for potential NRC and Agreement State AOs and other events of interest. (c)

- Provide assistance to RES in the evaluation of potential AOs, including Commission briefings or responses to Commission questions. (d)

Director, Office of State and Tribal Programs (STP)
(038)

- Assigns an AO coordinator to represent the office on matters pertaining to potential AOs and other events of interest. Identifies these individuals to RES. (a)

- Establishes internal written procedures to ensure that the writeups received from the Agreement States for AOs and other events of interest, as well as information received on

Organizational Responsibilities and Delegations of Authority
(8.1-03) (continued)

Director, Office of State and Tribal Programs (STP)
(038) (continued)

other reported events, are made available for review by NMSS. (b)

- Coordinates with NMSS, RES, and the Agreement States on written descriptions for potential AOs and other events of interest and on the review and identification of Agreement State events as potential AOs. (c)

Office AO Coordinators
(039)

All NRC office AO coordinators identify potential AO issues and provide information as needed to the RES AO coordinator. Such coordinators informally discuss and transmit AO issues of concern with the RES AO coordinator.

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 RES for review and processing. (041)

Proposing Events for Evaluation as Potential AOs or Changes to the AO Reporting Procedure
(8.1-04) (continued)

- Any individual, NRC office, other Government agency, licensee, certificate holder, or member of the public may contact RES and recommend changes in the AO reporting program; the review, selection, and processing procedures; or the method of dissemination to the public or Congress. (042)

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).

References

(8.1-07) (continued)

Federal Register, Vol. 62, No. 74, U.S. Government Printing Office, "Abnormal Occurrence Report: Implementation of Section 208 Energy Reorganization Act of 1974; Revision to Policy Statement," April 17, 1997.

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

"Report to Congress on Abnormal Occurrences, Fiscal Year 1999," NUREG-0090, Vol. 22.

SECY-97-029, "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Revision to Policy Statement," dated February 5, 1997.

SECY-98-175, "Proposed Guidelines for Appendix C, Other Events of Interest, to the Abnormal Occurrence Report to Congress," dated September 4, 1998.

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

Abnormal Occurrence Reporting Procedure

Handbook 8.1

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Part I
Review, Selection, and Processing of Potential AOs

Review of Reported Events (A)

The Offices of Nuclear Reactor Regulation (NRR), Nuclear Material Safety and Safeguards (NMSS), Nuclear Regulatory Research (RES), State and Tribal Programs (STP), and the regional offices review reported events to identify candidate potential abnormal occurrences (AOs). STP makes information directly received from Agreement States, including proposed AO writeups, available to NMSS and RES for review. Potential AOs are selected using the AO criteria contained in Part II of this handbook and may involve either an event or a condition. (1)

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. The documents reviewed also include nuclear materials licensee event reports submitted in accordance with 10 CFR Parts 20, 30 through 36, 39, 40, 50, 61, 70, 71, or 72. (2)

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 written procedures. NMSS also has primary responsibility for the review of events reported by the Agreement States to identify potential AOs. The regional offices review both nuclear reactor events and nuclear material events using their internal written procedures. (3)

Selection of Potential AOs and Preparation of Writeups (B)

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

The regional offices prepare writeups for events within their respective regions that they believe are potential AOs. NRR and NMSS will prepare writeups for potential AOs if their organization is most knowledgeable. The writeups must contain the AO reporting criteria and satisfy the reporting requirements of Section 208 of the Energy Reorganization Act of 1974. Also, the Commission provided direction in the staff requirements memorandum (SRM) on SECY-96-193, "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Final Policy Statement," which stated the following: "The staff should file incident information on potential AOs in the public document rooms (PDRs) as soon as possible. In following this direction, the staff should place already existing documents on these incidents in the PDRs and identify the incident as [a] potential AO." Thus, following the Commission's direction, the offices that prepare the AO writeups should place such documentation in the NRC Public Electronic Reading Room. (2)

RES sends quarterly requests for AO event assessments and writeups to the cognizant NRC offices. The quarterly requests may be combined, depending on the frequency of potential AOs. (3)

Agreement States usually voluntarily screen events for potential AOs and prepare AO writeups. In addition, NMSS, the office with primary responsibility for the review of all material events, conducts a review of all material events in the nuclear material events database (NMED) that have been reported by the NRC and Agreement State licensees. STP will notify the Agreement States of any additional potential AOs identified as a result of NRC staff review of Agreement State events. After STP confirms that Agreement State events meet the criteria for potential AOs, the

Selection of Potential AOs and Preparation of Writeups (B) (continued)

Agreement States prepare AO writeups and voluntarily submit them to NRC. These writeups are placed in the NRC Public Electronic Reading Room. (4)

Formal disagreements about potential AOs or AO writeups are resolved through the AO coordinators and, when necessary, by NRC managers. RES makes the final determination on which potential AOs and other events of interest should be submitted to the Executive Director for Operations (EDO). If an impasse occurs among NRC offices as to whether an event should be included in the report or if other offices disagree with RES's final determination, RES will submit supporting documentation and a RES recommendation to the EDO for resolution. (5)

Processing of Potential AOs (C)

RES reviews and, as necessary, revises the proposed AO writeups for the AO report. (STP returns revised writeups to the applicable Agreement State for review.) RES then prepares the draft-for-comment AO report and submits it to the cognizant NRC offices for review. The AO report includes (a) writeups of the AO events, (b) the AO criteria (Appendix A), (c) updates of previously reported AOs (Appendix B), and (d) other events of interest (Appendix C). (1)

STP provides a copy of the “Agreement State Licensee” section of the draft-for-comment AO report to the cognizant Agreement State for review. The Agreement States are requested to provide any comments within 15 days. (2)

RES coordinates resolution of comments received from the cognizant NRC offices, the regions, and the Agreement States and prepares a draft of the AO report for submittal to the EDO. (3)

Processing of Potential AOs (C) (continued)

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, to RES via an SRM. (4)

RES incorporates the Commission's comments as stated in the SRM, oversees the printing of the AO report, prepares a *Federal Register* notice (FRN) announcing its publication, and prepares the Chairman's letters forwarding the AO report to Congress. The Chairman sends a letter to the President of the Senate and another identical letter to the Speaker of the House. (5)

RES 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, RES authorizes the release of the report to the public. (6)

Guidance for Preparing AO Writeups (D)

General (1)

Each AO writeup should be a clear, concise, and accurate report of what happened, as required by Section 208. Also, AO reports are to be consistent with the provisions of the Privacy Act and the Freedom of Information Act. (a)

Do not cite references in the writeups. (b)

Format for Writeups (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)

Guidance for Preparing AO Writeups (D) (continued)

Format for Writeups (2) (continued)

Second Paragraph "Date and Place" – State the date and place, as required by Section 208. (b)

Third Paragraph "Nature and Probable Consequences" – Briefly explain what happened and what were the consequences, as required by Section 208. This part should be brief. A statement as to whether or not all regulatory requirements have been met should be included in the report. (c)

Next Marked Paragraph "Cause or Causes" – Briefly explain what caused the event, as required by Section 208. (d)

Stand-Alone Heading "Action(s) Taken To Prevent Recurrence" ("Licensee"/"NRC"/"Agreement State") – Briefly explain what actions were taken to prevent recurrence, as required by Section 208, by NRC licensees or the NRC. For Agreement States, briefly explain what actions were taken to prevent recurrence by the Agreement State and the Agreement State licensee. (e)

Last Paragraph – If the reporting requirements of Section 208 have been met for the AO event, then a statement such as "This event is closed for the purpose of this report" should be included in the last paragraph to indicate that the event has been closed. 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)

Guidance for Preparing AO Writeups (D) (continued)

Format for Writeups (2) (continued)

Appendix C – The guidelines for including events as "Other Events of Interest" were provided by the Commission in the SRM on SECY-98-175, dated September 4, 1998, and state that— (g)

> 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.' Guidelines for events to be included in the AO report for this purpose may include, but not necessarily be 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.

Examples of Writeups (3)

Two examples of acceptable AO writeups are shown below using the revised AO criteria that became effective on April 17, 1997 (62 FR 18820). These events are hypothetical.

- **99-01 Loss of Two of Three High-Pressure Injection Pumps at Oconee Nuclear Station Unit 3**

  The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.D.2) of this report notes that a major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action can be considered an AO.

Guidance for Preparing AO Writeups (D) (continued)

Examples of Writeups (3) (continued)

Date and Place – April 1, 1999; Oconee Unit 3, a pressurized-water nuclear reactor plant designed by Babcock and Wilcox Company, operated by the Duke Energy Corporation (formerly known as Duke Power Company), and located about 8 miles north of Clemson, South Carolina.

Nature and Probable Consequences – On April 1, 1999, the Oconee Unit 3 reactor was shut down and the reactor coolant system (RCS) was being cooled down for inspection of the high-pressure injection (HPI) discharge piping. The need for the inspection resulted from RCS leakage from a weld crack in the HPI makeup piping on Unit 2. Reactor pressure was approximately 270 psig, RCS temperature was approximately 205 °F, one reactor coolant pump (RCP) was running, and the low-pressure injection system was being used to cool down the RCS.

Plant cooldown evolutions appeared to be normal until the "B" HPI pump started to cavitate and makeup flow to the RCS was lost. An RCP seal water (which is also supplied by the HPI pump) low-flow signal automatically started the "A" HPI pump. However, it also began to cavitate. (The third HPI pump is not designed to automatically start on this signal and remained in the standby condition.) The operators stopped both pumps and began troubleshooting the problem. A Notification of Unusual Event was declared when it was recognized that the pumps would be inoperable past the shift that was on duty. Unit 3 pressure and temperature were stabilized, and there was no immediate concern that conditions would worsen.

Later investigations revealed that the potential for a more serious situation existed if there had been a small break loss-of-coolant accident, which is the design basis for the HPI

Guidance for Preparing AO Writeups (D) (continued)

Examples of Writeups (3) (continued)

system, before this event. If such an accident had occurred, all three of the HPI pumps would have automatically started and become inoperable very quickly. In addition, the pumps may have become air bound and unavailable when the pump suction was transferred to the borated water storage tank to inject into the RCS.

Cause or Causes – Loss of the HPI pumps occurred when all of the water was inadvertently pumped from the letdown storage tank (LDST) because of faulty level indication. The erroneous level indication was caused by the loss of approximately one-half of the water in the level detector reference leg because of a slight leak in the instrument fitting. This loss of the reference leg water caused the tank level instrument to indicate a water level higher than the actual level, a condition that may have existed since February 1999, the last time the reference leg was verified to be full. It also caused the loss of the low-level alarm. As a result of these conditions, the operators did not provide makeup water to the tank when it was needed, and the HPI pump continued to run until the tank was empty.

In addition, the control room operators did not properly monitor and detect the inaccurate LDST-level indications. They did not notice that for a short period of time the indicated level stopped decreasing and continuously showed the tank to be approximately half-full at the same time water was being pumped from the tank.

Actions Taken To Prevent Recurrence

Licensee – Corrective actions included (1) the addition of a second reference leg to the LDST to provide separate level

Guidance for Preparing AO Writeups (D) (continued)

Examples of Writeups (3) (continued)

indications, (2) enhanced operator training and procedures, and (3) the performance of an HPI System Reliability Study that is to be completed by December 31, 1999.

NRC – Escalated enforcement, which incorporated this issue, resulted in the determination that a Severity Level II violation existed, and the licensee was assessed a $330,000 civil penalty.

This event is closed for the purpose of this report.

- **99-02 Sodium Iodide Radiopharmaceutical Medical Event at Holy Cross Hospital in Meadowbrook, Maryland**

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion IV, "For Medical Licenses") to this report states, in part, that a medical misadministration that results in a dose to the patient equal to or greater than 10 gray (1,000 rad) to an organ (other than a major portion of the bone marrow, lens of the eye, or gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or is the wrong radiopharmaceutical will be considered an AO.

Date and Place – April 1, 1999; Holy Cross Hospital; Meadowbrook, Maryland.

Nature and Probable Consequences – A patient's referring physician intended for the patient to receive a thyroid uptake and scan. The licensee routinely performed this procedure using iodine-123 (I-123). However, because of an error, the patient was administered iodine-131 (I-131).

Guidance for Preparing AO Writeups (D) (continued)

Examples of Writeups (3) (continued)

The authorized user intended to administer 11.1 megabecquerel (MBq) (0.300 millicurie [mCi]) of I-123 to a patient for the evaluation of hyperthyroidism. However, no one prepared a written directive to indicate the type of thyroid procedure to administer. The patient was mistakenly listed on the licensee's schedule for a whole-body imaging as part of an evaluation for thyroid cancer therapy. The licensee routinely performs this type of procedure using I-131. Therefore, the licensee's technologist administered a 196.1-MBq (5.3 mCi) dosage of I-131 without obtaining a written directive. As a result of this error, the licensee's medical physicist determined that the patient's thyroid received an unintended dose of about 41.9 gray (4,190 rad) based on a 65-percent uptake.

The NRC's consultant stated that the impact of the misadministration on the status of the patient's health should be negligible, with no expected long-term disability. The licensee believes that no harm was done to the patient because the patient's condition required additional thyroid treatment using I-131. The patient was notified of the medical event on April 30, 1999, and a written report was prepared. The patient's referring physician was also notified.

Cause or Causes – The technologist performed a thyroid procedure using I-131 without a written directive from an authorized user. The licensee's authorized user was not involved in the process of administration of I-131 to clarify what type of thyroid evaluation was needed for the patient.

Actions Taken To Prevent Recurrence

Licensee – The licensee counseled the technologist on the importance of implementing the NRC regulations.

Guidance for Preparing AO Writeups (D) (continued)

Examples of Writeups (3) (continued)

NRC – The NRC staff conducted a special safety inspection on April 20, 1999, and is evaluating enforcement options.

This event is closed for the purpose of this report.

Examples of Appendix C Items, "Other Events of Interest" (4)

Two examples of acceptable Appendix C writeups are shown below using the guidelines that were provided by the Commission in the SRM on SECY-98-175, "Proposed Guidelines for Appendix C, Other Events of Interest, to the Abnormal Occurrence Report to Congress" dated September 4, 1998. It should be noted that each Appendix C item should include a brief discussion of the merits of including it in the report.

- **Loss of the Liquid Poison System at Big Rock Point**

  This event was discussed during the congressional hearing on July 30, 1998, and received substantial public and media attention.

  Big Rock Point was permanently shut down on August 29, 1997. The last fuel bundle was removed from the reactor vessel on September 20, 1997. On March 27, 1998, an unsuccessful attempt was made to empty the contents of the liquid poison system (LPS) since it was no longer needed. On April 24, 1998, a boroscopic inspection revealed that the discharge pipe of the LPS tank was completely severed approximately 15.2 centimeters (6 inches) above the water line.

Guidance for Preparing AO Writeups (D) (continued)

Examples of Appendix C Items, "Other Events of Interest" (4) (continued)

The purpose of the LPS was to inject boron into the reactor vessel to shut down the reactor in the event of a failure of the reactor control rod system. The LPS tank is filled with a concentrated solution of sodium pentaborate to accomplish the shutdown. The severed pipe rendered the system inoperable. The licensee determined that the probable root cause of the failure was inadequate curing of the phenolic coating on the discharge pipe at the time of manufacture in 1961. After the phenolic coating failed, the carbon steel discharge pipe was exposed and subject to corrosion. On the basis of metallurgical analysis performed by the licensee, the licensee estimated that the carbon steel pipe had failed between 1979 and 1984 because of corrosion. Therefore, the LPS had been inoperable during the last 14 years of reactor operation.

The small increase (4 percent) in core damage frequency associated with this event was due primarily to the low probability of a failure to scram. Currently the unit is undergoing decommissioning and the LPS is not required to be operable. Therefore, the failure of the LPS did not endanger public health and safety.

- **Loss of Exit Signs Containing Tritium at Marlboro Psychiatric Hospital in Marlboro, New Jersey**

  This example is included in this report because of (1) significant media interest, (2) pending legislation in the New Jersey legislature on limiting the use of devices containing tritium, and (3) NRC staff's current work to develop rulemaking for a registration program for certain types of NRC general licensees.

Guidance for Preparing AO Writeups (D) (continued)

Examples of Appendix C Items, "Other Events of Interest" (4) (continued)

On February 26, 1998, Marlboro Psychiatric Hospital, a general licensee in Marlboro, New Jersey, discovered the loss of three exit signs containing approximately 1.85 terabecquerel (50 curie) of tritium. The licensee noted this loss during a routine, weekly visual inspection of two vacant cottages located on the hospital grounds. The NRC conducted a safety inspection, which included confirmatory surveys of the vacant cottages from which the signs were missing. No contamination above the removable contamination criteria listed in the "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material" was found. The hospital investigated the loss and searched the premises but did not locate the signs. All remaining tritiated exit signs were removed from the Marlboro site and sent back to the manufacturer.

The NRC conducted a safety inspection and is in the process of determining a final enforcement action.

Part II
Abnormal Occurrence Criteria and Guidelines for Other Events of Interest

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 more severe impact on public health or safety and could include, but need not be limited to, the following: (A)

(1) 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, or use of management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

The following 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). The 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). (B)

Note that in addition to the criteria for fuel cycle facilities (Section III of the AO criteria) that are applicable to licensees and certificate holders, such as the gaseous diffusion plants, other criteria that reference "licensees," "licensed facility," or "licensed material" also may be applied to events at facilities of certificate holders. (C)

The guidelines for including events in Appendix C, "Other Events of Interest," of the AO report were provided by the Commission in the staff requirements memorandum on SECY-98-175, dated September 4, 1998, and are listed at the end of this part. (D)

Abnormal Occurrence Criteria

Criteria by types of events used to determine which 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.

Abnormal Occurrence Criteria (continued)

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 that, 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 meets 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).

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

[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 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.*

Abnormal Occurrence Criteria (continued)

1. *Any lost, stolen, or abandoned sources that exceed 0.01 times the A1 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 A1 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.*

Abnormal Occurrence Criteria (continued)

D. Other Events (That Is, 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)].

2. A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

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 a license technical specification (TS) [§ 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 five 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).

Abnormal Occurrence Criteria (continued)

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 five 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

A. A shutdown of the plant or a portion of the plant resulting from a significant event and/or violation of a law, a regulation, or a license/certificate condition.

B. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.

C. 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—

Abnormal Occurrence Criteria (continued)

A. *Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads or (2) equal to or greater than 10 Gy (1000 rads) 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 or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical,[2] (ii) is delivered by the wrong route of administration, (iii) is delivered to the wrong treatment site, (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 should 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 may include, but not necessarily be 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.

[2]*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.*