

March 15, 1999

FOR: The Commissioners
 FROM: William D. Travers /s/
 Executive Director for Operations
 SUBJECT: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 1998

PURPOSE:

To obtain Commissioners' approval of the draft abnormal occurrences (AOs) report.

DISCUSSION:

This paper presents a draft of the "Report to Congress on Abnormal Occurrences, Fiscal Year 1998" (NUREG-0090, Vol. 21) ([Attachment 1](#)), and proposed "Other Events of Interest" for inclusion in Appendix C ([Attachment 2](#)).

The draft report addresses five proposed AOs at facilities licensed or otherwise regulated by NRC. One event involved a seismic risk at a gaseous diffusion plant. Two events involved multiple brachytherapy misadministrations, another involved a radiopharmaceutical misadministration, and the last involved an exposure to a minor. The report also addresses one proposed AO, a brachytherapy misadministration, at a facility licensed by an Agreement State.

Appendix C, "Other Events of Interest," will include events and issues that the Commission will determine are appropriate. [Attachment 2](#) is provided for the Commission's consideration for this purpose. It includes four events at four nuclear power plants and discusses the issue of loss of control of licensed materials with two examples for illustration.

The AOs proposed in this report and the criteria for reporting them are as follows:

Fuel Cycle Facilities

- 98-1 Seismic Risk from Liquid Uranium Hexafluoride at the Withdrawal Facilities at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky -- A major condition or significant event not considered in the license/certificate that requires immediate remedial action.

Other NRC Licensees

- 98-2 Multiple Medical Brachytherapy Misadministrations by José N. De León, M.D., in Rio Piedras, Puerto Rico -- A medical misadministration that 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 the gonads, or (2) equal to or greater than 10 gray (Gy) (1000 rad) to any organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive.
- 98-3 Multiple Medical Brachytherapy Misadministrations at Ryder Memorial Hospital in Humacao, Puerto Rico -- A medical misadministration that 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 the gonads, or (2) equal to or greater than 10 gray (Gy) (1000 rad) to any organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive.
- 98-4 Medical Radiopharmaceutical Misadministration at Virginia Beach General Hospital in Virginia Beach, Virginia -- A medical misadministration that 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 the gonads, or (2) equal to or greater than 10 gray (Gy) (1000 rad) to any organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive.
- 98-5 Exposure to a Minor from a Radiopharmaceutical Therapy Event at Western Pennsylvania Hospital in Pittsburgh, Pennsylvania -- Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 mSv (5 rem) or more.

Agreement State Licensees

- 98-1 Medical Brachytherapy Misadministration at Tuomey Regional Medical Center in Sumter, South Carolina -- 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 and committed dose equivalent 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.

The proposed Appendix C items and their merits are as follows:

Nuclear Power Plants

1. St. Lucie Unit 1 -- Non-conservative recirculation actuation signal set point refueling water tank level. This event received significant media attention and resulted in the imposition of an \$88,000 civil penalty. The NRC letter to the licensee listing the violation stated the risk assessment of the event and characterized the risk as a substantial increase in the core damage frequency. An information notice was issued to address the potential generic aspects of the issue. Additionally, NRC is reviewing the event under its Accident Sequence Precursor Program.

2. Quad Cities -- Fire program deficiencies. Because of the potential safety significance of this event, NRC increased its attention to the facility's fire protection program.
3. Big Rock Point -- Loss of liquid poison system. This event was discussed at the Congressional hearing held on July 30, 1998, and received substantial public attention.
4. D.C. Cook -- Deficiencies in emergency core cooling systems. As a result of the deficiencies identified at D.C. Cook during NRC inspections, the NRC increased its attention to the facility's program. Also, a heightened public interest was generated by the issues raised.

Other NRC and Agreement State Materials Licensees

The proposed content for Appendix C includes a brief discussion of the loss of control of licensed materials issue and provides the following examples for illustration:

NRC Licensees

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

This example resulted in (1) significant media attention, (2) pending legislation in the New Jersey Legislature on limiting the use of devices containing tritium, and (3) the development of a rulemaking for a registration program for certain general types of NRC licensees.

Agreement State Licensees

Unauthorized Removal of Brachytherapy Sources from Moses Cone Health Systems, Inc., in Greensboro, North Carolina

This example resulted in (1) significant media attention, and (2) increased joint attention and effort undertaken by the North Carolina Division of Radiation Protection, NRC, Department of Energy, and the Federal Bureau of Investigation to locate the sources.

Included with this paper are a proposed draft letter to the President of the Senate ([Attachment 3](#)) and the Speaker of the House ([Attachment 4](#)) forwarding the AO report for Fiscal Year (FY) 1998.

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The Office of the General Counsel has reviewed the draft report and has no legal objections to its contents.

RECOMMENDATION:

That the Commission (1) approve the contents of the proposed AO report to Congress for FY 1998 and the proposed letters to Congress forwarding the AO report, and (2) select items for Appendix C.

Upon approval, the staff will submit the letters to the President of the Senate and the Speaker of the House to the Chairman for signature. The Office of Congressional Affairs will then arrange for appropriate distribution to Congress. A *Federal Register* Notice describing the NRC and Agreement State licensee AOs and announcing publication of the report will be issued.

SCHEDULING

It is requested that the Commission take action within two weeks of receipt of this draft report.

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Attachments: 1. Draft of "Report to Congress on Abnormal Occurrences, Fiscal Year 1998"
2. Proposed Appendix C Events
3. Letter to President of the Senate
4. Letter to Speaker of the House

ATTACHMENT 1

**REPORT TO CONGRESS
ON
ABNORMAL OCCURRENCES
FISCAL YEAR 1998**

Date Published: April 1999

Office for Analysis and Evaluation of Operational Data
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that 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. This report includes those events that NRC determined were AOs during Fiscal Year 1998.

The report addresses five AOs at facilities licensed or otherwise regulated by NRC. One event involved a seismic risk at a gaseous diffusion plant. Two events involved multiple brachytherapy misadministrations, one involved a radiopharmaceutical misadministration, and one involved an exposure to a minor. The report also addresses one AO at a facility licensed by an Agreement State. The proposed Agreement State AO involved a brachytherapy misadministration.

Appendix C of the report, "Other Events of Interest," includes:

(To be determined by the Commission.)

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PREFACE

INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission (NRC) determines is 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. This report discusses those events that NRC determined were AOs during Fiscal Year 1998.

NRC defines an AO for the purpose of this report using the criteria in Appendix A. The criteria were initially promulgated in an NRC policy statement that was published in the *Federal Register* on February 24, 1977 (42 FR 10950). This policy statement was published before medical licensees were required to report medical misadministrations to NRC, and few of the examples in the policy statement were applicable to these misadministrations. Therefore, in 1984, NRC adopted additional guidance for AO reporting of medical misadministrations.

In 1996, NRC revised the AO criteria, including criteria for medical misadministrations, and published them in the *Federal Register* on December 19, 1996 (61 FR 67072). Again in 1997, NRC revised these criteria to include AO criteria for gaseous diffusion plants and published them in the *Federal Register* on April 17, 1997 (62 FR 18820). The events included in this report were determined to be AOs based on the revised 1997 AO criteria that are summarized in Appendix A.

To disseminate information widely to the public, a *Federal Register* Notice is issued on events reported by facilities licensed or otherwise regulated by NRC or an Agreement State that have been determined to be AOs. At a minimum, each notice must contain the date on which and place where the AO occurred and must describe its nature and probable consequences. Information on activities licensed by Agreement States is also publicly available at

the State level. Copies of the notice are distributed to the NRC Public Document Room (PDR) and Local Public Document Rooms (LPDRs). Potential AOs reported by NRC licensees are placed in the PDR before NRC prepares the AO report to Congress. Potential AOs identified by Agreement States are placed in the PDR when NRC receives such information via NRC's Regulatory Information Distribution System.

NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described herein meet the criteria for being reported as AOs. Information reported for each AO includes (1) the date and place, (2) nature and probable consequences, (3) cause or causes, and (4) actions taken to prevent recurrence.

Appendix B presents recent information on previously reported AOs as it becomes available. Appendix C presents information on other events that the Commission determines is appropriate. These events are not reportable as AOs but are reportable as "Other Events of Interest." Appendix A to this report contains the guidelines for selecting events as "Other Events of Interest."

THE REGULATORY SYSTEM

The system of licensing and regulation by which NRC carries out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations* (10 CFR). Public participation is an element of the regulatory process. To accomplish its objectives, NRC regularly conducts licensing proceedings, inspection and enforcement activities, evaluation of operating experience, and confirmatory research, while maintaining programs for establishing standards and issuing technical reviews and studies.

NRC adheres to the philosophy that the health and safety of the public are best ensured by establishing multiple levels of protection. These levels can be achieved and maintained through regulations specifying requirements that will ensure the safe use of radioactive materials. The regulations contain design and quality assurance criteria appropriate for the various activities regulated by NRC. An inspection and enforcement program assists in ensuring compliance with the regulations.

REPORTABLE OCCURRENCES

Operating experience is an essential element in the regulatory process for ensuring that licensed activities are conducted safely. Licensees are required to report certain incidents or events to NRC. Such reporting helps to identify deficiencies and to ensure that corrective actions are taken to prevent recurrence.

NRC and the industry review operating experience to help identify safety concerns early; to improve dissemination of such information; and to feed back the experience into licensing, regulations, and operations. To more effectively collect, collate, store, retrieve, and evaluate operational data, the information is maintained in computer-based data files.

Except for records exempt from public disclosure by statute or regulation, NRC routinely disseminates information concerning reportable occurrences at facilities licensed or otherwise regulated by NRC to the industry, the public, and other interested groups as these events occur.

Dissemination includes special notifications (to licensees and other affected or interested groups) and public announcements. In addition, information on reportable events is available on the NRC Website and is routinely sent to the NRC's LPDRs throughout the United States and to NRC's PDR in Washington, D.C. Congress is routinely informed of reportable events occurring in facilities licensed or otherwise regulated by NRC.

AGREEMENT STATES

Section 274 of the Atomic Energy Act, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes, and the States assume regulatory authority over, byproduct, source, and special nuclear materials (in quantities not capable of sustaining a chain reaction). Agreement States must maintain programs that are adequate to protect public health and safety and compatible with the Commission's program for such material. Currently, there are 30 Agreement States.

In early 1977, the Commission determined that events that meet the criteria for AOs occurring at Agreement State licensed facilities should be included in the annual report to Congress. Agreement States report event information to NRC in accordance with compatibility criteria established by the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the *Federal Register* on September 3, 1997 (62 FR 46517). Procedures have been developed and implemented for evaluating material events to determine those that should be reported as AOs. AOs reported by the Agreement States to NRC are included in the annual report to Congress and in the *Federal Register* Notice issued to provide wide dissemination of information to the public. The AO criteria found in Appendix A are applied uniformly to events that occur at facilities regulated by NRC and the Agreement States.

FOREIGN INFORMATION

NRC exchanges information with various foreign governments that regulate nuclear facilities. This foreign information is reviewed and considered in the NRC's assessment of operating experience and in its research and regulatory activities. Although foreign information may occasionally be referred to in the AO reports to Congress only domestic AOs are reported.

REOPENING OF CLOSED ABNORMAL OCCURRENCES

NRC reopens previously closed AOs if significant new information about an AO becomes available. Similarly, previously reported "Other Events of Interest" are updated if significant new information becomes available.

NUCLEAR POWER PLANTS

Using the criteria and guidelines in Appendix A to this report, none of the events that occurred at U.S. nuclear power plants during this reporting period was determined to be significant enough to be reported as an abnormal occurrence (AO) in this reporting period.

FUEL CYCLE FACILITIES (Other than Nuclear Power Plants)

Using the criteria and guidelines in Appendix A to this report, one event that occurred at a fuel cycle facility during this fiscal year was determined to be significant enough to be reported as an AO in this reporting period:

98-1 SEISMIC RISK FROM LIQUID URANIUM HEXAFLUORIDE AT THE WITHDRAWAL FACILITIES AT THE PADUCAH GASEOUS DIFFUSION PLANT, PADUCAH, KENTUCKY.

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Part III, "For Fuel Cycle Facilities") to this report states that a major condition or significant event not considered in the license/certificate that requires immediate remedial action will be considered for reporting as an AO.

Date and Place -- February 18, 1998; Paducah Gaseous Diffusion Plant, a uranium enrichment plant, operated by Lockheed Martin Utility Services for the United States Enrichment Corporation (USEC) and located about 16 kilometers (10 miles) west of Paducah, Kentucky.

Nature and Probable Consequences -- On October 31, 1997, USEC submitted a certificate amendment request that provided an updated Safety Analysis Report, containing a new accident analysis, for Paducah. The seismic accident analysis stated that equipment (piping, condensers, and accumulators) in the withdrawal facilities containing liquid uranium hexafluoride (UF_6) could fail at a 70-year return earthquake [0.05 gravitational acceleration (g) peak ground acceleration (pga)] rather than at the 250-year return design basis earthquake (0.15 g pga). However, the consequences of the accident analysis were noted as minimal because of the assumptions made in the accident analysis. The NRC's request for additional information (RAI) dated February 5, 1998, raised concerns about the conservative nature of assumptions for the seismic accident analysis. In response to the RAI, USEC confirmed that the seismic accident analysis assumption of no liquid UF_6 in the withdrawal facilities' accumulators underestimated the potential source term for the seismic accident analysis.

The accumulators are normally empty and serve only as a reservoir for liquid UF_6 when cylinders are changed after being filled, or during periods of equipment problems or surveillances. However, with no operational restrictions on the amount of liquid UF_6 in the accumulators, a seismic event could occur with the accumulators full. Consequences from a 0.05 g pga earthquake with full accumulators in the withdrawal facilities could involve onsite fatalities and significant offsite injuries from exposure to the released UF_6 and reaction products.

Cause or Causes -- The cause of this event was an inadequate seismic design for the facility and an inadequate accident analysis that failed to consider the full range of allowable operations of the withdrawal facilities.

Actions Taken To Prevent Recurrence

Licensee/Certificate Holder -- Immediate corrective actions included restricting operations in the withdrawal facilities to limit the amount of liquid UF_6 available for release. Long-term corrective actions were to install seismic modifications that will allow the withdrawal facilities' equipment to withstand a design-basis earthquake. The modifications have been completed as directed by the NRC.

NRC -- An immediately effective "confirmatory order modifying certificate" to incorporate the immediate and long-term corrective actions was issued on April 22, 1998.

This event is closed for the purpose of this report.

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OTHER NRC LICENSEES (Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

Using the criteria in Appendix A to this report, the following events that occurred at facilities licensed or otherwise regulated by NRC during this reporting period were determined to be significant enough to be reported as abnormal occurrences (AOs):

98-2 MULTIPLE MEDICAL BRACHYTHERAPY MISADMINISTRATIONS BY JOSÉ N. DE LEÓN, M.D., IN RIO PIEDRAS, PUERTO RICO

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion IV, "For Medical Licensees") to this report states that a medical misadministration that 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 the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ and that represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

Date and Place -- Between April 27, 1995, and June 26, 1996; private medical office of José N. De León, M.D., Rio Piedras, Puerto Rico

Nature and Probable Consequences -- Nine patients were treated after surgery for non-malignant eye growths with a strontium-90 (Sr-90) eye applicator, at Dr. De León's private medical office. Each of the nine patients received a dose of 4000 centigray (cGy) (4000 rad) instead of the intended dose of 2000 cGy (2000 rad). The NRC staff identified this event during Fiscal Year 1998.

On June 1, 1994, Dr. De León submitted to NRC a Quality Management Program (QMP) indicating that his 4.625 gigabecquerel (125 millicurie) Sr-90 eye applicator device would deliver to a patient a dose of 2000 cGy (2000 rad) in 26 seconds. In April 1995, Dr. De León hired a health physics consultant to calculate a decay correction for the surface dose rate of the Sr-90 eye applicator. In April 1995, Dr. De León submitted a revised QMP to the NRC, incorporating the surface dose rate corrections performed by the consultant, stating that the Sr-90 eye applicator device would deliver a 2000 cGy (2000 rad) dose in 60 seconds.

On December 11, 1997, the NRC conducted a special inspection of Dr. De León's licensed activities. During this inspection, the NRC determined that in April 1995 Dr. De León's consultant had made a calculation error. Without verifying the consultant's calculations, Dr. De León had adjusted the treatment time from 26 seconds to 60 seconds.

When Dr. De León became aware of this error, he indicated that (1) all patients or next of kin were notified, (2) a free examination was offered to all patients, which was declined, and (3) there were no problems or complications reported by patients associated with the misadministrations. Dr. De León also indicated that it is unlikely for patients to develop any harmful effects as a result of the misadministration.

The NRC hired a medical consultant to review the medical aspects of the misadministration. The NRC's medical consultant reviewed the information obtained from the NRC, Dr. De León, and Ryder Memorial Hospital, and concluded that (1) the range for a single fraction for eye radiation treatments, recommended by the medical community using a Sr-90 applicator, is about 1800 - 3000 cGy (1800 - 3000 rad), (2) the highest single dose, using a Sr-90 applicator, recommended in published medical reports is 3000 cGy (3000 rad), and (3) the patients treated by Dr. De León are at a higher risk for harmful effects because of the high doses given in single fractions.

Cause or Causes -- Dr. De León's consultant made a calculation error in correcting the surface dose rate of the Sr-90 applicator for radioactive decay and Dr. De León failed to verify or question the consultant's calculation before using the revised surface dose rate in patient treatments.

Actions Taken To Prevent Recurrence

Licensee -- Dr. De León has retired; he has properly transferred the Sr-90 eye applicator to a foreign user and he has obtained from NRC a termination of his license.

NRC -- The NRC's Advisory Committee on the Medical Use of Isotopes will be recommending courses of action to the NRC. NRC will perform additional inspections of NRC licensees authorized to possess and use Sr-90 eye applicators to confirm the use of proper decay corrections and source calibrations. In addition, the NRC staff will review this case with the Secretary of Health of the Commonwealth of Puerto Rico for possible action.

This event is closed for the purpose of this report.

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98-3 MULTIPLE MEDICAL BRACHYTHERAPY MISADMINISTRATIONS AT RYDER MEMORIAL HOSPITAL, IN HUMACAO, PUERTO RICO
The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion IV, "For Medical Licensees") to this report states that a medical misadministration that 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 the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ and that represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

Date and Place -- Between April 22, 1995, and February 21, 1996; at Ryder Memorial Hospital; Humacao, Puerto Rico

Nature and Probable Consequences -- Twelve patients treated with a strontium-90 (Sr-90) eye applicator at the Ryder Memorial Hospital received a dose of 4000 cGy (4000 rad) instead of the intended dose of 2000 cGy (2000 rad). Two patients received a second treatment dose of 4000 cGy (4000 rad) to the same eye. These treatments were performed by Dr. José De León, who, in addition to his private practice in Rio Piedras in Puerto Rico, was authorized by NRC to practice at the Ryder Memorial Hospital in Humacao, Puerto Rico. The NRC staff identified this event during Fiscal Year 1998.

On June 28, 1994, Ryder Memorial Hospital notified the NRC that it had canceled the authorization given to the ophthalmologists named on their license to use Sr-90 at its facility, and a Quality Management Program was not needed for this activity. However, during a routine inspection of Ryder Memorial Hospital, conducted between November 17 and December 11, 1997, the NRC staff learned that Dr. De León had used his Sr-90 eye applicator at the Ryder Memorial Hospital without authorization from the hospital. NRC was unable to determine whether Dr. De León had been told by Ryder Memorial Hospital that his authority was canceled for the use of Sr-90 eye applicator.

On December 11, 1997, the NRC conducted a special inspection of Dr. De León's licensed activities. During this inspection, the NRC determined that in April 1995 Dr. De León's consultant had made a calculation error. Without verifying the consultant's calculations, Dr. De León adjusted the treatment time from 26 seconds to 60 seconds.

Ryder Memorial Hospital representatives and Dr. De León, notified the patients or next of kin of the misadministrations. The information presented by Ryder Memorial Hospital describing the effects on patients from misadministrations was based on the information submitted by Dr. De León. Specifically, Dr. De León indicated that the delivered dose of 4000 cGy (4000 rad) falls within the dose range used by the medical community to prescribe these treatments and no adverse effects were expected.

The NRC medical consultant reviewed the information obtained from the NRC, Dr. De León, and Ryder Memorial Hospital, and concluded that (1) the range for a single fraction for eye radiation treatments, recommended by the medical community using a Sr-90 applicator, is about 1800 - 3000 cGy (1800 - 3000 rad), (2) the highest single dose, using a Sr-90 applicator, recommended in published medical reports is 3000 cGy (3000 rad), and (3) the

patients treated by Dr. De León are at a higher risk for harmful effects because of the high doses given in single fractions.

Cause or Causes -- Dr. De León's consultant made an error in calculating the surface dose rate of the Sr-90 applicator, and Dr. De León failed to verify the consultant's calculation before incorporating the revised surface dose rate in patient treatments. In addition, Dr. De León performed ophthalmic brachytherapy using his Sr-90 eye applicator device at Ryder Memorial Hospital under Ryder Memorial Hospital's NRC license, without the hospital's authorization.

Actions Taken To Prevent Recurrence

Licensee -- Ryder Memorial Hospital reiterated its withdrawal of Dr. De León's authority to use the Sr-90 eye applicator device at Ryder Memorial Hospital and does not intend to authorize future use of the Sr-90 eye applicator for ophthalmic brachytherapy. In addition, Dr. De León has retired; he has properly transferred the Sr-90 eye applicator to a foreign user and he has obtained from NRC a termination of his license.

NRC -- The NRC's Advisory Committee on the Medical Use of Isotopes will be recommending courses of action to the NRC. NRC will perform additional inspections of NRC licensees authorized to possess and use Sr-90 eye applicators to confirm the use of proper decay corrections and source calibrations. In addition, the NRC staff will review this case with the Secretary of Health of the Commonwealth of Puerto Rico for possible action.

This event is closed for the purpose of this report.

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98-4 IODINE-131 MEDICAL MISADMINISTRATION AT VIRGINIA BEACH GENERAL HOSPITAL, IN VIRGINIA BEACH, VIRGINIA

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion IV, "For Medical Licensees") to this report states that a medical misadministration that 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 the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

Date and Place -- November 21, 1997; Virginia Beach General Hospital; Virginia Beach, Virginia.

Nature and Probable Consequences -- A patient was administered a dosage of 199.8 megabecquerel (MBq) (5.4 millicurie [mCi]) of iodine-131 (I-131) for a thyroid procedure instead of an 11.1 MBq (0.300 mCi) dosage of iodine-123 (I-123). As a result, the patient's thyroid received a dose of 4000 centigray (cGy) (4000 rad), instead of the intended dose of 2.0 cGy (2.0 rad).

On November 20, 1997, the referring physician prescribed a thyroid function procedure, which, at Virginia Beach General Hospital, required the administration of about 11.1 MBq (0.300 mCi) of I-123. Due to poor communication between the referring physician and her staff (a staff nurse), the patient was scheduled for a whole-body thyroid scan, which required the administration of approximately 185 MBq (5 mCi) of I-131. On November 21, 1997, the technologist who was to perform the procedure attempted to contact the referring physician to ask questions about the requested procedure. However, the referring physician was not available, and the staff nurse who had originally taken the request from the referring physician and scheduled the procedure confirmed that the physician wanted an I-131 scan. The technologist, without a written directive, decided to proceed with the procedure and administered the dosage of 199.8 MBq (5.4 mCi) of I-131 to the patient. The misadministration was identified on November 24, 1997, when the patient returned for a 72-hour whole-body scan.

The licensee stated that no adverse health effects are expected from the misadministration. The NRC's medical consultant determined that the impact of the misadministration on the patient's health should be negligible, with no expected long-term disability.

Cause or Causes -- This event was caused by the licensee's failure to prepare a written directive before the administration of the I-131 dosage and inadequate followup by the technologist involved in the I-131 procedure.

Actions Taken To Prevent Recurrence

Licensee -- New procedures were initiated that required all I-131 procedures to be scheduled through the Nuclear Medicine Department, and additional quality management measures were implemented. The licensee also initiated changes to the computerized scheduling system and provided retraining of the staff.

NRC -- An inspection was conducted to review the circumstances of the misadministration. A Notice of Violation was issued for failure of the licensee to prepare a written directive before the administration of I-131.

This event is closed for the purpose of this report.

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98-5 EXPOSURE TO A MINOR FROM A RADIOPHARMACEUTICAL THERAPY EVENT AT WESTERN PENNSYLVANIA HOSPITAL IN PITTSBURGH, PENNSYLVANIA

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.2, "For All Licensees") to this report states that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 mSv (5 rem) or more will be considered for reporting as an AO.

Date and Place -- July 28, 1998; Western Pennsylvania Hospital; Pittsburgh, Pennsylvania

Nature and Probable Consequences -- A female patient was prescribed a whole-body iodine-131 (I-131) thyroid scan following a thyroidectomy. The technologist asked the patient if she was breast-feeding but she did not reply and was administered a dosage of 111 megabecquerel (3 millicurie) of I-131. Two days later, while the thyroid scan was being performed, the patient said that she had breast-fed her 4-year-old son during the past few evenings. The licensee performed a bioassay on the child on August 3, 1998, and determined that the TEDE for the child based on the International Commission on Radiological Protection calculations was 89.5 millisievert (8.95 rem), and the dose to the thyroid was about 184 centigray (cGy) (184 rad).

The NRC medical consultant evaluated the event and estimated that the dose to the child's thyroid using the Medical Internal Radiation Dose calculations was about 128 to 152 cGy (128 to 152 rad) and presented a discussion of potential clinical consequences.

The hospital was notified of the consultant's findings and was given a copy of the consultant's report. The child has been examined by a pediatric endocrinologist and the hospital continues to monitor the patient and her child.

Cause or Causes -- The patient failed to answer the technologist's question regarding breast feeding and the hospital failed to receive an answer to the question before dose administration.

Action Taken To Prevent Recurrence

Licensee -- The licensee developed a new response form for women aged between 10 and 50 years for (1) asking them if they are nursing, (2) informing them of the harm to a child if they are breast-feeding after I-131 administration, and (3) obtaining a signed statement before administering them radioactive material.

NRC -- NRC sent a letter to the licensee requiring it to prepare a plan describing how to prevent similar events. The licensee responded on October 8 and 12, 1998, listing adequate actions to prevent recurrence of similar events.

This event is closed for the purpose of this report.

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AGREEMENT STATE LICENSEES

Using the criteria and guidelines in Appendix A to this report, the following event, which occurred at the facility of an Agreement State licensee during this reporting period, was determined to be significant enough for reporting as an AO:

AS 98-1 MEDICAL BRACHYTHERAPY MISADMINISTRATION AT TUOMEY REGIONAL MEDICAL CENTER IN SUMTER, SOUTH CAROLINA
The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.1, "For All Licensees") to this report states that 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 and committed dose equivalent 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 will be considered for reporting as an AO.

Date and Place -- September 23, 1997; Tuomey Regional Medical Center; Sumter, South Carolina.

Nature and Probable Consequences -- On September 23, 1997, a patient was scheduled by a referring physician (urologist) for a palladium-103 (Pd-103) permanent prostate seed implant via transrectal ultrasound guidance. However, the referring physician had two patients with identical names and the wrong individual got the orders for the Pd-103 treatment. The patient was identified at the Medical Center by verbal means (asking the patient's name) and by checking the name on the patient's wristband. In addition, the patient had signed a consent in the chart stating he was at the hospital for seed implant for treatment of prostate cancer. The patient received 67 seeds of Pd-103 at 37 megabecquerel (MBq) (1 millicurie [mCi]) per seed, thus a total implant activity of 2479 MBq (67 mCi). On the basis of pre-implant dosimetry, the periphery of the prostate was to receive a maximum dose of 9000 centigray (cGy) (9000 rad). The posterior wall of the bladder and anterior wall of the rectum would receive approximately 4000 cGy (4000 rad) and the whole-body dose would be less than 1 cGy (1 rad). The procedure was performed without complication.

On September 25, 1997, the referring physician notified Tuomey Regional Medical Center that he had two patients with identical names and that the wrong individual had received the implant. On September 29, 1997, the authorized user met with the individual who had received the Pd-103 treatment and discussed the potential early and late side effects, and all necessary precautions.

The licensee stated that the early consequences from this type of implant usually are dysuria and possible hematuria, which, if they occur, resolve in several days. Late consequences could be an approximately 25 percent chance of impotence. Damage to the bladder and rectum occurs in fewer than 1 percent of patients.

Cause or Causes -- The referring physician had two patients with identical names. The wrong individual arrived at Tuomey Regional Medical Center with orders from the referring physician for the Pd-103 seed implant. The patient who should have had these orders had been to Tuomey Regional Medical Center for a pre-operative interview. When the wrong individual presented for treatment at Tuomey Regional Medical Center with orders for the Pd-103 seed implant, the registration process failed to note that he was not the same individual who had undergone the pre-operative interview.

Actions Taken To Prevent Recurrence

Licensee -- The licensee performed a comprehensive review of the patient identification process once the incident occurred. As a result, the patient identification system was revised on a hospital-wide basis in order to prevent recurrence of this type of event.

State Agency -- The State agency investigated the event and a Notice of Violation and Enforcement Conference was held on February 10, 1998. A Notice of Noncompliance was issued for failure to meet the objective that each administration is done in accordance with a written directive. The licensee responded in writing and no additional actions were required.

This event is closed for the purpose of this report.

* * * * *

APPENDIX A 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:

- (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, use of, or 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).

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.

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.
 - 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, exceeds 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).

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.⁽¹⁾

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A_2 or 0.01 times the A_1 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)].
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 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 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 system).

III. For Fuel Cycle Facilities

- A. 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.
- 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:

- 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⁾ *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 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.

APPENDIX B
UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, no previously reported abnormal occurrences were updated.

APPENDIX C
OTHER EVENTS OF INTEREST

"Other Events of Interest" include events that do not meet the abnormal occurrence criteria but 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.

(To be determined by the Commission.)

ATTACHMENT 2

PROPOSED APPENDIX C EVENTS

NUCLEAR POWER PLANTS

1. Non-Conservative Recirculation Actuation Signal (RAS) Set Point for Refueling Water Tank Level at St. Lucie Unit 1

This event received significant media attention. The NRC letter to the licensee listing the violation contained a statement of the risk assessment of the event and characterized the risk as a substantial increase in the core damage frequency. An information notice was issued to address the potential generic aspects of the issue.

St. Lucie Unit 1, is a pressurized water reactor designed by Combustion Engineering and operated by Florida Power & Light Company. It is located 19.3 kilometers (12 miles) southeast of Fort Pierce, Florida.

On October 27, 1997, St. Lucie Unit 1 was defueled in support of a steam generator replacement refueling outage. As part of the outage, obsolete engineered safety features actuation system (ESFAS) bistables (switches) were being replaced to improve system reliability and calibration methods. The equipment to be replaced included all four channels of the refueling water tank (RWT) low-level bistables. A signal from these RWT low-level bistables causes the operating mode of the safety injection system to change from the injection mode to the recirculation mode following a loss-of-coolant accident (LOCA).

Because of the RWT bistable changes, a system engineer performed additional verification to ensure that the RWT level set point agreed with the instrument loop scaling requirement. This review showed that the RWT low-level bistable set point corresponded to a water level of 91.4 centimeters (cm) (36 inches [in.]) above the bottom of the tank. This was less than the Technical Specifications requirement of 121.9 cm (48 in.) above the bottom of the tank. The incorrect set point was specified in the functional test procedure and was applied to all four channels of the Unit 1 RWT level instrument bistables.

In January 1993, the St. Lucie engineering staff had issued an engineering calculation to change the span of the RWT level measurement loop so that the bottom of the tank would be referenced as "zero feet." The level instruments are actually 30.5 cm (1 foot [ft]) above the bottom of the RWT and the 0-cm (0-ft) mark previously referenced the height of the level instruments.

Before the change in the span of the RWT level, the functional test procedure correctly specified a low-level set point of 121.9 cm (48 in.) above the true bottom of the RWT. After the change in the span of the RWT level, the procedure was not changed. Subsequently, the procedure incorrectly specified a low-level set point of 91.4 cm (36 in.) above the bottom of the RWT.

Among the possible consequences of the incorrect RWT low-level bistable set points include failure of the emergency core cooling system (ECCS) pumps. The bistables in question initiate the RAS for automatic swapover of the ECCS pumps' suction from the RWT to the containment sump. If the ECCS pumps' suction swapover occurred at too low a level in the RWT, the ECCS pumps could have inadequate suction pressure, which could result in damage to the pumps within a few minutes. Emergency operating procedures direct operators to monitor the automatic swapover and, if it does not occur at 121.9 cm (48 in.) in the RWT, to take manual actions. On the basis of tests performed on the training simulator, the licensee concluded that, for a small-break LOCA, the incorrect set points would not have resulted in damage to the ECCS pumps. For a large-break LOCA without operator intervention, the incorrect set points would have resulted in ECCS pump damage. However, there was a high probability that operators would have acted to prevent damage to the ECCS pumps.

An engineering calculation was issued with the necessary information to revise both the loop calibration and the RAS bistable set point. However, engineering personnel failed to comply with the existing configuration management process in that an incorrect engineering output document, a calculation, was used for implementation of the design change. The inappropriate use of the calculation resulted in the design change not going through the formal plant design change review process to ensure that implementation requirements were translated into all aspects of configuration management, such as procedures.

The licensee's corrective actions included strengthening engineering procedures governing the preparation of set point calculations. Remaining set points for the Unit 1 ESFAS and all other set points for the reactor protection system and auxiliary feedwater actuation system for Units 1 and 2 were reviewed. Engineering personnel were trained on the revised procedures. Training was also given to maintenance personnel to describe the event and their responsibilities regarding safety-related instrumentation calibrations.

* * * * *

2. Deficient Fire Program at Quad Cities

NRC increased its attention to the Quad Cities fire protection program and its post-fire safe-shutdown methodologies in response to the potential safety significance of this issue.

Licensees of each U.S. commercial nuclear plant had been asked to perform an individual plant examination of external events (IPEEE) to discover potential vulnerabilities. The guidance required the licensees to examine plant fires. In February 1997, the licensee for Quad Cities submitted the results of the IPEEE analysis, which disclosed that most of the risk of severe accidents was attributed to fires, primarily those in the turbine building.

The Quad Cities facilities are mirror images of each other and they began commercial operation in the early 1970s. Units 1 and 2 share the turbine building. The common turbine building houses the main turbine, generator, exciter, condenser, feedwater heaters, feedwater and condensate pumps, the condenser circulating water system, and electrical switchgear for both units. The main control room, which contains equipment and panels for both units, is located adjacent to the south wall of the turbine building. The equipment and panels for each unit are located in separate areas of the control room. Because the control room is located at the south end of the turbine building, most of the major power, instrumentation, and control cabling from both units are routed along the length of the turbine building.

Based on the results of the IPEEE for Quad Cities, Commonwealth Edison Company (ComEd), in addition to its post-fire safe shutdown, added another method to provide reactor water makeup. This method, known as the interim alternative shutdown method, was a risk-reduction method and was installed in March 1997. The staff viewed this action as a positive compensatory measure; however, concerns remained about several fire protection and post-fire safe shutdown implementation weaknesses. After reviewing the IPEEE, the NRC staff met with ComEd staff at NRC headquarters on March 31, 1997, to discuss the Quad Cities IPEEE. In April 1997, the NRC staff visited the site, gained additional insights related to plant fire vulnerabilities, and

made recommendations regarding needed short-term actions.

The licensee subsequently identified concerns not related to the IPEEE that could have impacted the implementation of the post-fire shutdown methodology and declared all post-fire shutdown paths for both units inoperable. The licensee shut down Unit 2 in September 1997 and Unit 1 in December 1997. Subsequently, the NRC allowed the restart of the plants on the basis of its review and inspection of the licensee's interim safe shutdown analysis, post-fire safe shutdown operating procedures, and risk reduction compensatory measures. The staff agreed that this interim shutdown methodology was an adequate short-term measure and was acceptable until full compliance with Appendix R could be achieved. Currently, ComEd is completing its safe shutdown analysis optimization study and is instituting modifications that will reduce the number of manual shutdown operator actions that must be taken from outside the control room, improving fire protection features in certain fire risk vulnerable areas of the plant, improving unit interdependence, and improving its safe shutdown response timeline estimations. Currently, ComEd's fire protection improvement program is scheduled to be completed by the end of the spring 2000 refueling outage for Unit 1 and the spring 2001 refueling outage for Unit 2.

Even though the fire protection and post-fire safe shutdown system weaknesses did not result in an actual challenge or failures of a safety system, the potential that a severe fire could challenge plant safety did exist.

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3. Loss of Liquid Poison System (LPS) at Big Rock Point

This event was discussed during the Congressional hearing held 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 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.

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.

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4. Deficiencies in Emergency Core Cooling Systems at D.C. Cook

As a result of the deficiencies found at D.C. Cook during NRC inspections, the NRC increased its attention to the facility's program. Also, a heightened public interest was generated by the issues raised.

D.C. Cook Units 1 and 2 are pressurized water reactors designed by Westinghouse and operated by the American Electric Power Company. They are located approximately 17.7 kilometers (11 miles) south of Benton Harbor, Michigan.

A design inspection was conducted at the D.C. Cook Nuclear Power Plant by the special inspection staff of NRC from August 4 through September 12, 1997. The NRC staff evaluated the capability of the residual heat removal system, the associated emergency core cooling systems (ECCS), and the component cooling water system to perform the safety functions required by their design bases, their adherence to their design and licensing bases, and the consistency of the as-built configuration and system operations with the Updated Final Safety Analysis Report.

During the recirculation phase following a postulated loss-of-coolant accident, spray nozzles deliver water from the containment spray system to the lower containment in an annulus area beneath the ice condenser. The inspection team found that the plant construction did not provide a flow path for the spray water to get from this annulus area to the containment sump. As a result, cooling water from the spray system could not promptly return to the containment sump, and thereby could potentially reduce the available net positive suction head for operation of the spray pump and cause pump cavitation with eventual pump failure. Both units were shut down as a result of this deficiency. In addition, as a result of flow bias errors and level instrument uncertainties associated with the refueling water storage tank (RWST), manual switchover of the ECCS pump suction from the RWST to the containment sump could occur before the assumed amount of water had become available in the sump to support pump operation. However, by adding the calculated volume of water known to result from melting ice to the sump inventory, vortexing and pump cavitation could be avoided.

Also, fibrous material, which was to have been removed from containment, was found to be installed on the electrical cable trays inside the containments of both units. This material could be postulated to dislodge during a loss-of-coolant accident and potentially block more than 50 percent of the containment sump screens. In addition, some clearances around the edge of the sump screens were found to exceed the limit of 0.64 centimeters (cm) (0.25 inches [in.]), thereby allowing particles greater than 0.64 cm (0.25 in.) to enter the cooling system and potentially block the recirculation throttle valves.

Any of these deficiencies could have potentially created a common-cause failure of the recirculation system to circulate water because of insufficient water reaching the sump or debris clogging the recirculation throttle valves. Subsequent analysis showed that the identified deficiencies did not result in a significant reduction in the degree of protection of public health or safety.

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NRC AND AGREEMENT STATE MATERIALS LICENSEES

During FY 1998, a number of events occurred that involved the loss of control of licensed materials and resulted in the materials entering the public domain in an uncontrolled manner, in some cases causing radioactive contamination or radiation exposures.

In FY 1998, there were 949 events involving materials licensees reported by NRC and Agreement State licensees, including fuel facilities. Of these events, 272 resulted in licensed materials entering the public domain: 93 events were reported by NRC and 179 were reported by Agreement State licensees.

The events concerning loss of control of licensed materials involved both medical and industrial uses. Examples are radioactive sources in (1) medical treatments or research and development, (2) gauges that can be used in industries such as construction and civil engineering to measure the moisture density in soils, or to monitor a production process to ensure quality control, (3) chemical agent monitors/chemical agent detectors used by the military to detect the presence of chemical warfare agents, (4) tritium contained in exit signs or used in illuminating mortar-sighting mechanisms by the military, and (5) radiography cameras used in industrial settings for checking welds, castings, and assembled machinery (e.g., jet engines) and in ceramics. Of these events, the portable moisture density gauges were the most commonly lost licensed devices. However, in FY 1998, there was no report of contamination or overexposure as a result of these events. In cases in which the gauges were recovered, the radioactive sources were in the shielded position. The health hazard if the sources remain in the shielded/locked position is low, since the radiation levels outside the devices are low (less than 2 milliroentgen per hour).

Although not meeting the AO criteria, the frequency of these types of events and the growing public interest and concern has caused the NRC to pay more attention to the issue of the loss of control of licensed materials. The NRC and Agreement State licensees have issued generic communications to inform licensees about these events in order to prevent future incidents and, in some cases, have taken enforcement actions. For illustration purposes, the following two examples are events involving loss of control of licensed materials that occurred in FY 1998.⁽³⁾

1. 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 rule-making for a registration program for certain types of NRC general licensees.

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.

2. Unauthorized Removal of Brachytherapy Sources from Moses Cone Health Systems, Inc., in Greensboro, North Carolina

This example is included in this report because of (1) significant media interest, (2) increased effort from the North Carolina Division of Radiation Protection (NCDRP), the NRC, the Department of Energy (DOE), and the Federal Bureau of Investigation (FBI) to locate the missing sources.

On March 4, 1998, the Radiation Safety Officer (RSO) at Moses Cone Health System, Inc., in Greensboro, North Carolina, during a quarterly physical inventory of sealed sources, noticed that the entire inventory of 18 cesium-137 (Cs-137) brachytherapy sources was missing from the locked storage safe (a "hot lab" within the Radiation Oncology Department). In addition to the 18 sources missing from the safe, a new Cs-137 source that was still in its shipping container was also missing. The activities of the sources ranged from 0.44 to 2.3 gigabecquerel (GBq) (12 - 62 millicurie [mCi]). The total activity missing from the facility was 22 GBq (604 mCi).

The RSO notified the NCDRP and reported that, although a hospital-wide search was underway, the sources had not been located. The NCDRP notified the NRC and other Federal, State, and local officials to inform them about the incident. The NCDRP conducted its own investigation on March 5 and March 6, 1998, but did not locate the missing sources. The investigation efforts were repeated March 9 - 12, 1998, with no success.

On March 20, 1998, a joint effort by NCDRP, NRC, DOE, and FBI was undertaken. On March 24, 1998, after extensive searching for the missing sources, DOE terminated its effort. NCDRP is continuing the investigation and has not reached a final conclusion about the cause of this event. It is believed, however, that inadequate security contributed to the event. An information notice was sent to all medical licensees in North Carolina concerning this event.

The licensee has taken certain measures to prevent future incidents, including the installation of keypad entry systems for the physics laboratory and the "hot lab" door. The safe has been re-keyed and the key is under the direct control of the RSO at all times.

ATTACHMENT 3

The Honorable Albert J. Gore, Jr.
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

I am forwarding the U.S. Nuclear Regulatory Commission's (NRC's) "Report to Congress on Abnormal Occurrences, Fiscal Year 1998" for events at nuclear facilities. These reports are required by Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438). In the context of the Act, an abnormal occurrence (AO) is 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 (Public Law 104-66) requires that AOs be reported to Congress annually.

The report addresses five AOs at facilities licensed or otherwise regulated by NRC. One event involved a seismic risk at a gaseous diffusion plant. Two events involved multiple brachytherapy misadministrations, one involved a radiopharmaceutical misadministration, and one involved an exposure to a minor. The report also addresses one AO, a brachytherapy misadministration, at a facility licensed by an Agreement State. Agreement States are those States that have entered into a formal agreement with NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 30 Agreement States.

Sincerely,
Shirley Ann Jackson

Enclosure: "Report to Congress on Abnormal Occurrences, Fiscal Year 1998"

ATTACHMENT 4

The Honorable J. Dennis Hastert
Speaker of the United States
House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

I am forwarding the U.S. Nuclear Regulatory Commission's (NRC's) "Report to Congress on Abnormal Occurrences, Fiscal Year 1998" for events at nuclear facilities. These reports are required by Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438). In the context of the Act, an abnormal occurrence (AO) is 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 (Public Law 104-66) requires that AOs be reported to Congress annually.

The report addresses five AOs at facilities licensed or otherwise regulated by NRC. One event involved a seismic risk at a gaseous diffusion plant. Two events involved multiple brachytherapy misadministrations, one involved a radiopharmaceutical misadministration, and one involved an exposure to a minor. The report also addresses one AO, a brachytherapy misadministration, at a facility licensed by an Agreement State. Agreement States are those States that have entered into a formal agreement with NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 30 Agreement States.

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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 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.
 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.
 3. Additional information for most of these events is readily available in the NRC Public Document Room.