

December 15, 1997

FOR: The Commissioners

FROM: L. Joseph Callan /s/  
Executive Director for Operations

SUBJECT: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 1997

**PURPOSE:**

Approval of final draft.

**DISCUSSION:**

Included with this paper are a proposed draft letter to the President of the Senate and the Speaker of the House forwarding the abnormal occurrence (AO) report for fiscal year (FY) 1997 (Attachment 1) and a final draft of "Report to Congress on Abnormal Occurrences, Fiscal Year 1997" (NUREG-0090, Vol. 20) (Attachment 2).

The draft report incorporates comments from the staff's review of the proposed AOs in an earlier version. It addresses three AOs at facilities licensed or otherwise regulated by NRC. One AO involved an event at a nuclear power plant, one involved a brachytherapy misadministration, and one involved an occupational overexposure. Four AOs submitted by the Agreement States are included: two involved overexposures and two involved radiopharmaceutical misadministrations. One update of a previously reported AO is included in this report.

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

**Nuclear Power Plants**

97-1 Loss of Two of Three High-Pressure Injection Pumps at Oconee Nuclear Station, Unit 3 -- A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

**Other NRC Licensees**

97-2 Medical Brachytherapy Misadministration at Centre Community Hospital, State College, Pennsylvania -- A medical misadministration that results in a dose that is equal to or greater than 1 gray (100 rad) to the lens of the eye and is delivered to the wrong treatment site.

97-3 Overexposure of a Worker at Mallinckrodt, Inc., in Maryland Heights, Missouri -- Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2500 millisievert (mSv) (250 rem) or more.

**Agreement State Licensees**

AS 97-1 Multiple Transuranic Overexposures to a Worker at Isotope Products Laboratories in Burbank, California -- Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent of 250 mSv (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads, of 2500 mSv (250 rem) or more. In addition, a serious deficiency in management or procedural controls in major areas.

AS 97-2 Overexposure of a Radiographer and an Untrained Technician at Wolf Creek Mine in Walker County, Alabama -- Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent of 250 mSv (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads, of 2500 mSv (250 rem) or more. In addition, a serious deficiency in management or procedural controls in major areas.

AS 97-3 Radiopharmaceutical Misadministration at Mad River Community Hospital in Arcata, California -- A medical misadministration that results in a dose that is equal to or greater than 10 gray (1000 rad) to any organ (other than a major portion of the bone marrow, to the lens of the eye, or to the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive.

AS 97-4 Radiopharmaceutical Misadministration at Tuomey Regional Medical Center in Sumter, South Carolina -- A medical misadministration that results in a dose that is equal to or greater than 10 gray (1000 rad) to any organ (other than a major portion of the bone marrow, to the lens of the eye, or to the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive.

An AO that was included in FY 1996, AO Report to Congress, AO 96-3 "Medical Brachytherapy Misadministrations by José L. Fernández, M.D., in Mayagüez, Puerto Rico," needed to be updated or closed out. It is included in Appendix B as "Update of Previously Reported Abnormal Occurrences." The staff has not identified any events to be included in Appendix C as "Other Events of Interest."

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 approve the contents of the proposed FY 1997 AO Report to Congress and the proposed letters to Congress forwarding the AO report.

Upon approval, forwarding letters to the President of the Senate and the Speaker of the House will be submitted to the Chairman for signature. The Office of Congressional Affairs will then arrange for appropriate distribution to Congress. A Federal Register notice describing the proposed NRC licensee AOs and announcing publication of the report will be issued.

**SCHEDULING**

It is requested that Commission action be taken within two weeks of receipt of this draft report.

L. Joseph Callan  
Executive Director for Operations

CONTACT: Harriet Karagiannis, AEOD  
301-415-6377

Attachments: 1. Proposed Letters to Congress  
2. Draft of "Report to Congress on Abnormal Occurrences, Fiscal Year 1997"

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ATTACHMENT 1

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 1997" for events at nuclear facilities. These reports are required by Section 208 of the Energy Reorganization Act of 1974 (PL 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 (PL 104-66) requires that AOs be reported to Congress annually.

The report addresses three AOs at facilities licensed or otherwise regulated by NRC. One AO involved an event at a nuclear power plant, one involved a brachytherapy misadministration, and one involved an overexposure. Four AOs submitted by the Agreement States are included: two involved overexposures and two involved radiopharmaceutical misadministrations. Recent information about a previously reported AO is also included in this report.

Sincerely,  
Shirley Ann Jackson

Enclosure: "Report to Congress on Abnormal Occurrences, Fiscal Year 1997"

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The Honorable Newt Gingrich  
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 1997" for events at nuclear facilities. These reports are required by Section 208 of the Energy Reorganization Act of 1974 (PL 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 (PL 104-66) requires that AOs be reported to Congress annually.

The report addresses three AOs at facilities licensed or otherwise regulated by NRC. One AO involved an event at a nuclear power plant, one involved a brachytherapy misadministration, and one involved an overexposure. Four AOs submitted by the Agreement States are included: two involved overexposures and two involved radiopharmaceutical misadministrations. Recent information about a previously reported AO is also included in this report.

Sincerely,  
Shirley Ann Jackson

Enclosure: "Report to Congress on Abnormal Occurrences, Fiscal Year 1997"

ATTACHMENT 2

REPORT TO CONGRESS  
ON  
ABNORMAL OCCURRENCES  
Fiscal Year 1997

Date Published: February 1998

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 (PL 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 (PL 104-66) requires that AOs be reported to Congress annually. This report includes those events that NRC determined to be AOs during fiscal year 1997.

The report addresses three AOs at facilities licensed by or otherwise regulated by NRC. One involved an event at a nuclear power plant, one involved a brachytherapy misadministration, and one involved an occupational overexposure. Four AOs submitted by the Agreement States are included. Two involved overexposures, and two involved radiopharmaceutical misadministrations. Recent information about a previously reported AO is included in this report.

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- 96-3 Medical Brachytherapy Misadministration by Jose L. Fernández, M.D., in Mayagüez, Puerto Rico
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## PREFACE

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### INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974 (PL 93-438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the 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 (PL 104-66) requires that AOs be reported to Congress annually. This report includes those events that NRC determined to be AOs during fiscal year 1997.

NRC identifies 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 (Vol. 42, No. 37, pages 10950-10952). 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 (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 (April 17, 1997: 62 FR 18820). The events included in this report were determined to be AOs based on the 1997 revised AO criteria that are summarized in Appendix A.

To provide wide dissemination of information to the public, a Federal Register notice is issued on events reported by facilities licensed by or otherwise regulated by NRC that have been determined to be AOs. At a minimum, each notice must contain the date and place of the occurrence and a description of its nature and probable consequences. Information on activities licensed by Agreement States is publicly available at the State level. Copies of the notice are distributed to the NRC Public Document Room (PDR) and all 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 upon receipt by NRC 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 in this report meet the criteria for reporting as AOs. Information reported for each AO includes the date and place, nature and probable consequences, cause or causes, and actions taken to prevent recurrence.

Appendix B presents recent information on previously reported AOs as it becomes available. Appendix C gives information on events that the Commission determines can be of interest to Congress and the public. These events are not reportable as AOs but are provided 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. 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 follows 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 nuclear materials. The regulations include 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 input to the regulatory process for ensuring that licensed activities are conducted safely. Licensees are required to report certain incidents or events to NRC. This reporting helps to identify deficiencies and to ensure that corrective actions are taken to prevent recurrence.

NRC and the industry provide detailed review of operating experience to help identify safety concerns early; to improve dissemination of such information; and to feedback the experience into licensing, regulations, and operations. In addition, NRC and the industry are continuing to improve the operational data systems, which include not only the type and quality of reports required to be submitted, but also the methods used to analyze data. 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, information concerning reportable occurrences at facilities licensed by or otherwise regulated by NRC is routinely disseminated 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 routinely sent to the NRC's LPDRs throughout the United States and to the NRC 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.

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 periodic 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 (September 3, 1997): 62 FR 46517. Procedures have been developed and implemented for the evaluation of material events to determine those that should be reported as AOs. AOs reported by the Agreement States to NRC are included in the periodic report to Congress. The AO criteria included in Appendix A are applied uniformly to events that occur at facilities regulated by NRC and the Agreement States.

## FOREIGN INFORMATION

NRC participates in an exchange of information with various foreign governments that have nuclear facilities. This foreign information is reviewed and considered in the NRC's assessment of operating experience and in its research and regulatory activities. Reference to foreign information may occasionally be made in the AO reports to Congress; however, 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.

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# REPORT TO CONGRESS ON ABNORMAL OCCURRENCES--FISCAL YEAR 1997

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## NUCLEAR POWER PLANTS

Using the criteria and guidelines in Appendix A of this report, the following event, which occurred at a nuclear power plant during this reporting period, was determined to be significant enough to be reported as an abnormal occurrence (AO).

### 97-1 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.

**Date and Place** - May 3, 1997; 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 May 3, 1997, 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 205F, one reactor coolant pump (RCP) was running, and the Low Pressure Injection System was being used to cool down the RCS. Makeup water to the RCS to compensate for the temperature decrease was being supplied from the letdown storage tank (LDST) by one of the three HPI pumps. Makeup to the LDST consisted of periodic batch additions as needed. These plant conditions were below the point where the technical specifications required that the HPI system must be operable; that is, required to mitigate a small-break loss-of-coolant accident.

Plant cool-down evolutions appeared to be normal until the "B" HPI pump started to cavitate and makeup flow to the reactor coolant system was lost. A 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 system, prior to 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. This would have significantly complicated recovery from the accident, but would have been within the Emergency Operating Procedure guidance and training provided to the operators. It would, however, increase the probability of core damage. The length of time that Unit 3 was in this degraded status could not be accurately determined, but the condition may have existed since start-up in March 1997, when plant conditions required that the HPI system be operable.

**Cause or Causes** - Loss of the HPI pumps occurred when all of the water was inadvertently pumped from the 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 1997, 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, resulting in the HPI pump continuing to run until the tank was empty. The LDST level detection system consists of two level instruments connected to a common reference leg. Thus, the condition affected both level detectors equally.

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 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, 1997.

**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. Information Notice 97-38, "Level-Sensing System Initiates Common-Mode Failure of High-Pressure-Injection Pumps," was issued on June 24, 1997, to alert other licensees to this event.

This event is closed for the purpose of this report.

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### FUEL CYCLE FACILITIES (Other than Nuclear Power Plants)

Using the criteria and guidelines in Appendix A of this report, no events that occurred at fuel cycle facilities during this reporting period were determined to be significant enough to be included in this report.

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

Using the criteria and guidelines in Appendix A of this report, the following events that occurred at other NRC licensees during this reporting period were determined to be significant enough to be reported as AOs.

#### 97-2 MEDICAL BRACHYTHERAPY MISADMINISTRATION AT CENTRE COMMUNITY HOSPITAL, STATE COLLEGE, PENNSYLVANIA

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

**Date and Place** - December 20, 1996; Centre Community Hospital; State College, Pennsylvania.

**Nature and Probable Consequences** - A patient was prescribed a brachytherapy treatment using a high dose-rate remote afterloading device (HDR) to treat a surface skin cancer. During the treatment, the mask used to hold the HDR treatment catheter containing the radioactive source in position at the treatment facial site, the right lateral edge of the nose where it conjuncts with the cheek, failed, and the catheter was inadvertently repositioned. As a result, the patient's right lateral chin received an unprescribed radiation dose.

The NRC's medical consultant evaluated the misadministration and estimated that the patient's skin of the right chin received a radiation dose of approximately 2000 centigray (2000 rad) and 165 to 170 centigray (165 to 170 rad) to the lens of the left eye. The medical consultant indicated that the dose to the lens of the eye is about in the dose range for cataract formation however, no other adverse effects to the patient are expected.

The licensee indicated that the patient had not been informed of the misadministration; however, the patient's referring physician and family had been informed.

**Cause or Causes** - The mask failed to hold the HDR treatment catheter in the correct position. NRC determined that the use of the HDR device to treat surface skin cancer was not authorized by the facility's license. Therefore, NRC had not reviewed the licensee's procedures for securing the treatment catheter to a patient.

#### **Actions Taken to Prevent Recurrence**

**Licensee** - The licensee provided corrective actions in a letter to NRC. The letter includes a commitment not to perform any skin surface treatments until a license amendment is granted.

**NRC** - NRC issued a Confirmatory Action Letter confirming that the licensee agreed to cease performance of any additional skin surface applications until a license amendment approving the procedure was obtained. NRC conducted an Enforcement Conference with the licensee and issued a Notice of Violation for unauthorized use of the HDR.

This event is closed for purposes of this report.

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97-3 OVEREXPOSURE OF A WORKER AT MALLINCKRODT, INC., IN MARYLAND HEIGHTS, MISSOURI

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") of this report states that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more will be considered for reporting as an AO.

**Date and Place** - May 14-15, 1997; Mallinckrodt, Inc.; Maryland Heights, Missouri.

**Nature and Probable Consequences** - On May 14, 1997, an employee was removing radioactive waste from the hot cell where rhenium-186 (Re-186) was used. The employee was performing this task manually, using gloves, instead of remotely. When he left the area, he attempted to perform a personal contamination survey but the survey meter immediately went off the scale. He assumed that the high count rate was due to background radiation from an adjacent radioactive material transport cart and, subsequently, forgot to resurvey himself in a low background area before he left the facility that evening. Upon arrival at work the next day, he was told that his urine sample, which he had submitted before going home the previous night, indicated iodine-131 radiation contamination and that he was restricted from working with radioactive material. At that time, he performed a personal contamination survey and detected significant levels of contamination on his left thumb which subsequently was identified as rhenium-186. The iodine-131 contamination level did not exceed the AO criteria for exposure to radiation from licensed material.

The licensee estimates that the individual received a shallow-dose equivalent of 6090 millisievert (609 rem) to an area of about 0.75 square centimeters (0.12 square inches) on the palm side of the thumb of his left hand. Lower levels of contamination were found on the back of his right hand and fingers. On May 15, 1997, the employee had undergone decontamination to the extent that only approximately 4 percent of the activity remained.

The licensee surveyed the offsite locations where the employee had been after leaving work on May 14, 1997. Low levels of Re-186 contamination were found on three locations inside the employee's vehicle and on various items in the bathroom and kitchen of his home. The employee's vehicle and home were decontaminated. The employee was examined by a physician who identified no immediate health effects. However, according to a report from an NRC consultant, a small possibility exists that localized skin cancer may develop.

**Cause or Causes** - The cause of the event was a procedural deficiency in handling waste from the Re-186 hot cell. Normally, radioactive waste in other hot cells at the facility was handled with remote tools. However, in this case, procedural controls did not require remote handling of the waste. Once the employee completed the work, poor radiation work practices were exhibited as he cross-contaminated his hands when he removed his gloves. In addition, the worker did not investigate the detection of high count rates during his first attempt to perform a contamination survey.

**Actions Taken to Prevent Recurrence**

**Licensee** - The staff was instructed on the importance of conducting proper personal contamination surveys and the proper use of protective clothing. The use of Re-186 was suspended until improvements to existing waste disposal procedures could be evaluated and implemented. Plans were made (1) to compile all existing contamination protection procedures into one contamination protection procedure, (2) to evaluate the use of a portal type monitoring system, and (3) to post personal-monitoring reminder signs at all laboratory exits.

**NRC** - NRC conducted a special safety inspection, and appropriate enforcement action will be taken.

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 of this report, the following events, which occurred at Agreement State licensees during this reporting period, were determined to be significant enough to be reported as AOs.

AS 97-1 MULTIPLE TRANSURANIC OVEREXPOSURES TO A WORKER AT ISOTOPE PRODUCTS LABORATORIES IN BURBANK, CALIFORNIA

Appendix A (see Criterion I.A.1, "For All Licensees") of 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 (DDE) (external dose) and committed dose equivalent (CDE) (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 will be considered for reporting as an AO. In addition, Appendix A (see Criterion I.D.3, "Other Events") of this report states that a serious deficiency in management or procedural controls in major areas will be considered for reporting as an AO.

**Date and Place** - Between January 1 and December 31, 1995; Isotope Products Laboratories; Burbank, California.

**Nature and Probable Consequences** - A radiochemist was assigned to make transuranic and other types of sources. The transuranics utilized included the isotopes of plutonium-238 (Pu-238), Pu-239, Pu-240, americium-241 (Am-241), and curium-244 (Cm-244). During January 1995, while making a Cm-244 source, it was discovered that the exhaust fan of the fume hood where the source was being fabricated was not working. An analysis of room air samples confirmed the loss of Cm-244 into the working area.

Bioassay results disclosed that the fecal and urine samples provided by the radiochemist contained Cm-244 and Am-241. The licensee hired dosimetry and radiation protection consultants as directed by the State Agency. Careful analysis of the bioassay data by these consultants, which included dose summation and retrospective time correction for various intakes, suggested that during 1995 the radiochemist received a TEDE of 383.20 mSv (38.32 rem) and a CDE of 6900 mSv (690 rem) to the bone surfaces. The specific exposures were as follows: (1) committed effective dose equivalent (CEDE) of 271.8 mSv (27.18 rem) from Cm-244, (2) CEDE of 80 mSv (8 rem) from Am-241, (3) CEDE of 4.4 mSv (0.44 rem) from Pu-238, Pu-239, and Pu-240, and (4) DDE of 27.0 mSv (2.70 rem) from external radiation.

The State Agency discovered this incident during a routine inspection on December 5, 1995. During a follow-up inspection, the State Agency learned that another Cm-244 incident took place and was significant. The State Agency also learned of other exposure incidents that indicated the licensee had a deficient contamination control program, an inability to conduct internal dose assessments, and inadequate management oversight.

**Cause or Causes** - The licensee's radiation protection program was inadequate and lacked important elements needed to ensure the radiation safety of its workers. Some of these inadequacies were the lack of (1) work permits, (2) glove boxes for certain types of work, and (3) radiation procedural controls.

#### **Actions Taken to Prevent Recurrence**

**Licensee** - After the licensee's consultants conducted their review and comprehensive audit of the existing radiation protection program, they made recommendations to ensure future compliance with the license and regulations. The licensee hired a competent radiation safety officer, and the radiochemist was assigned duties that did not involve the handling or processing of radioactive materials.

**State Agency** - The State Agency completed its investigation and is committed to closely tracking the licensee's radiation protection program to ensure continued compliance.

This event is closed for the purpose of this report.

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AS 97-2 OVEREXPOSURE OF A RADIOGRAPHER AND AN UNTRAINED TECHNICIAN AT WOLF CREEK MINE IN WALKER COUNTY, ALABAMA

Appendix A (see Criterion I.A.1, "For All Licensees") of 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 (DDE) (external dose) and committed dose equivalent (CDE) (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 will be considered for reporting as an AO. In addition, Appendix A (see Criterion I.D.3, "Other Events") of this report states that a serious deficiency in management or procedural controls in major areas will be considered for reporting as an AO.

**Date and Place** - July 1, 1996; Wolf Creek Mine, Walker County, Alabama

**Nature and Probable Consequences** - A radiographer, employed by Certified Testing and Inspection of Cottdale, Alabama, and a technician, employed by Ultron, Inc., of Mt. Vernon, Illinois, were performing industrial radiography at the Wolf Creek Mine in Walker County, Alabama, when they became so distracted by problems with excessively exposed film that they forgot they had an exposure in progress and entered the high radiation area without making a survey and changed the film with the source in the unshielded exposed position. The radiographer had received prior radiation safety training, however, the technician, an employee of Ultron, Inc., had not received prior radiation safety training. The radiography film and the device used to support the source and the film during exposures were being supplied to the radiographer by Ultron, Inc.

Consequently, both individuals received unintended radiation exposure. The State Agency estimated that the radiographer received a dose of 530 millisievert (mSv) (53 rem) to his head and 48 mSv (4.8 rem) to the center of his body and the Ultron, Inc., technician received a dose of 110 mSv (11 rem) to his head and 28 mSv (2.8 rem) to the center of his body. Neither individual reported any acute radiation symptoms.

The radiography film supplied by Ultron, Inc., had faster and different exposure characteristics than the film usually used by Certified Testing and thus was being overexposed during processing in the darkroom. The darkroom, which was supplied by Certified Testing, utilized a homemade "safe light," which had been made a safe light by the application of red spray paint. The radiographer did not realize beforehand that the light would not be "safe" for the film supplied by Ultron, Inc.

**Cause or Causes** - The radiographer entered a designated high radiation area with his alarm ratemeter turned off and without following his normal practice of cranking in the source and surveying the guide tube and camera. The radiographer interpreted the silence from the alarm ratemeter as an indication of safe conditions. Unfortunately when turned off the alarm ratemeter gives the same indication as it does when indicating safe conditions. In addition, the radiographer did not utilize a collimator to reduce the exposure to himself and the Ultron, Inc., technician.



**Actions Taken to Prevent Recurrence**

**Licensee** - The licensee stated that the radiographer did not develop any symptom of acute radiation exposure and that its personnel were reinstructed in the importance of performing surveys and using a collimator. The licensee committed to the State Agency to verify the training of all technicians, including those of the company that hires the licensee to perform radiography.

**State Agency** - The State Agency cited the Licensee for the following four violations: (1) excessive exposure to a radiation worker, (2) excessive exposure to a member of the public (the Ultron, Inc. technician representative), (3) failure to prevent unauthorized entry into the High Radiation Area, and (4) failure to exercise ALARA by using a collimator. A civil penalty was considered but not imposed. The State Agency recommended that both individuals contact the State and seek medical attention if any symptoms of acute exposure should appear.

This event is closed for the purpose of this report.

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AS 97-3            RADIOPHARMACEUTICAL MISADMINISTRATION AT MAD RIVER COMMUNITY HOSPITAL IN ARCATA, CALIFORNIA

Appendix A (see Criterion IV, "For Medical Licensees") of this report states that a medical misadministration that results in a dose that is equal to or greater than 10 gray (Gy) (1000 rad) to any organ (other than a major portion of the bone marrow, to the lens of the eye, or to the gonads) 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** - February 28, 1996; Mad River Community Hospital; Arcata, California.

**Nature and Probable Consequences** - A patient was prescribed a dosage of 3.7 megabecquerel (MBq) (0.1 millicurie [mCi]) of iodine-131 (I-131) for a thyroid scan and uptake procedure. However, the patient was administered a dosage of 262.7 MBq (7.1 mCi) of I-131. As a result, the patient's thyroid received a dose of about 9100 centigray (cGy) (9100 rad), instead of the prescribed dose of 130 cGy (130 rad).

The licensee stated that such a dose may induce a hypothyroid state requiring the patient to take thyroid hormone.

**Cause or Causes** - The wrong dosage was administered on the assumption that the patient was prescribed a whole body thyroid scan for a cancer metastatic disease evaluation.

**Actions Taken to Prevent Recurrence**

**Licensee** - Procedures for scheduling a whole body scan for thyroid cancer metastases were revised to include a detailed patient preparation and history. The revised procedures required that the approving radiologist sign the I-131 administration policy before ordering a radiopharmaceutical. In addition, the nuclear medicine technologist attended a continuing education program at San Francisco General Hospital, which included a segment on the effects of studies involving therapy dosages.

**State Agency** - The State Agency conducted numerous follow-up inspections to ensure that the licensee's actions taken to prevent recurrence had been implemented.

This event is closed for the purpose of this report.

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AS 97-4            RADIOPHARMACEUTICAL MISADMINISTRATION AT TUOMEY REGIONAL MEDICAL CENTER IN SUMTER, SOUTH CAROLINA

Appendix A (see Criterion IV, "For Medical Licensees") of this report states that a medical misadministration that results in a dose that is equal to or greater than 10 gray (Gy) (1000 rad) to any organ (other than a major portion of the bone marrow, to the lens of the eye, or to the gonads) 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** - December 11, 1996; Tuomey Regional Medical Center; Sumter, South Carolina.

**Nature and Probable Consequences** - A patient was prescribed a dosage of 74 megabecquerel (MBq) (2.0 millicurie [mCi]) of iodine-131 (I-131) for a treatment of Graves disease. However, the patient was administered a 388.5 MBq (10.5 mCi) dosage of I-131. As a result, the patient's thyroid received a dose of 40,400 centigray (cGy) (40,400 rad) instead of the prescribed dose of 7700 cGy (7700 rad).

The licensee stated that the administered dose of I-131 to the patient's thyroid is not expected to have major health effects.

**Cause or Causes** - The wrong dosage was administered to the patient because the written order for the I-131 procedure was misread by the administering technologist.

**Actions Taken to Prevent Recurrence**

**Licensee** - The licensee will have the written order on hand before ordering radiopharmaceuticals from the pharmacy and will have a second person verify the dosage before administration to the patient.

**State Agency** - The State Agency accepted the licensee's report and corrective action as appropriate. No further action was requested.

This event is closed for the purpose of this report.

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## APPENDIX A ABNORMAL OCCURRENCE CRITERIA AND GUIDELINES FOR OTHER EVENTS OF INTEREST

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

- (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 set forth 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 certified 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.<sup>(1)</sup>
    1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A<sub>1</sub> 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<sub>2</sub> or 0.01 times the A<sub>1</sub> 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 to 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, <sup>(2)</sup> or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

#### Guidelines for "Other Events of Interest"

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

occurrence.

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## APPENDIX B UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

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During this reporting period, the following update of a previously reported abnormal occurrence (AO) is included in the report.

### OTHER NRC LICENSEES

96-3      MEDICAL BRACHYTHERAPY MISADMINISTRATION BY JOSE L. FERNÁNDEZ, M.D., IN MAYAGÜEZ, PUERTO RICO

This AO was originally reported in fiscal year 1996, NUREG-0090, Vol. 19, "Report to Congress on Abnormal Occurrences."

The AO criteria used for this event was based on the AO criteria that were effective in FY 1996, which stated that administering therapeutic radiation such that the actual dose is greater than 1.5 times the prescribed dose, or the event (regardless of any health effects) affects two or more patients at the same facility, should be considered an AO.

On January 14, 1994, Dr. Fernández acquired an eye applicator device, which contained a strontium-90 (Sr-90) source of approximately 3219 megabecquerel (87 millicurie) activity, from the estate of a deceased licensee in Mayagüez, Puerto Rico. (Eye applicator devices are used for the supplemental treatment of non-malignant growths on the eye after surgery is performed.) Because the eye applicator device was not calibrated properly, patients received unprescribed radiation doses. The NRC medical consultant stated that the long-term consequences of the misadministered radiation treatments to the 25 patients that received the highest dose could include: (1) increased risk of cataracts and (2) increased risk of infections, caused by severe thinning or ulceration of the sclera, which could cause blindness if not detected early and aggressively treated. No adverse health effects were reported during a reexamination of seven of these 25 patients by Dr. Fernández. However, the NRC medical consultant indicated that the possible adverse consequences to these patients may not appear for a period of up to 10 years after irradiation.

Dr. Fernández purchased the medical practice and the Sr-90 source from the estate of the deceased former licensee, Dr. Luis A. Vázquez of Mayagüez, Puerto Rico. Consequently, Dr. Fernández had the records of all of the administrations that were made, using the Sr-90 source, while it was licensed to Dr. Vázquez. In a letter to Dr. Fernández dated October 28, 1996, NRC confirmed with Dr. Fernández that he would preserve the patient records of the former licensee and perform a computer search to identify the patients who were treated with the eye applicator.

The AO report is updated as follows:

The consultant hired by Dr. Fernández identified that 202 of the patients treated were involved in misadministration.

In addition, NRC reviewed the records of administrations done by Dr. Luis A. Vázquez after September 1990 and identified 559 dose administrations in which 41 resulted in overdosing misadministration. Dr. Fernández and the clinic, in possession of Dr. Vázquez' patient records, made all reasonable efforts to notify the patients involved in these misadministrations according to the requirements of 10 CFR 35.33; however, 24 patients were not notified because of inaccurate information on the record, such as a wrong address or telephone number.

NRC compiled information on patients that received overdosing misadministration by Dr. Fernández and Dr. Vázquez and sent the information to the Commonwealth of Puerto Rico, Department of Health, which is considering follow-up actions, including reminding the patients annually about the need to receive periodic eye exams by specialized physicians. On June 11, 1997, NRC issued a Notice of Violation and Proposed Imposition of a Civil Penalty to Dr. Fernández for the violations identified during NRC inspections that represented a significant lack of program oversight and careless disregard of regulatory requirements. Dr. Fernández paid the \$8000 Civil Penalty, and on July 17, 1997, filed an NRC Form 314, "Certificate of Disposition of Materials" requesting the termination of his license. Since Dr. Fernández disposed of the licensed material in his possession, the NRC terminated his license on September 5, 1997.

This event is closed for the purpose of this report.

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## APPENDIX C OTHER EVENTS OF INTEREST

"Other Events of Interest" are reported because they may possibly be perceived by the public to be of health or safety significance. Such items would not involve a major reduction in the level of protection provided for public health or safety; therefore, they would not be reported as abnormal occurrences. During fiscal year 1997, no "Other Events of Interest" were reported.

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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.