REPORT TO CONGRESS

on

ABNORMAL OCCURRENCES

FISCAL YEAR 2004

Office of Nuclear Regulatory Research
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Attachment 1

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ABSTRACT

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 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 the NRC must report AOs to Congress annually. This report describes those events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 2004.

The report describes four events at NRC-licensed facilities that meet the criteria to be classified as AOs. One event involved a uranium hexafluoride (UF_6) release at a fuel cycle facility. Another event, also at a fuel cycle facility, revealed excessive uranium concentrations found in ash deposits in various locations in an incinerator. A third event involved a patient undergoing therapeutic brachytherapy treatment. The fourth event involved an unintentional excessive dose of sodium iodide (I-131) administered to a patient. The report also addresses 13 AOs at facilities licensed by Agreement States. Agreement States are those States that have entered into formal agreements with the 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 33 Agreement States. During FY 2004, the NRC received notification of 13 events that occurred at Agreement State-licensed facilities, including 8 therapeutic medical events, 3 diagnostic medical events, 1 event involving an unintentional therapeutic dose of I-131 to an embryo/fetus, and 1 event involving an extremity overexposure to a radiopharmacy trainee.

Appendix A to this report presents the NRC's criteria for selecting AOs, as well as the guidelines for selecting "Other Events of Interest." Appendix B, "Update of Previously Reported Abnormal Occurrences," provides an update concerning one event that the NRC initially reported in the annual report to Congress for FY 2003. Specifically, that update addresses inspection and enforcement actions that the NRC undertook following an unplanned radiological overexposure to a radiographer. Appendix C, "Other Events of Interest," describes licensee record accountability discrepancies at two nuclear power plants, loss of offsite power at another nuclear power plant, and a stuck source in an exposed position at an irradiator facility.

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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 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 the NRC must report AOs to Congress annually. This report describes those events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 2004. [Agreement States are those States that have entered into formal agreements with the 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 33 Agreement States.

For the purpose of this report, the NRC defined AOs using the criteria set forth in Appendix A. The NRC initially promulgated those criteria in a policy statement that the Commission published in the *Federal Register* on February 24, 1977 (42 FR 10950), followed by several revisions in subsequent years.

The 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. The information reported for each AO includes the date and place, nature and probable consequences, cause(s), and actions taken to prevent recurrence.

Appendix A to this report presents the NRC's criteria for selecting AOs, as well as the guidelines for selecting "Other Events of Interest." Appendix B, "Update of Previously Reported Abnormal Occurrences," provides an update concerning one event that the NRC initially reported in the annual report to Congress for FY 2003. Specifically, that update addresses inspection and enforcement actions that the NRC undertook following an unplanned radiological overexposure to a radiographer. Appendix C, "Other Events of Interest," presents information concerning events that are not reportable to Congress as AOs, but are included in this report based on the Commission's guidelines, as listed in Appendix A to this report. Specifically, these events included licensee record accountability discrepancies at two nuclear power plants, loss of offsite power at another nuclear power plant, and a stuck source in an exposed position at an irradiator facility.

To widely disseminate information to the public, the NRC issues *Federal Register* notices describing AOs at facilities licensed or otherwise regulated by the NRC or an Agreement State. Information on activities licensed by Agreement States is also publicly available from the Agreement States.

THE REGULATORY SYSTEM

The system of licensing and regulation by which the 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 one essential element of the regulatory process. To accomplish its objectives, the NRC regularly conducts licensing proceedings, inspection and enforcement activities, operating experience evaluations, and confirmatory research. In addition, the NRC maintains programs to establish standards and issue technical reviews and studies.

The 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 ensure the safe use of radioactive materials. Those regulations contain design and quality assurance criteria appropriate for the various activities regulated by the NRC. An inspection and enforcement program assists in ensuring compliance with the regulations. The NRC is striving to make the regulatory system more risk-informed and performance-based, where appropriate.

REPORTABLE OCCURRENCES

Review and response to operating experience are essential to ensure that licensed activities are conducted safely. Toward that end, the regulations require that licensees must report certain incidents or events to the NRC. Such reporting helps to identify deficiencies and ensure that corrective actions are taken to prevent recurrence.

The NRC and the industry review and evaluate operating experience to identify safety concerns. Information from the review and evaluation is disseminated and fed back to licensees through licensing activities and regulations. Operational data are maintained in computer-based data files for more effective collection, storage, retrieval, and evaluation.

Except for records that statutes or regulations exempt from public disclosure, the NRC routinely disseminates information on reportable occurrences at licensed or regulated facilities to the industry, the public, and other interested groups when the occurrences happen. This dissemination is achieved through public announcements and special notifications to licensees and other affected or interested groups. In addition, the NRC routinely informs Congress of significant events occurring at licensed or regulated facilities.

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 are compatible with the Commission's program for such materials. Currently, there are 33 Agreement States.

In early 1977, the Commission determined that events that meet the criteria for AOs at facilities licensed by Agreement States should be included in the quarterly report to Congress.

Therefore, AOs reported by the Agreement States to the NRC are included in the AO report and in the *Federal Register* notice issued to disseminate the information about each AO to the public. 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 materials events to determine those that should be reported as AOs. The AO criteria in Appendix A are applied uniformly to events at facilities regulated by the NRC and the Agreement States.

FOREIGN INFORMATION

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

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC provides updates of previously reported AOs "Other Events of Interest" if significant new information becomes available. These updates appear in Appendix C to this report.

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ABBREVIATIONS

µCi	microcurie
AEA	Atomic Energy Act
AIT	Augmented Inspection Team
AO	abnormal occurrence
Bq	becquerel
CFR	*Code of Federal Regulations*
cm	centimeter
CT	computerized tomography
Ci	curie
Cs-137	cesium-137
ERA	Energy Reorganization Act
FR	*Federal Register*
FY	Fiscal Year
GBq	gigabecquerel
GDC	General Design Criterion
GDNR	Georgia Department of Natural Resources
Gy	gray
Gy/min	gray per minute
HF	hydrogen fluoride
HDR	high-dose-rate (afterloader)
I-123	iodine-123
I-125	iodine-125
I-131	iodine-131
Ir-192	iridium-192
IVB	intravascular brachytherapy
LAD	left anterior descending (artery)
LOCA	loss-of-coolant accident
LOOP	loss of offsite power
MBq	megabecquerel
mCi	millicurie
mm	millimeter
mrem	millirem
MST	mountain standard time
mSv	millisievert

NPP	nuclear power plant
NRC	U.S. Nuclear Regulatory Commission
PVNGS	Palo Verde Nuclear Generating Station
RSO	radiation safety officer
SAR	safety analysis report
SFP	spent fuel pool
Sr-90	strontium-90
Sv	sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
Tl-201	thallium-201
TLD	thermoluminescent dosimeter
TS	technical specification
UCLA	University of California at Los Angeles
UF_6	uranium hexafluoride
wt%	percent by weight

ABNORMAL OCCURRENCES
IN FISCAL YEAR 2004

NUCLEAR POWER PLANTS

During this period, no events occurred at U.S. nuclear power plants that were significant enough to be reported as AOs.

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FUEL CYCLE FACILITIES
(Other Than Nuclear Power Plants)

This section discusses the events that occurred at NRC-licensed or regulated facilities during this reporting period, which were significant enough to be reported as AOs based on the criteria in Appendix A to this report.

04-01 Uranium Hexafluoride Release at Honeywell Speciality Chemicals, Inc. in Metropolis, Illinois

Criterion III.A.,"For Fuel Facilities," of Appendix A to this report states that 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 will be considered for reporting as an AO.

Date and Place — December 22, 2003; Honeywell International, Inc., Honeywell Specialty Chemicals, Metropolis, Illinois.

Nature and Probable Consequences — On December 22, 2003, a uranium hexafluoride (UF_6) release occurred from one of the plant's chemical process lines. The release lasted approximately 40 minutes. The licensee observed a visible cloud crossing the site boundary and declared a site area emergency, which was terminated approximately 4 hours later. Approximately 25 members of the public were temporarily evacuated from their homes, and approximately 75 persons remained sheltered in their homes for a time. Four members of the public went to the hospital. Three of the four were examined and released, while the fourth was held for observation and released the next day. One member of the public showed skin reddening on portions of his face and part of one arm, which indicated a hydrogen fluoride (HF) acid burn. Honeywell's initial estimate of a release of 7 pounds of UF_6 was later refined to be approximately 70 pounds. Based on air samples and environmental measurements by the State and a Honeywell contractor, and urinalyses for workers and members of the public, the NRC concluded that the release was below the agency's limits and had minimal impact on worker or public health and safety. Honeywell shut the plant down and agreed to discuss corrective actions with the NRC before restarting operations to determine whether the NRC had any objection to restarting specific operations.

Cause(s) — An NRC Augmented Inspection Team (AIT) and Honeywell's Root Cause Investigation Team identified similar root and contributing causes. The Honeywell Root Cause Investigation Team provided its findings to the NRC in a meeting on February 11, 2004.

Key causes were as follows:

- The licensee failed to have a written procedure for an infrequent evolution and, thus, relied on the operator's memory to perform the required actions.
- The licensee's corrective action program had not adequately corrected a previously identified lack of procedures for certain activities, the licensee had not adequately aligned staff to the need for procedures for activities.
- The licensee did not have an alarm to warn operators that the system was becoming pressurized. The licensee did not have procedures or measures to respond to abnormal conditions during operations. The licensee did not have procedures or processes for documenting when equipment was not in proper working order.

In addition, the AIT and Honeywell Root Cause Investigation Team identified problems in implementing the emergency plan once the licensee identified the release, including problems in communication with State and local authorities.

Actions Taken to Prevent Recurrence

Licensee — In addition to the Root Cause Investigation Team, Honeywell chartered a Plant Engineering Team, a "Triangle of Prevention" Team, and a Corporate "Deep Dive" Team to review the facility and operations. These teams reviewed certain UF_6 safety and environmental improvements, management processes, change management, mechanical integrity, and the emergency plan. As a result of these reviews, Honeywell developed a list of corrective and improvement actions to be completed before restarting operations. On March 4, 2004, Honeywell submitted a list of the actions to be taken for each phase of the restart. Honeywell has also worked with State and local authorities to improve emergency response, and the company conducted an emergency drill with local agencies on March 11, 2004. That drill identified items that needed to be improved, including use of the dedicated phone for communicating with off site authorities. Honeywell plans to improve this communication method. In addition, Honeywell is in the process of implementing other corrective and improvement actions.

NRC — The NRC developed a Restart Readiness Oversight Plan to review Honeywell's actions, including safety and emergency preparedness improvements. The NRC has reviewed actions the licensee planned to prevent recurrence. In addition, the NRC observed an emergency drill of the revised Emergency Plan and procedures.

The NRC held two public meetings in Metropolis, Illinois (on March 18 and April 21, 2004) during the restart phase to inform the public of the licensee's plans and progress and to describe the NRC's oversight activities and results. In addition, the NRC completed inspections of the licensee's corrective actions before the restart of licensed operations. On May 10, 2004, the NRC issued a Notice of Violation for two significant violations identified during the AIT inspection. Specifically, those violations involved (1) reconfiguration of the fluorination system without detailed instructions (which allowed a UF_6 leak to occur), and (2) failure to maintain and execute various response measures in the emergency response plan.

The NRC performed followup inspections specifically focused on Honeywell's implementation of its corrective actions on June 10 and August 13, 2004. The areas inspected included

plant operations, chemical safety, emergency preparedness, maintenance and surveillance, management organization and controls, and operator training. The June inspection did not identify any violations, but the August inspection identified two Severity Level IV violations. Those cited violations concerned the conduct of operations that were not adequately described in written operating procedures and an inadequate evaluation of the radiological conditions associated with storage of bed material and filter fines.

On September 30, 2004, the NRC held a public meeting with Honeywell to discuss the company's progress in implementing long-term corrective actions that will ensure sustained performance improvements. Honeywell's long-term efforts were primarily directed at procedures and training, plant material conditions, and emergency preparedness. The NRC also described the additional inspections completed since the restart of licensed operations at the site and the agency's plan to continue increased oversight.

The NRC performed an additional inspection in December 2004, and identified a violation that involved the failure of the licensee's operations personnel to properly perform pre-fill inspections of UF_6 cylinders. This failure resulted in Honeywell's shipment of 14 cylinders with prohibited Hund valves attached. Based upon the results of this inspection, together with those of the previous inspections, the NRC has determined that the heightened oversight of licensed activities performed at the Honeywell facilities will continue.

This event is open for the purpose of this report.

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04-02 Incinerator Event at Westinghouse Columbia Fuel Fabrication Facility in Columbia, South Carolina

Criteria III.A., "For Fuel Cycle Facilities," of Appendix A to this report states that 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 will be considered for reporting as an AO.

Date and Place — Discovered on March 5, 2004; Westinghouse Columbia Fuel Fabrication Facility; Columbia, South Carolina.

Nature and Probable Consequences — The licensee uses a standard industrial incinerator to reduce uranium-contaminated process waste volume and facilitate uranium recovery from the waste. During a technical review of a proposed procedure change, the licensee determined that its incinerator off-gas system was being operated outside the approved safety basis. Samples of ash deposited at various locations in the incinerator exceeded the assumed uranium concentration for incinerator ash. The licensee immediately stopped incinerator operations and performed a complete incinerator clean-out. The licensee determined that approximately 271 kilograms of ash at a maximum uranium concentration of approximately 30 wt% had accumulated in the incinerator's secondary combustion chamber. The licensee had performed a criticality analysis that concluded no ash would accumulate in the secondary combustion chamber, and the maximum uranium concentration of ash in the incinerator system could not exceed 21.6 wt%. No criticality safety controls were in place

to prevent the accumulation of fly-ash containing excessive uranium concentrations.

Cause(s) — The licensees' criticality safety staff failed to recognize that fly-ash could accumulate in the incinerator's secondary combustion chamber, and ash uranium concentrations could exceed 21.6 wt%. Contributing factors were the failure to control incinerator operations that allowed the increased uranium concentration in the fly-ash, and failure to recognize excessive material accumulation or uranium concentration increases.

Actions Taken to Prevent Recurrence

Licensee — The licensee immediately stopped incinerator operations and initiated a project to prevent future material accumulations. The licensee also initiated a program to upgrade criticality safety at the plant, including assigning additional staff to the nuclear criticality safety program, improving ownership of criticality safety by production and engineering staff, improving management and ownership of change, performing a comprehensive review of existing criticality safety analyses, using the integrated safety analysis process to prioritize changes to administrative criticality safety controls, and implementing a comprehensive program throughout the plant to ensure procedure compliance.

NRC — On May 13, 2004, the NRC issued Inspection Report 70-1151/2004-001, which described the event. On July 19, 2004, the NRC issued an Information Notice to fuel cycle licensees concerning the use of less-than-optimal bounding assumptions in criticality safety analyses at fuel cycle facilities. On July 28, 2004, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $24,000 to the licensee for failure to establish and maintain double-contingency protection in the incinerator and failure of management controls to detect the accumulation of a critical mass of fissile material in an unsafe geometry vessel. Although the normal civil penalty assessment process would have fully mitigated the civil penalty, the NRC exercised enforcement discretion in accordance with Section VII.A.1 of the Enforcement Policy and proposed a base civil penalty to reflect the safety significance of the issue, which resulted in a substantial increase in the likelihood of a nuclear criticality event. On October 21, 2004, the NRC conducted a management meeting with the licensee to discuss the incinerator event and its proposed corrective actions. The NRC will follow the corrective actions through the agency's inspection and oversight programs.

This event is closed for the purpose of this report.

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OTHER NRC LICENSEES

(Industrial Radiographers, Medical Institutions, etc.)

04-03 Iodine-125 Brachytherapy Seed Medical Event at Albert Einstein HealthCare Network in Philadelphia, Pennsylvania

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — October 16, 2003 (identified on November 20, 2003); Albert Einstein HealthCare Network in Philadelphia, Pennsylvania.

Nature and Probable Consequences — A patient received a permanent brachytherapy implant using iodine-125 (I-125) seeds as treatment for prostate carcinoma on October 16, 2003. The authorized user prescribed a dose of 145 Gy (14,500 rads) to the prostate gland. The implant was performed under ultrasound guidance, and 89 sources were implanted as prescribed in the written directive. On November 17, 2003, the patient returned for a routine postoperative computerized tomography (CT) scan. On November 20, 2003, a review of the scan revealed that many of the seeds were not located in the prostate as intended, but were in adjacent tissue where they were ineffective during treatment. As a result, the prostate gland received an inadequate dose of 18.6 Gy (1,860 rads), while the adjacent tissue received a dose of approximately 115 Gy (11,500 rads). An NRC medical consultant determined that the probable consequences to the patient would be comparable to the effects of external beam radiation treatment for prostate cancer and would not cause further damage to the patient. The patient and the patient's referring physician were notified of the event.

Cause(s) — The licensee determined that this medical event was caused by human error, the most likely being the misidentification of the prostate gland on the intra-operative ultrasound. Other possible causes include shifting of the needle grid in the patient on the operating room table or the suction of the seeds into the needle tract after the removal of the individual needles from the patient.

Actions Taken to Prevent Recurrence

Licensee — The licensee's corrective actions for future prostate brachytherapy treatments include new requirements that an outside radiation oncologist with expertise in prostate brachytherapy will monitor authorized users, and an experienced prostate brachytherapist will observe authorized users as they perform prostate implant procedures. In addition, the licensee implemented revised procedures, including performing a pre-operative CT scan; reviewing pre-planned ultrasound studies prior to, during, and after the procedure; and reviewing postoperative pelvic x-rays within 1 day of the procedure. Furthermore, the Radiation Safety Committee will review all forms, documents, education, and oversight associated with the

permanent prostate implant program, and will make recommendations or amendments, as necessary, to reflect programmatic changes.

NRC — The NRC staff conducted a special safety inspection on December 5, 2003, and did not identify any violations associated with the licensee's actions. The NRC also reviewed the licensee's current prostate implant program, and concluded that 12 other I-125 prostate implants had been completed without incident.

This event is closed for the purpose of this report.

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04-04 Diagnostic Medical Event at William Beaumont Hospital in Royal Oak, Michigan

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) 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 — June 8, 2004; William Beaumont Hospital; Royal Oak, Michigan.

Nature and Probable Consequences — The licensee reported that a patient was prescribed a dose of 0.37 megabecquerels (MBq) [10 microcuries (μCi)] of I-131 for a thyroid uptake procedure, but instead received 33.86 MBq (915 μCi) of I-131. The pipette used to prepare I-131 therapy dosages earlier in the day was inadvertently used to draw the 0.37 MBq (10 μCi) I-131 uptake dosage. The technician properly disposed of the I-131 uptake dosage after identifying the error.

The technician then obtained the "uptake" pipette and prepared a second dosage from the I-131 bulk uptake solution. However, the "uptake" pipette had inadvertently been switched with the "therapy" pipette used earlier. This may have occurred because both the thyroid "uptake" pipette and the "therapy" pipette had illegible labels. As a result, the second dosage contained 0.074 MBq (2 μCi) of I-131 remaining from the earlier therapy administrations and the newly drawn I-131 prepared for the thyroid uptake. The total activity for the second dosage measured 33.86 MBq (915 μCi). The technician focused on drawing the calculated volume required to obtain the prescribed activity, rather than the radioactive activity measured in the dose calibrator and interpreted the "0.915 millicuries (mCi)" displayed on the dose calibrator as "9.15 μCi." The technician electronically transferred the dosage measurement from the dose calibrator to a dosage label. A second technician administered the dosage to the patient. Assuming a 55% uptake, the absorbed dose to the patient's thyroid was 26.75 Gy (2,675 rads) with an effective dose equivalent of 0.81 Gy (81 rads).

Cause(s) — This event was caused by human error. The nuclear medicine technologist who drew the dose misinterpreted the reading on the dose calibrator, and the technician who administered the dose did not verify the dose before administration.

Actions Taken to Prevent Recurrence

Licensee — The licensee implemented a requirement to use a new pipette each time an I-131 uptake dose is prepared, reprogrammed the computer to accept uptake dose activity rather than volume and stopped the computer from printing a dose label when the activity is not within the established range. The licensee also trained the radiopharmacy staff not to override the computer's failsafe mechanisms, and retrained the nuclear medicine technologist in the process for dose verification prior to administration.

NRC — The NRC staff conducted a special safety inspection on June 10, 2004. Then, on September 14, 2004, the NRC issued a Notice of Violation for a significant violation involving the administration of a dosage of liquid I-131 to a patient for a thyroid uptake study that was approximately 90 times larger than the 10-µCi dosage prescribed by the authorized user physician.

This event is closed for the purpose of this report.

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AGREEMENT STATE LICENSEES

This section discusses the events that occurred at Agreement State-licensed facilities during this reporting period, which were significant enough to be reported as AOs based on the criteria in Appendix A to this report.

AS 04-01 I-125 Brachytherapy Seed Medical Event at Central Arkansas Radiation Therapy Institute in Conway, Arkansas

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — December 4, 2003; Central Arkansas Radiation Therapy Institute; Conway, Arkansas.

Nature and Probable Consequences —The licensee reported that a patient received a radiation dose to an unintended area during an I-125 prostate-seed implant procedure. The patient was prescribed treatment with 122 I-125 seeds, with each seed containing an activity of 13.3 MBq (0.36 mCi). During the patient's post-implant CT scan on December 18, 2003, the licensee discovered that the seeds had been implanted 2 centimeters (cm) too low and missed treating the upper portion of the prostate gland. As a result, 68 cm^3 of adjacent tissue received the prescribed dose of 144 Gy (14,400 rads). The licensee has not estimated the actual dose delivered to the prostate. The licensee administered additional treatment to deliver the intended dose to the upper 2 cm of the prostate gland. The licensee notified the patient and the patient's referring physician of the event.

Cause(s) — This event was attributed to human error in that the treatment site was not verified.

Actions Taken to Prevent Recurrence

Licensee — The licensee wrote a new procedure to implement the use of fluoroscopic guidance to ensure the correct placement of seeds.

State Agency —The State has reviewed and accepted the licensee's corrective actions.

This event is closed for the purpose of this report.

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AS 04-02 Dose to Fetus at Hillcrest Hospital of Mayfield Heights, Ohio

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that a medical event that results in 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 millisievert (mSv) (5 rem) or more, or to an embryo/fetus resulting in a

dose equivalent of 50 mSv (5 rem) or more will be considered for reporting as an AO.

Date and Place — November 20, 2003, Hillcrest Hospital; Mayfield Heights, Ohio.

Nature and Probable Consequences — The Ohio Bureau of Radiation Protection reported that a 19-year-old female patient was administered 5.18 gigabequerels (GBq) (140 mCi) of I-131 as prescribed for thyroid carcinoma. At the time, the patient was unaware that she was pregnant and she completed the required forms indicating that she was not pregnant. However, on December 5, 8, and 11, 2003, quantitative tests confirmed that the patient was pregnant. The licensee provided the results to the patient's endocrinologist, who recommended performing a fetal dose calculation. The licensee was notified and its consultant informed the endocrinologist that the fetus would have received a whole body dose of 0.19 Gy (19.8 rads). The endocrinologist sent the results to the Center for Human Genetics at the University Hospital in Cleveland, Ohio, where an assessment determined that the pregnancy could safely continue.

Cause(s) — This event was caused by human error. At the time of the administration, the patient was unaware of her pregnancy status and completed forms indicating that she was not pregnant.

Actions Taken to Prevent Recurrence

Licensee — The licensee has implemented pregnancy testing for patients of child bearing age, who receive radiation therapy.

State Agency — The Ohio Bureau of Radiation Protection was notified of this event on January 16, 2004, and performed a special inspection on January 22, 2004. The State found the licensee's corrective actions adequate to prevent recurrence.

This event is closed for the purpose of this report.

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AS 04-03 High Dose Rate Afterloader Medical Event at New Orleans Cancer Institute at Memorial Medical Center

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — March 31, 2004; New Orleans Cancer Institute; New Orleans, Louisiana.

Nature and Probable Consequences — A cancer patient undergoing therapeutic radiation treatment for prostate cancer received 18 Gy (1,800 rads) to the wrong treatment site. This error occurred using a high dose rate (HDR) afterloader device with a radioactive source containing 270.7 GBq (7.32 Ci) of Ir-192. The event occurred after the dosimetrist made

an error while inputting data into the afterloader's dosimetry software program. Although the dosimetrist appropriately clicked the "catheter tip" selection, the dosimetrist did not highlight and choose "catheter tip." Therefore, the computer cursor stayed on the "connector end" selection. This resulted in a 2-cm positioning error, which caused the source to stop short of the target so that the total prescribed dose was not delivered. The patient was informed of the event, and the remaining dose was delivered by external beam therapy.

Cause(s) — This event was attributed to operator error.

Actions Taken to Prevent Recurrence — Actions taken to prevent recurrence include implementing procedures to add a visual check and documentation that the treatment plan was administered with the source position calculated from the tip end of the catheter or needle. This procedure will be added to the pre-treatment checklist, which is performed and signed by the radiation oncologist, physicist, and dosimetrist. The checklist will be performed prior to initial treatment and at treatment plan changes, and will be part of the patients' permanent records. Also, the licensee contacted the device's manufacturer regarding the confusion associated with the default orientation in the software program, and requested an adjustment to the program. The manufacturer stated that this could not be done at this time, but is discussing the issue. The manufacturer offered additional training to the licensee's employees, and the licensee is sending its employees to the training.

State Agency — The State accepted the licensee's implementation of new procedures and its corrective actions as appropriate.

This event is closed for the purpose of this report.

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AS 04-04 Diagnostic Medical Event at Northeast Alabama Regional Medical Center

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — August 10, 2004; Northeast Alabama Regional Medical Center; Montgomery, Alabama.

Nature and Probable Consequences — A patient received 111 MBq (3,000 µCi) of I-131 instead of the prescribed dose of 0.93 MBq (25 µCi). The licensee discovered the event on August 12, 2004, when the patient returned for the whole body scan 48 hours later. The referring physician had requested a diagnostic I-131 scan to assess a thyroid nodule, which requires 0.93 MBq (25 µCi). The technologist misunderstood the order by assuming that the referring physician wanted a whole body scan to assess thyroid cancer, and administered 111 MBq (3,000 µCi) of I-131 without requesting clarification or approval from the authorized users.

Two authorized users determined that the patient could become hypothyroid. Therefore, patient followup assessments included thyroid profiles and thyroid uptakes to determine thyroid function.

Cause(s) — This event was attributed to human error. The technologist misunderstood the treatment ordered by the referring physician and failed to verify the written directive.

Actions Taken to Prevent Recurrence

Licensee — The licensee implemented corrective measures to ensure that authorized users approve all procedures involving the administration of radiopharmaceuticals and re-instructed nuclear medicine personnel.

State Agency — The State conducted an inspection.

This event is closed for the purpose of this report.

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AS 04-05 Occupational Exposure at Palmetto Health and Baptist Hospital in Columbia, South Carolina

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that 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 shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) will be considered for reporting as an AO.

Date and Place — March 17, 2004; Palmetto Health and Baptist Hospital; Columbia, South Carolina.

Nature and Probable Consequences — The licensee reported that a pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent to the hand of 7,420 mSv (742 rem), a deep dose equivalent to the hand of 70 mSv (7.02 rem), and a thyroid dose of 0.9 mSv (0.09 rem). The exposures occurred when a spill took place while compounding I-131 from a vial. The pharmacist trainee cleaned up the area, decontaminated his skin, and reported the spill to the imaging manager the following day. The imaging manager conducted a second survey of the area, which showed that no contamination remained from the spill. The pharmacist trainee completed a spill report but did not reveal his contamination in the report. The pharmacist trainee left for vacation and 11 days later, after his return, informed the Radiation Safety Officer (RSO) that his forearm had been contaminated during the I-131 spill. Immediate actions were taken to determine whether any contamination still remained on his arm. Elevated levels were discovered on his right forearm and left fingertips. The appropriate hospital/nuclear medicine personnel were notified. The pharmacist trainee was suspended from any and all duties involving radioactive material.

Cause(s) — This event occurred as a result of human error and failure to follow established procedures. An initial crimp failure on the vial may also have contributed to the spill.

Actions Taken to Prevent Recurrence

Licensee —The licensee retrained all staff in spill procedures, emphasizing proper notification of supervisors. Additionally, at the prompting of the licensee, the vial supplier reevaluated the process of ensuring that each crimp is acceptable for shipment, although the supplier believed it was more likely an isolated incident.

State Agency — The State agency conducted inspections and cited the licensee for violations of regulations for controlling radiation.

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AS 04-06 Gamma Stereotactic Radiosurgery (Gamma Knife) Medical Event at Radiosurgical Center of Memphis in Memphis, Tennessee

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — January 24, 2003; Radiosurgical Center of Memphis; Memphis, Tennessee.

Nature and Probable Consequences — The licensee reported that a patient received 27 Gy (2,700 rads) to a brain metastasis instead of the intended 18 Gy (1,800 rads) during gamma knife treatment. The physicist did not determine that an error had occurred until the treatment was complete. The RSO determined that one of the four brain metastases received greater than the prescribed dose. The other three brain metastases received the prescribed dose. The tumor that received the incorrect dose was at the periphery of the brain next to the skull in a non-critical area so that much of the extra dose was delivered to the space between the brain and the skull. The cause of the incident was that a 14-millimeter (mm) (.55-inch) collimator helmet was used instead of the prescribed 8-mm (.31 inch) collimator helmet. The personnel setting up the treatment neglected to change the helmet. The referring physician was notified of the event.

Cause(s) — The cause was human error, in that the event resulted from use of the wrong collimator helmet.

Actions Taken to Prevent Recurrence

Licensee — The licensee established a new procedure to require the physician, physicist, and nurse to sign off on the treatment time, helmet size, and position before each shot. Also, new labels identifying the size of the helmet were attached to each of the four helmets. These labels can be seen by personnel via the TV monitor located at the control panel

outside the treatment room. The physician will verify the correct size before the control panel button is pushed to start the treatment.

State Agency — The State reviewed and approved the licensee's new procedures.

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AS 04-07 Strontium-90 Eye Applicator Brachytherapy Medical Event at St. Francis Hospital in Memphis, Tennessee

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) 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 — March 25, 2004; St. Francis Hospital; Memphis, Tennessee.

Nature and Probable Consequences — A 79-year-old patient was prescribed radiation treatment for pterygium (an eye abnormality). The patient was to receive 20 Gy (2,000 rads), but instead received 70 Gy (7,059 rads). The prescribed dose was to be administered via a Sr-90 radioactive source with an activity of 3.7 GBq (100 mCi) for a duration of 42.5 seconds. However, the manual timer was incapable of being set for fractions of a second and interpreted the entry to be 4 minutes and 25 seconds. During the treatment, the physician questioned the treatment time and terminated the treatment after 2 minutes and 30 seconds. The patient and physician were notified of the event.

Cause(s) — The wrong treatment time was programmed for the patient's eye treatment.

Actions Taken to Prevent Recurrence

Licensee — The licensee updated its procedures, which require use of an additional person to operate a second timer during brachytherapy eye treatment.

State Agency — The Tennessee Department of Radiological Health conducted an onsite inspection on March 29, 2004. The State investigated, reviewed, and approved the licensee's new procedures.

This event is considered closed for the purpose of this report.

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AS 04-08 Therapeutic Medical Event at Southern Regional Medical Center in Riverdale, Georgia

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and is 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 — July 1, 2004; Southern Regional Medical Center; Riverdale, Georgia.

Nature and Probable Consequences — The licensee informed the Georgia Department of Natural Resources (GDNR) that a patient received 3.7 GBq (100 mCi) of I-131 instead of the prescribed dose of 0.64 GBq (17.3 mCi). Three patients were scheduled for I-131 treatments on the same day. An inpatient was scheduled to receive 3.7 GBq (100 mCi), and two outpatients were scheduled to receive less than 1.2 GBq (33 mCi). One of the outpatients was mistakenly injected with the 3.7 Gbq (100 mCi) dose intended for the inpatient and was also allowed to leave the facility without receiving proper instructions. The licensee did not discover the error until after the patient had left the facility with her children. The authorized user who signed the written directive was at the facility when the dose was administered. The temporary RSO was at South Fulton Hospital, but was notified of the event. The licensee contacted the patient to notify her of the event, checked her into a room, and gave her proper instructions for release. The GDNR received a report from the licensee's medical physicist consultant stating that the patient's two children would not have received overexposures or effects from radiation. The consultant estimated that the most likely dose to the patient's children was 0.5 mSv (0.05 rem), with a maximum possible dose of 1.0 mSv (0.1 rem).

Cause(s) — This event was attributed to human error. The wrong patient was administered a therapeutic dose of I-131 that was prescribed for someone else.

Actions Taken to Prevent Recurrence

Licensee — The licensee discussed the incident with all technicians who prepare and administer I-131, revised nuclear medicine protocols pertaining to the therapeutic use of I-131 and patient instructions, and revised procedures to incorporate better practices to prevent this type of error from recurring.

State Agency — The State agency reviewed and approved the corrective actions that the licensee implemented to prevent recurrence.

This event is considered closed for the purpose of this report.

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AS 04-09 Intravascular Brachytherapy Medical Event at Ireland Cancer Center in Middleburg Heights, Ohio.

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — December 22, 2003; Ireland Cancer Center; Middleburg Heights, Ohio.

Nature and Probable Consequences — The licensee reported that a patient received a radiation dose to an unintended site 3 cm proximal to the prescribed treatment site during an intravascular brachytherapy (IVB) treatment procedure. The dose delivered to the unintended site was approximately 18.40 Gy (1,840 rads). The event involved an IVB device that used a 3.5-mm catheter and a source train that contained Sr-90 with an activity of 2.0 GBq (53.8 mCi). The source train traveled to a location approximately 3 cm proximal to the intended treatment site. It was determined that there was a kink in the delivery catheter, which kept the source train from traveling to the correct site. The kink was not substantial enough to affect the flow of sterile water used to send and retrieve the source train. The kink was discovered the following day during medical physics quality checks. The attending physician was notified of the event.

Cause(s) — The cause of the event was determined to be a kink in the delivery catheter, which kept the source train from traveling to the correct site.

Actions Taken to Prevent Recurrence

Licensee — Corrective actions incorporated by the licensee included additional cine films taken during procedures to verify the placement of the catheter. When there is any doubt of the placement of the catheter, the treatment will be aborted. The treatment team will then evaluate whether to attempt treatment with a different catheter.

State Agency — The Ohio Department of Health conducted an investigation, reviewed the licensee's corrective actions, and found them adequate to prevent recurrence.

This event is considered closed for the purpose of this report.

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AS 04-10 Intravascular Brachytherapy Medical Event at Swedish Medical Center in Seattle, Washington

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — November 18, 2003; Swedish Medical Center; Seattle, Washington.

Nature and Probable Consequences — A patient undergoing an IVB treatment for coronary restenosis received 13.78 Gy (1,378 rads) to an unintended site (healthy tissue). The licensee reported that the source train was partially inserted into a small artery, and the routing did not follow a direct path. When the difficulty occurred, the source train had been partially inserted 65 mm proximal to the intended site. The source train contained a total activity of 2.91 GBq (78.56 mCi). A 143-second exposure time elapsed before the cardiologist withdrew the source train, even though the licensee's procedure requires sources to be immediately withdrawn once a problem occurs. The delay occurred as the cardiologist first worked to fully insert the source train and then discussed correcting the problem with the oncologist. The catheter was examined, and there were no kinks or bends. It was determined that there were no failures of the IVB device. It was suspected that the pressure from the artery and the tortuous route to the site caused a contraction of a portion of the catheter and resulted in the seeds becoming stuck at a particular location. The cardiologist was suspended from licensed activities until the details of the event were fully understood. The patient and the patient's referring physician were notified of the event.

Cause or Causes — It is suspected that the pressure from the small artery and the tortuous route to the site caused a contraction of a portion of the source train and resulted in the seeds becoming stuck at a particular location.

Actions Taken to Prevent Recurrence

Licensee — Corrective actions included reemphasizing the importance of adhering to established procedures and protocols before administering radiopharmaceuticals, and ensuring that all staff completed refresher training.

State Agency — The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

This event is closed for the purpose of this report.

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AS 04-11 Diagnostic Medical Event at Swedish Medical Center in Seattle, Washington

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — September, 24, 2004; Swedish Medical Center; Seattle, Washington.

Nature and Probable Consequences — The licensee reported that a patient received 190.9 MBq (5.16 mCi) of I-131, instead of the prescribed 74 MBq (2 mCi) for a post thyroid treatment follow-up scan. The prescribing physician realized that the error occurred on September 27, 2004, when the patient underwent the scan. A viable follow-up scan was performed even though the error occurred. The treating physician notified the patient of the error on September 27, 2004.

Cause or Causes — The licensee stated that human error led to procedural checks not being performed prior to the administration.

Actions Taken to Prevent Recurrence

Licensee — Corrective actions included re-emphasis on the importance of adhering to established procedures and protocols prior to the administration of radiopharmaceuticals and the completion of staff refresher training.

State Agency — The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

This event is considered closed for the purpose of this report.

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AS 04-12 Therapeutic Medical Event at University of California at Los Angeles Harbor Medical Center in Torrance, California

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) 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 — June 7, 2002; University of California at Los Angeles (UCLA); Harbor Medical Center; Torrance, California. This event was not identified as an AO until the preparation of the FY 2004 report.

Nature and Probable Consequences — A patient receiving treatment for thyroid ablation was administered a dose of 4.44 GBq (120 mCi) of I-131 instead of the prescribed dose of 1.18 GBq (32 mCi) of I-131.

On June 7, 2002, five patients were scheduled to be treated with I-131. Five vials containing I-131 arrived from the radiopharmacy and were properly labeled with the patients' names. The nuclear medicine technologist incorrectly thought that the name on the 4.736 GBq (128mCi) vial did not match any of the patient's names scheduled for treatment that day. Assuming that this vial was incorrectly labeled, the 4.736 GBq (128 mCi) dosage was administered to the patient for whom the technologist thought the dose was intended. However, the technologist failed to

verify whether any of the remaining four dosages were labeled for that patient. In fact, a vial was correctly labeled as prepared for that patient.

The authorized user was present during the administration to supervise the administration of the radiopharmaceutical, and to verify that the correct radiopharmaceutical and dosage were administered. The authorized user did not perform an independent verification, but instead assumed that the nuclear medicine technologist had verified that the dosage was correct. The error was discovered about 5 hours later, when the patient scheduled to receive the 4.736 GBq (128 mCi) dosage arrived at the medical center for treatment. The authorized user went to the home of the patient who received the inadvertent administration and verified that appropriate radiation safety precautions were in place. The patient's treatment plans were modified to accommodate the larger dosage. The authorized user stated that the dosage was intended to ablate the thyroid and render the patient hypothyroid, and that was accomplished with the larger dose. He further stated the patient is doing well, with no complications.

Cause(s) — This medical event was caused by human error which resulted in the licensee's failure to follow proper policies and procedures and verify the prescribed dosage for a specific patient.

Actions Taken to Prevent Recurrence

Licensee — The licensee re-instructed all nuclear medicine personnel on the importance of following the division's policies and procedures and the use of a third party to check the prescription dose and patient identification before administration. Additionally, the RSO will review all I-131 therapy documents and administrations.

State Agency — The State cited the licensee for failure to provide written notification to the referring physician and the patient within 15 days after the occurrence of the medical event. The State has reviewed and approved the licensee's corrective actions.

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AS 04-13 Diagnostic Medical Event at University Hospital in Cincinnati, Ohio

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 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 (1,000 rads) 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 — March 10, 2004; University Hospital; Cincinnati, Ohio.

Nature and Probable Consequences — The licensee reported that a patient was given 74 MBq (2,000 µCi) of I-131 for a thyroid cancer work-up instead of the prescribed dose of 7.4 MBq (200 µCi) of I-123 for a thyroid uptake scan. The patient scheduled to receive the I-123 dose responded affirmatively to being the patient that was to receive the I-131 dose. The

technologist did not follow procedures regarding proper identification of the patient, which requires two separate methods for verifying patient identification.

Cause or Causes — The technologist failed to follow established procedures.

Actions Taken to Prevent Recurrence

Licensee — The licensee disciplined the technologist in accordance with hospital policy and reiterated to all technologists the need to thoroughly check patient identification using two approved methods. Additionally, the Radiation Safety Committee modified the Quality Management Program to require a photo as one method of verifying patient identification.

State Agency — The Ohio Department of Health conducted an investigation of the event on May 11, 2004, and reviewed the licensee's corrective actions. The State found the licensee's corrective actions adequate to prevent a recurrence of the event.

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

An accident or event will be considered an 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
(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.

The guidelines for including events in Appendix C, "Other Events of Interest," of this report were provided by the Commission in the Staff Requirements Memorandum on SECY-98-175, dated September 4, 1998, and are listed at the end of this appendix.

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[1] to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 mSv (25 rem) or more; or an annual sum of the deep dose

[1]An unintended radiation exposure for the purpose of reporting as an AO includes any occupational exposure, exposure to the general public, or exposure as a result of a medical event involving the wrong patient that exceeds the reporting values established in the regulation. All other reporting medical events will be considered for reporting as an AO under the criteria "For Medical Licensees."

In addition, unintended radiation exposures includes any exposure to a nursing infant, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman.

equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, bone marrow, and the gonads, of 2,500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with § 20.1301 using § 20.1302 (b) (1) or § 20.1302 (b) (2) (ii).

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[2]

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

[2] Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the ERA of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

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(a); 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) [10 CFR 50.36(c)].

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod 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 event that:

A. Results in a dose that is (1) equal to or greater than 1 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 (1,000 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,[3] or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source or sources.

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, as such, should be included in an appendix to the annual AO report as "Other Events of Interest." Guidelines for events to be included in the AO report for this purpose may include, but are not necessarily limited to, events that do not meet the AO 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.

[3] "The wrong radiopharmaceutical" as used in the AO criterion for a medical event refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

APPENDIX B
UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, significant new information became available regarding an event of interest that the NRC previously reported in the FY 2003 Report to Congress on Abnormal Occurrences.

1. U.S. Inspection Services Industrial Radiography Occupational Overexposure at a Temporary Jobsite

Date and Place — September 9, 2003; temporary job site; Charleston, West Virginia.

Nature and Probable Consequences — On September 9, 2003, a radiographer received a significant overexposure while radiographing pipe welds. The licensee estimated that the radiographer received a total effective dose equivalent of 205 mSv (20.5 rem), an eye dose equivalent of 70 mSv (7 rem), a shallow dose equivalent to the whole body (thigh) of 1,400 mSv (140 rem), and a maximum extremity dose of 2,350 mSv (235 rem). A second radiographer also received elevated doses, however, his doses were within the annual regulatory limits. The licensee did not expect either individual to experience any permanent adverse health consequences, as a result of the event.

The local radiography field office issued the radiography crew a radiography camera, radiation source drive mechanism (crank assembly), and guide tube before they began work. The crank assembly issued to the radiography crew was previously constructed by the field office manager using parts from two non-functioning crank assemblies. After the radiographer's overexposure, the licensee determined that the modified crank assembly did not include all of the required parts or the four retaining bolts used to hold together the halves of the assembly.

The radiographer was in the process of setting up the radiography equipment for the final exposure of the day when the event occurred. When the radiographer attempted to crank the source from the camera, he realized the source was positioned at the end of the guide tube. The radiographer immediately cranked the source into the camera. The radiography crew observed that the self-reading pocket dosimeter exposure indicators were off-scale.

Cause(s) — Inadequate oversight of equipment maintenance activities resulted in the licensee's failure to identify (1) a crank assembly was modified and its safety features were compromised, (2) daily checks of the crank assembly were not sufficiently defined or rigorous enough to identify equipment problems, and (3) a radiation survey instrument was not properly tested and calibrated following an inappropriate repair.

Actions to Prevent Recurrence — The licensee implemented corrective actions to (1) increase management oversight of day-to-day operations and maintenance activities; (2) increase the number and formality of controls for the routine testing, repair, and use of equipment; (3) ensure that all staff possessed the latest copies of licensee's operating and emergency procedures; and (4) provide training to all staff regarding the event, the conduct of radiation surveys, and the conduct of inspection and maintenance activities.

NRC — The NRC conducted followup inspections in September and October 2003. As a result of the inspections and information that the licensee provided during a predecisional

enforcement conference, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $19,200 on June 15, 2004, for multiple significant violations related to an overexposure of radiographer, including issues such as failure to survey, failure to calibrate and inspect equipment, and failure to follow procedures. Although normal application of the civil penalty assessment process would have resulted in a base penalty, the NRC exercised discretion and proposed twice the base penalty because of the licensee's particularly poor performance. The NRC also conducted followup inspections of the licensee's three field operations in 2004 to verify the adequacy of its implementation of the corrective actions.

This event is closed for the purpose of this report.

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APPENDIX C

OTHER EVENTS OF INTEREST

This appendix discusses "Other Events of Interest" that do not meet the abnormal occurrence (AO) criteria in Appendix A, 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, including a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

NUCLEAR POWER PLANTS

1. Vermont Yankee Misplaced Spent Nuclear Fuel Pieces

This event did not meet the AO criteria because it did not involve a major reduction in the degree of protection of public health or safety. Nonetheless, this event is included in this report because it received significant interest from members of Congress, the media, representatives of potentially impacted State governments, and citizen interest groups.

In March 2004, the NRC's resident inspectors at Entergy's Vermont Yankee Nuclear Power Plant performed inspections in accordance with NRC Temporary Instruction 2515/154, "Spent Fuel Material Control and Accounting at Nuclear Power Plants," and determined that there were two fuel rod segments (approximately 9 and 17 inches in length) that had been removed from their parent assemblies. Records indicated that those two segments were stored in an unlocked, uncovered, 5-gallon stainless steel container located on the bottom of the spent fuel pool (SFP).

In response to the inspectors' finding, Entergy personnel utilized a boroscope to look inside the pipes of the uncovered container on April 20, 2004. In doing so, Entergy discovered that the two fuel rod segments were not in that container. Entergy promptly initiated an extensive investigation, utilizing site and contractor personnel, to search for the missing fuel rod segments. On July 13, 2004, during its investigation, Entergy discovered the fuel segments in a different location in the SFP. There was no actual safety consequence from this event because the pieces had always been in the SFP.

The NRC conducted a special safety inspection and is in the process of determining a final enforcement action. As a result of the inspection, the NRC determined that the licensee failed to follow its "Special Nuclear Material Inventory and Accountability" procedure, resulting in a significant failure of the special nuclear material accounting program at Vermont Yankee, which increased the possibility of shipping these pieces off site for inappropriate burial in a low-level waste site. The NRC is currently evaluating whether enforcement action is warranted in this case.

This event is closed for the purpose of this report.

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2. Loss of Offsite Power at Palo Verde

The following event did not meet the AO criteria since it did not involve a loss of plant capability to perform essential safety functions so that a release of radioactive materials could occur from a postulated transient or accident. Nonetheless, this event is included in this report because it received significant media and some congressional interest.

On June 14, 2004, an electrical fault occurred on a 230-kV transmission line in northwest Phoenix, Arizona, approximately 47 miles from the Palo Verde Nuclear Generating Station (PVNGS). A protective relay failed to isolate the fault from the local power grid for approximately 38 seconds. This uninterrupted fault caused the protective tripping of a number of 230- and 500-kV transmission lines, a nearly concurrent trip of all three PVNGS units, and the loss of six additional nearby generation units.

Because of the loss of offsite power, the PVNGS licensee declared a Notice of Unusual Event for all three units. Subsequently, the Unit 2 Train "A" emergency diesel generator started but failed during electrical loading (as a result of a failed voltage regulator diode). This de-energized electrical buses supplying certain safety equipment for operators. Because of this failure, the licensee elevated the emergency classification for Unit 2 to an Alert. Within 10 minutes, all three units were placed in a stable shutdown condition on natural circulation cooling. Forced circulation cooling was restored to all units within 25 hours after the event. The three units returned to operation within 7 days after the event.

The NRC dispatched an AIT to PVNGS on June 14, 2004, immediately following the event. The AIT concluded that the licensee implemented sufficient immediate corrective actions for continued operation of the facility. The AIT found that, while the facility was safely shut down and stabilized, a number of system failures, as well as procedure and human performance issues, complicated the event and recovery efforts. On July 12, 2004, a public meeting was conducted in Goodyear, Arizona, to discuss the AIT findings. The inspection report was issued on July 16, 2004.

The NRC conducted a followup inspection in September 2004 to address the issues identified during the AIT inspection. The followup inspection assessed the AIT observations for safety significance and compliance with NRC regulations. This assessment identified 10 findings of very low safety significance. The NRC inspectors determined that the corrective actions taken by the licensee were appropriate to address the root and contributing causes of the event. Enhancements to the offsite transmission network at neighboring switchyards improved the reliability and independence of the offsite electrical grid. The enhancements should ensure that PVNGS will not be challenged by a similar uncleared fault at neighboring switchyards. The NRC issued the followup inspection report in December 2004.

This event is closed for the purpose of this report.

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3. Missing Fuel Rod Segments at Humboldt Bay Power Plant in Eureka, California

This event did not meet the AO criteria because it did not involve a major reduction in the degree of protection of public health or safety. Nonetheless, this event is included in this report because it received significant public interest.

On July 16, 2004, Pacific Gas and Electric Company (the licensee), notified the NRC of a discrepancy between inventory records and the physical location of three spent fuel rod segments, each approximately 18 inches long, that were previously known to be at the Humboldt Bay Power Plant. The licensee submitted a 30-day followup report pursuant to 10 CFR 20.2201(b)(2)(ii) on August 16, 2004. The licensee searched for the segments in the most likely and accessible locations within the onsite spent fuel pool. After this search failed to locate the segments, the licensee made a 1-hour notification to the NRC on August 17, 2004, pursuant to 10 CFR 74.11(a), stating that the fuel rod segments were considered to be missing. The issue received a moderate level of public and media attention.

During the fall of 2003, the licensee began a detailed examination of the contents of its spent fuel pool in preparation for eventual removal of the fuel assemblies stored in the pool to an onsite dry cask storage facility. While in the process of performing a record review of the spent fuel pool inventory, the licensee identified a discrepancy on June 23, 2004, that called into question the location of three segments of a portion of a single spent fuel rod removed from an assembly (designated A-49) in 1968. Records from 1968 indicate that a single fuel rod from assembly A-49 was cut into three 18-inch segments that were placed in a small container with an intention to ship the segments to an offsite lab for analysis. The records further show that the offsite shipment never occurred, and the three 18-inch segments in their special storage container were placed somewhere in the spent fuel pool without a record of the specific location. The licensee has been unable to locate these three 18-inch rod segments in the spent fuel pool, and has not found any records documenting their shipment off site. The licensee notes that records of the shipment of assembly A-49 show it was sent to West Valley, New York, for reprocessing on August 6, 1969. The records for the assembly shipment did not mention that a rod had been removed from the assembly.

The licensee is continuing a search of the less accessible areas in the spent fuel pool where the three fuel rod segments may be located. In addition, the licensee is continuing its review of plant records and interviewing plant personnel who were on site during the period from 1968 through 1969. The licensee still contends that the most likely location for the missing spent fuel rod segments is in the spent fuel pool. The licensee has identified five other possible locations, including the low-level radioactive waste disposal sites at Richland, Washington, Beatty, Nevada, or Barnwell, South Carolina; the fuel reprocessing center at West Valley, New York; and the General Electric research facility at Vallecitos, California.

The potential for theft or diversion of the missing fuel segments has been considered, although the NRC has not formally evaluated this possibility. The information that the NRC has received from the licensee's investigation and the agency's own inspections does not indicate that the fuel segments were stolen or diverted. In addition, the physical security at the site and the extensive array of radiation detectors make it highly unlikely that the missing fuel rod segments could have been diverted or stolen without detection.

However, the NRC expects the licensee to address this unlikely possibility in a root-cause analysis and will evaluate the licensee's assessment in followup inspections.

The NRC conducted onsite inspections at Humboldt Bay on July 12–16, August 5–13, and September 13–17, 2004, to monitor the licensee's investigation and actions regarding the three missing 18-inch fuel rod segments. Then, on September 29, 2004, the NRC and the licensee held a management meeting in the area of Eureka, California, to provide a public forum for discussion of actions taken to date by the licensee and the NRC. The NRC also dispatched a special inspection team to Humboldt Bay on November 2, 2004, to review the results of the licensee's investigation, assess the root-cause evaluation, determine whether the licensee is in compliance with applicable regulations, and identify which findings may have generic implications. The special inspection will continue throughout the licensee's investigation, potentially lasting into the third quarter of FY 2005.

The NRC's actions for this event are ongoing, and this event remains open for the purpose of this report.

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Other NRC Licensees

4. Radiation Exposure of Individuals during a Stuck Source Rack Event

This event is not considered an AO because it did not result in a dose to an individual that met the AO reporting criteria. Nonetheless, this event is included in this report because it has received significant media coverage.

On April 21, 2004, two employees at Baxter Healthcare Corporation (Baxter) of Aibonito, Puerto Rico, were exposed to radiation when they entered the panoramic irradiator facility without knowing that a source rack, containing a large amount of cobalt-60 in sealed sources, was stuck in an unshielded position. One individual received 44 mSv (4.4 rem) deep dose equivalent, and the other individual received 28 mSv (2.8 rem) deep dose equivalent. Had the two individuals continued on their intended path, they would have received life-threatening doses of at least 4.5 Gy (450 rads).

The source rack became stuck during testing shortly before 1:00 p.m., when a maintenance ladder that was inadvertently left in the path of the source rack movement following repair work, prevented the source rack from returning to its safe storage location in the pool. The irradiator operator bypassed the interlocks, then entered the irradiator and walked through the partially shielded interim area with an assistant. They were preparing to enter the sterilization room when they identified elevated radiation levels by observing the needle movement on a portable survey meter. The two individuals immediately exited the irradiator following the same path.

When the employees entered the irradiator, the licensee did not realize that the source rack was stuck in the unshielded position, but believed that the fault alarms that activated the interlocks were still related to the ongoing problem with a source-up switch experienced many times earlier on that day. Repair of that switch required entry into the irradiator. Therefore, the licensee approved personnel to bypass safety interlocks in order to gain entry

into the irradiator through the product exit barrier door, passing through the interim area to enter the sterilization room to correct the switch problem. Employees had experienced repeated problems with switches or other malfunctions causing the interlocks to prevent entry over a period of years, and had become accustomed to believing that, when interlocks prevented entry, it was due to such problems and not to elevated radiation levels from an unshielded source rack. The licensee had in place operating and emergency procedures that, had they been followed, would have prohibited entry into the irradiator under such conditions.

The NRC immediately sent an inspector to oversee the source rack recovery operations. An NRC Special Inspection Team reached the site on April 27, 2004, and upgraded the inspection to an AIT investigation. On October 25, 2004, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $44,400 for three significant, willful violations, including failures to (1) adhere to emergency procedures, (2) perform an adequate survey, and (3) provide an individual with a radiation monitoring device.

This event is closed for the purpose of this report.

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ROUTING AND TRANSMITTAL SLIP

Date 12/03/2004

TO: (Name, office symbol, room #, building, agency/post)	Initials	Date
1. JONES, RES/DSARE/RPERWMB		
2 . BUSH-GODDARD, RES/DSARE/RPERWM		
3. TROTTIER, RES/DSARE/RPERWMB		
4. ELTAWILA, RES/DSARE		
5. GARRITY, DSARE		
6. PAPERIELLO, D/RES		
7. FLETCHER, DISTACPHED.		

REMARKS

SUBJECT: FINAL DRAFT REPORT TO CONGRESS ON AO - FISCAL YEAR 2004
G:\DSARE\RPERWMB\Jones\AORpt04.wpd
G:\DSARE\RPERWMB\Jones\ao04compap.wpd and
G:\DSARE\RPERWMB\Jones\Ltrs to Congress04.wpd

FROM: (Name, org. symbol, Agency/Post)	Room # - Bldg.
Juanda D. Fletcher, RES - ITEM NO.: 12#01	T9-C34
	Phone # 415-6238