DRAFT REPORT TO CONGRESS

on

ABNORMAL OCCURRENCES

FISCAL YEAR 2006

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

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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) 2006.

Appendix A "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest," to this report presents the NRC's criteria for selecting AOs, as well as the guidelines for selecting "Other Events of Interest." Appendix B, "Updates of Previously Reported Abnormal Occurrences," notes that the NRC does not have any updated information on events reported in the FY 2005 Report to Congress on Abnormal Occurrences. Appendix C, "Other Events of Interest," presents nine events of interest identified during FY 2006 on ground-water contamination due to undetected leakage of radioactive water at nuclear power plants.

This report describes three events at NRC-licensed facilities that meet the criteria to be classified as AOs, as defined in Appendix A. The first AO involved a spill of high-enriched uranium at a fuel fabrication facility, the second AO involved a medical event, and the third AO involved an unintended dose to an embryo/fetus.

Reports from Agreement States are also included. Agreement States are those States who 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 34 Agreement States (Minnesota became the 34th Agreement State on March 31, 2006). During FY 2006, Agreement States reported six events that occurred at Agreement State-licensed facilities that met the AO criteria, including four medical events, one unintended dose to an embryo/fetus, and one industrial event.

The NRC revised the Appendix A criteria to make them more risk-informed and they became effective on October 12, 2006. These criteria are consistent with the NRC's Strategic Plan for FY 2004-2009, Title 10 of the Code of Federal Regulations (CFR) Part 35, "Medical Use of Byproduct Material," and Title 10 CFR Appendix P, "Category 1 and 2 Radioactive Material." The revised criteria can be found in Appendix D of this report, "Revised Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." The NRC will use the revised criteria to select AOs for the annual report to Congress in FY 2007.

Also, the Energy Policy Act of 2005 (EPAct) expanded the NRC's regulatory jurisdiction by amending the definition of byproduct material to include discrete sources of radium-226, accelerator-produced radioactive material, and discrete sources of naturally occurring radioactive material. The NRC is developing a rule to implement the EPAct. Once the rule is promulgated, the NRC and Agreement States will monitor events that may meet the revised AO criteria.

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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) 2006. [Agreement States are those States who 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.]

Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest," to this report presents the NRC's criteria for selecting AOs, as well as the guidelines for selecting "Other Events of Interest." Appendix B, "Updates of Previously Reported Abnormal Occurrences," notes that the NRC does not have any updated information on events reported in the FY 2005 Report to Congress on Abnormal Occurrences. 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, this appendix contains nine new events of interest on ground-water contamination due to undetected leakage of radioactive water at nuclear power plants. Appendix D, "Revised Abnormal Occurrence Criteria and Guidelines for Other Events of Interest," presents the NRC's revised criteria for selecting AOs and guidelines for selecting "Other Events of Interest." The revised criteria will be used to determine AOs for FY 2007.

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.

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). Stakeholders are informed and involved, as appropriate, to ensure openness in the NRC regulatory process, as stipulated in the NRC Strategic Plan FY 2004-2009 (NUREG-1614,

Volume 3, August 2004). To accomplish its mission of protecting public health and safety, 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 are normally 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. Licensing, inspection, and enforcement programs provide a regulatory framework to ensure compliance with regulations. The NRC is striving to make the regulatory system more risk-informed and performance-based, where appropriate.

REPORTABLE EVENTS

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 industry review and evaluate operating experience to identify safety concerns. NRC disseminates the information from these reviews and evaluations to licensees through licensing activities and regulations. Operational data are maintained in computer-based data files for more effective collection, storage, retrieval, and evaluation.

The NRC routinely disseminates publically available information and records on reportable events as defined in Title 10 of the Code of Federal Regulations at licensed or regulated facilities to the industry, the public, and other interested groups. 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. States who enter into such agreements with the Commission are known as Agreement States. 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. At the end of FY 2006, there were 34 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 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 the NRC in accordance with compatibility criteria established by the "Policy Statement on Adequacy and Compatibility of Agreement State Programs,"

published in the *Federal Register* notice on September 2, 1997 (62 FR 46517). The NRC has developed and implemented procedures 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 if significant new information becomes available. These updates appear in Appendix B to this report.

OTHER EVENTS OF INTEREST

The NRC provides 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. "Other Events of Interest" appear in Appendix C to this report. Appendix D presents the NRC's revised criteria for selecting AOs and guidelines for selecting "Other Events of Interest." The revised criteria will be used to determine AOs for FY 2007.

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ACRONYMS AND ABBREVIATIONS

AEA	Atomic Energy Act
ALARA	As Low As Reasonably Achievable
AO	abnormal occurrence
Bq	becquerel
CFR	*Code of Federal Regulations*
Ci	curie
cm	centimeter
FR	*Federal Register*
FY	Fiscal Year
GBq	gigabecquerel
GDC	General Design Criterion
Gy	gray
HDR	high dose-rate
HEU	high-enriched uranium
I-125	iodine-125
I-131	iodine-131
in	inch
KBq	kilobecquerel
LLTF	Lessons Learned Task Force
LTP	license termination plan
µCi	microcurie
MBq	megabecquerel
mCi	millicurie
mrem	millirem
mSv	millisievert
NMT	nuclear medicine technologist
NRC	U.S. Nuclear Regulatory Commission
SFP	spent fuel pool
Sv	sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
TS	technical specification

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ABNORMAL OCCURRENCES
IN FISCAL YEAR 2006

NUCLEAR POWER PLANTS

During this period, no events at U.S. nuclear power plants were significant enough to be reported as abnormal occurrences (AOs) based on the criteria in Appendix A to this report.

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FUEL CYCLE FACILITIES
(Other Than Nuclear Power Plants)

During this reporting period, one event at an NRC-licensed fuel fabrication facility was significant enough to be reported as an AO based on the criteria in Appendix A to this report.

06-01 Spill of High-Enriched Uranium Solution at Fuel Fabrication Facility

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

Date and Place — May 4, 2006, location withheld for security reasons

Nature and Probable Consequences — In a facility authorized to process high-enriched uranium (HEU), a transfer of HEU solution through a transfer line resulted in a portion of the HEU solution, approximately 35 liters, leaking into a glovebox where criticality was possible and subsequently to the floor where criticality was also possible because of the presence of an elevator pit.

Immediately before the event, the facility operator decided to move the unused filter glovebox to another location. Workers opened and drained the filters so that the filter glovebox could be moved. After draining the filters, workers failed to reseal the system tightly. During the next transfer of HEU solution through the line, HEU solution leaked into the filter glovebox. On several occasions before the event, workers had reported signs of a yellowish liquid in the filter glovebox. Supervisors had failed to fully investigate the reports because they assumed the yellowish liquid was natural uranium solution which had been used to initially test the Blended Low Enrichment Uranium process. The downblending facility, where the spill occurred, was constructed in 2003 and licensed on January 13, 2004.

Criticality was possible in the filter glovebox because of the size and shape of the glovebox and because there were no controls in the filter glovebox to prevent accumulation of solution. The solution leaked out of the filter glovebox through uncontrolled drains to the floor. Investigation of the event revealed that the floor contained an uncontrolled accumulation point, an elevator pit, where criticality was also possible. In different circumstances, the total volume of the transfer would have been more than enough for criticality to be possible in the filter glovebox or the elevator pit. If a criticality accident had occurred in the filter glovebox or the elevator pit, it is

likely that at least one worker would have received an exposure high enough to cause acute health effects or death. The NRC conducted a team inspection to determine the root causes of the event and performed a series of three readiness reviews before allowing this portion of the facility to restart. The NRC issued an order to the licensee delineating specific actions designed to address this and other performance issues at the facility.

Cause(s) — Failure to maintain configuration control of facility equipment and failure to comply with procedures.

Actions Taken to Prevent Recurrence — The operator stopped all processing of HEU in the affected processing area, removed the enclosure and associated piping, filled in an uncontrolled accumulation point (the elevator pit) with concrete, and conducted an extensive review to identify any similar configuration issues.

This event is closed for the purpose of this report.

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OTHER NRC LICENSEES

(Industrial Radiographers, Medical Institutions, etc.)

During this reporting period, two events at NRC-licensed or regulated facilities were significant enough to be reported as AOs based on the criteria in Appendix A to this report.

06-02 Medical Event at Bozeman Deaconess Hospital in Bozeman, Montana

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 — May 9, 2006, Bozeman, Montana

Nature and Probable Consequences — The licensee reported that a patient was prescribed a brachytherapy treatment of 145 Gy (14,500 rad) to the prostate gland for prostate cancer using 82 iodine-125 seeds, but instead received a 130 Gy (13,000 rad) dose to an unintended treatment site. The brachytherapy seeds were implanted under ultrasound guidance; however, a post-treatment computerized tomography scan confirmed that only 10 seeds were implanted in the prescribed location of the prostate, resulting in a dose of 8.6 Gy (860 rad) delivered to the intended treatment site. The urologist implanted 69 seeds inferior to the prostate in the wrong treatment site and recovered the remaining 3 seeds. The referring physician and the patient were informed of this event and were advised that the patient may experience discomfort during urination. The NRC staff conducted a reactive onsite inspection on May 16, 2006. An NRC contracted medical consultant experienced in radiation oncology reviewed the case and agreed with the licensee's analysis and conclusions. An NRC inspection report has been issued.

Cause(s) — This medical event was caused by human error because the licensee did not verify that the sources were positioned in the proper location in the prostate. The urologist misidentified the anatomy viewed under the ultrasound guidance procedure.

Actions Taken to Prevent Recurrence — The licensee revised its procedures, requiring a fluoroscopic examination early in the implant procedure to ensure that the seeds are placed in the correct location, thus resolving any questions concerning ultrasound images prior to commencing with the implant. The licensee also implemented additional staff training.

This event is closed for the purpose of this report.

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06-03 Dose to an Embryo/Fetus at Munson Medical Center in Traverse City, Michigan

Criterion I.A.1, "For All Licensees," of Appendix A to this report states that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 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 — May 3, 2006, Traverse City, Michigan

Nature and Probable Consequences — The licensee reported an unintended dose to an embryo/fetus. On May 3, 2006, the licensee administered a therapy dosage of 5.55 GBq (150 mCi) of I-131 to a 26-year-old female patient who had affirmed in writing that she was not pregnant. On May 22, 2006, the patient informed the licensee that she had been approximately 10 to 14 days pregnant at the time of the administration. Based on this new information, the licensee estimated that the dose to the embryo/fetus was approximately 400 mSv (40 rem). The referring physician and patient were informed of this event. The NRC-contracted medical consultant agreed with the licensee's dose estimate and concluded that this event should result in no harm to the embryo because the administration occurred during a stage of development when the thyroid does not take up iodine. The medical consultant recommended that a complete thyroid evaluation be performed after delivery.

Cause(s) — This medical event was caused by the patient's incorrect written statement that she was not pregnant prior to receiving the therapy dosage. The licensee did not require an independent pregnancy test for women of child-bearing age prior to administering the dosage.

Actions Taken to Prevent Recurrence — The licensee implemented a procedure that requires pregnancy tests for all women of childbearing age prior to any therapy dosage of radioactive material, a checklist to ensure that the pregnancy test is ordered, and staff training.

This event is closed for the purpose of this report.

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AGREEMENT STATE LICENSEES

During this reporting period, six events at Agreement State-licensed facilities were significant enough to be reported as AOs based on the criteria in Appendix A to this report.

AS 06-01 Industrial Radiography Occupational Overexposure at Anvil International in North Kingston, Rhode Island

Criterion I.A.1, "For All Licensees," 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 shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

Date and Place — March 3, 2006, North Kingston, Rhode Island

Nature and Probable Consequences — The licensee reported that a radiographer and a trainee received unintended radiation exposures in excess of those specified in the AO criteria. The incident occurred at a permanent radiography facility and involved an iridium-192 source with an activity of 3.44 TBq (93 Ci). After performing surveys outside a dedicated radiography cell, where radiation levels confirmed that radiography was in process in the cell, the radiographer and the trainee went to an alternate location and performed equipment maintenance and training. They were joined by a third radiographer, who was performing radiography inside the cell. All three radiography personnel entered the cell to view the radiography setup and examine the guide tube for training purposes. However, they entered without a survey meter and were unaware that the source was still exposed. As a result, the first radiographer and the trainee handled the collimator and guide tube (which contained the source) for approximately 15 - 60 seconds. The first radiographer received a dose to the left hand ranging from 1.4 to 2.8 Sv (140 rem to 280 rem). The trainee received a dose to the left hand ranging from 11 Sv to 85 Sv (1,100 rem to 8,500 rem). The third radiographer did not receive a dose in excess of regulatory exposure limits, since he did not handle the equipment.

Cause(s) — This event was caused by the failure of radiography personnel to follow safety procedures and use survey meters inside the cell.

Actions Taken to Prevent Recurrence

Licensee — The licensee provided additional training to the personnel. The licensee also solicited the assistance of a medical physicist and the source manufacturer in determining the dose to the radiographers. The licensee also committed to keep the State updated on the medical conditions of the radiographer and trainee until they are released from medical oversight.

State Agency — On March 7, 2006, the State issued a suspension letter to the licensee. On March 8 and March 16, 2006, the State, accompanied by NRC Region I staff, conducted an investigation of the event. On April 13, 2006, the State issued a Notice of Violation and on November 3, 2006, terminated the license after an onsite inspection to confirm decommissioning actions.

This event is closed for the purpose of this report.

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AS 06-02 Medical Event at 21st Oncology, Inc., in Coral Springs, Florida

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 — March 31 through April 7, 2006, Coral Springs, Florida

Nature and Probable Consequences — The licensee reported that an 80-year-old female patient received 100 Gy (10,000 rad) to an unintended area of approximately 2 cm (0.8 in) that was three times the prescribed dose for the mammosite brachytherapy procedure, using a high dose rate (HDR) afterloader containing an iridium-192 source with an activity of 240.5 GBq (6.5 Ci). The patient received less than 30 percent of the prescribed dose to the prescribed treatment site. The source stopped 6 cm (2.4 in) short of the intended position. The patient visited the attending physician for followup on May 2, 2006. The physician discovered that the patient's skin was abnormally red. The referring physician, patient, and patient's family were notified of the incident. The patient was treated for erythema (skin reddening) and moist desquamation (skin thinning and weeping).

Cause(s) — This medical event was caused by human error. The authorized user entered an incorrect distance into the computer entry data.

Actions Taken to Prevent Recurrence

Licensee — The licensee developed new procedures requiring the authorized user to verify the source wire distances during HDR treatments and provided additional training in these procedures.

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

This event is closed for the purpose of this report.

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AS 06-03 Medical Event at the McKay Dee Hospital, Inc., in Ogden, Utah

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 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

Date and Place — June 19, 2006, Ogden, Utah

Nature and Probable Consequences — The licensee reported that a patient undergoing treatment for hyperthyroidism received 1.08 GBq (29.3 mCi) of I-131 instead of the prescribed dosage of 0.56 GBq (15 mCi). On June 19, 2006, two patients were scheduled to receive I-131 treatments at the same time. However, the first patient was administered the second patient's prescribed dosage resulting in the patient receiving a higher than intended dose. The error was identified by the licensee prior to the administration of I-131 to the second patient. The administration resulted in a thyroid dose of 1,066 Gy (106,600 rad). The patient and referring physician were notified of the error. No negative health effects from this administration are expected. On July 17, 2006, the licensee sent a letter to the State confirming that a medical event had occurred.

Cause(s) — This medical event was cause by human error. The licensee failed to verify the prescribed dosage for a specific patient.

Actions Taken to Prevent Recurrence

Licensee — Corrective actions taken by the licensee included revising procedures to improve patient identification techniques and not scheduling patients with similar treatments at concurrent times.

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

This event is closed for the purpose of this report.

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AS 06-04 Medical Event at Central Arkansas Radiation Therapy Institute in Little Rock, 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 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 — March 28, 2006, Little Rock, Arkansas

Nature and Probable Consequences — The licensee reported that a patient undergoing implant brachytherapy for prostate cancer received a radiation dose to an unintended area during an I-125 prostate-seed implant procedure. The patient was prescribed 108 Gy (10,800 rad) to the base of prostate gland with 84 I-125 seeds but it was delivered 4 cm (1.6 in) inferior to the intended treatment site. The post-implant dose calculation confirmed that the dose was delivered to the wrong treatment site. The patient will require further brachytherapy treatment. The patient did not incur adverse health effects as a result of the medical event. The patient and referring physician were notified of the medical event.

Cause(s) — This medical event was caused by human error. The urologist was not able to clearly identify the base of the prostate gland during the ultrasound used to view the target organ during the treatment.

Actions Taken to Prevent Recurrence

Licensee — The licensee implemented a new policy to ensure that the urologist clearly defines the base of the prostate and urethra.

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

This event is closed for the purpose of this report.

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AS 06-05 Medical Event at Children's Memorial Medical Center in Chicago, Illinois

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 prescribed in a written directive will be considered for reporting as an AO.

Date and Place — July 24, 2006, Chicago, Illinois

Nature and Probable Consequences — The licensee reported that a patient received a higher than intended dosage of 74 MBq (2 mCi) of I-131 instead of the prescribed dosage of 0.19 MBq (0.005 mCi). The physician did not prepare a written directive. The authorized user noted the error on July 25, 2006. The licensee estimated a whole body dose of 0.0189 Sv (1.89 rem) and a dose to the thyroid of 41.4 Sv (4,140 rem), based on a 59.2-percent uptake. Using the same assumptions, the intended dosage of 0.19 MBq (0.005 mCi) would have given the patient a thyroid dose of 0.104 Sv (10.4 rem). The patient and referring physician were notified of the medical event. The patient incurred no adverse health effects from the medical event.

Cause(s) — This medical event was caused by inadequate verbal communications between the nuclear medicine technologist (NMT) and the physician and the lack of a written directive.

Actions Taken to Prevent Recurrence

Licensee — The licensee reviewed previous administrations of radioiodine to confirm that this event was an isolated occurrence. The licensee added additional procedures to ensure proper oversight by a physician during all future radioidodine administrations.

State Agency — The State investigated the event and concurred with the licensee's dose estimates. The State issued a Notice of Violation to the licensee.

This event is closed for the purpose of the report.

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AS 06-06 Dose to an Embryo/Fetus at McLeod Regional Medical Center in Florence, South Carolina

Criterion I.A.2, "For All Licensees," of Appendix A to this report states that 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 will be considered for reporting as an AO.

Date and Place — May 26, 2006, Florence, South Carolina

Nature and Probable Consequences — The licensee reported an unintended dose to an embryo/fetus. The licensee administered 555 MBq (15 mCi) of technetium-99m on May 24, 2006, and 518 KBq (0.014 mCi) of I-131 on May 25 as a prelude to a thyroid ablation to a patient. Prior to the administrations and following a detailed explanation provided by the physician, the patient signed an informed consent indicating that she was not pregnant. The licensee's radioactive materials license requires that a pregnancy test be done on any female of child-bearing age undergoing radiation therapy. However, the patient convinced the attending NMT that she could not possibly be pregnant. The NMT did not perform the pregnancy test and on May 26, 2006, administered 0.548 GBq (14.8 mCi) of I-131 to the patient for a thyroid ablation. At approximately 32 - 34 weeks of pregnancy, the patient visited an obstetrician and mentioned that she had undergone a thyroid ablation procedure when she was approximately 17 weeks pregnant. The obstetrician notified the licensee on October 3, 2006. The licensee estimated that the fetus received a whole body dose of 0.0517 Gy (5.17 rad) and a thyroid dose of 139.2 Gy (13,920 rad). The child was born in November 2006. The newborn appears to have no apparent problems resulting from the radiation exposure with the exception of an underactive thyroid gland (hypothyrodism). The child is currently receiving a small amount of thyroid supplement. The referring physician and patient were notified of the event.

Cause(s) — This event was caused by human error. At the time of the administration, the patient indicated that she was not pregnant, and the licensee failed to perform the required pregnancy test.

Actions Taken To Prevent Recurrence

Licensee — The licensee provided instructions to staff emphasizing its policy to administer a pregnancy test to female patients of child-bearing age prior to undergoing radiation therapy.

State Agency — The State reviewed and approved the corrective actions taken by the licensee and will followup at the next inspection. The State is in the process of issuing a Notice of Violation.

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

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

The following criteria for determining an AO and the guidelines for "Other Events of Interest" were stated in an NRC policy statement published in the *Federal Register* on December 19, 1996 (61 FR 67072). The policy statement was revised to include criteria for gaseous diffusion plants and was published in the *Federal Register* on April 17, 1997 (62 FR 18820).

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

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.

<u>Abnormal Occurrence Criteria</u>
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 equivalent (external dose) and committed dose equivalent (intake of radioactive

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[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.

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 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

[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.

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.

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[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.

Guidelines for "Other Events of Interest"

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as "Other Events of Interest." Guidelines for events to be included in the AO report for this purpose may include, but not necessarily be limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

APPENDIX B
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, no new significant information became available regarding any AO event that the NRC previously reported in the “Report to Congress on Abnormal Occurrences: Fiscal Year 2005.”

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

Ground Water Contamination Caused by Undetected Leakage of Radioactive Water

The NRC recently identified several instances of unintended releases of radioactive liquids at multiple facilities caused by undetected leakage from facility structures, systems, or components that contain or transport radioactive fluids. Subsequent water sampling in and around these plants identified tritium as the primary source of contamination. Tritium is a mildly radioactive isotope of hydrogen that occurs both naturally and during the operation of nuclear power plants. Nuclear plants normally release water containing tritium and other radioactive substances under controlled, monitored conditions that the NRC mandates to protect public health and safety.

The NRC established a Liquid Radioactive Release Lessons Learned Task Force in response to the unplanned, unmonitored releases of radioactive liquids into the environment. Although some of the events occurred in 2005, they are included in this report because the Task Force produced a report published on September 1, 2006. The report's most significant conclusion was that, although there had been industry events where radioactive liquid was released to the environment in an unplanned and unmonitored fashion, there were no instances identified where the release had an impact on public health and safety. The task force also concluded that under the existing regulatory requirements, the potential exists for unplanned and unmonitored releases of radioactive liquids to migrate off site and into the public domain without detection. The NRC staff is currently evaluating and responding to the task force recommendations.

1. Braidwood Nuclear Power Plant

In March 2005, the Illinois Environmental Protection Agency notified Exelon Generation Company LLC (the licensee) of the potential for tritium in a nearby residential well. Following notification, the licensee began monitoring ground water between the community and the Braidwood plant (Joilet, Illinois) by installing additional offsite and onsite monitoring wells to identify the source and spread of the tritium contamination.

After further characterization and identification of tritium near the north site boundary, the licensee notified the NRC and immediately suspended all further planned liquid radioactive releases until it had identified and corrected the cause of the leakage. The licensee attributed the tritium to historical leakage from vacuum breaker valves along the blowdown line that is routinely used for radioactive liquid releases. Although the Braidwood piping was below

ground, the vacuum breaker valve vaults communicate with the surface through manholes. Review of historical records found that leaks had occurred both above and below ground over the period of 1996 to 2005, and surveys confirmed that some material moved offsite. One residential well was found to contain tritium at very low concentrations.

The licensee sampled onsite and offsite monitoring well locations and found tritium contamination. Based on the information provided, there is no indication that NRC effluent release limits have been exceeded, and the release does not present a health and safety hazard to plant personnel or to the public. The licensee has corrected the cause of the leakage and has undertaken remediation activities to reduce the levels of tritium in the ground water at the Braidwood site.

2. Byron Nuclear Power Plant

On February 10, 2006, Exelon Generation Company LLC (the licensee) informed the NRC that elevated levels of tritium had been detected in several vacuum breaker valve vaults at Byron Station, near Rockford, Illinois. The licensee sampled and analyzed standing water in the blowdown line vacuum breaker vaults and found that five of the six vaults had detectable levels of tritium. The licensee suspended all radioactive liquid effluent releases through the blowdown line until it could correct the cause of the leakage.

The licensee sampled residential wells and did not find any detectable offsite contamination. By April 2006, the licensee had completed repairs to the vacuum breaker valves and vaults, including sealing the vault floors. After completing the repairs, the licensee recommenced liquid effluent discharges through the circulating water system blowdown line.

3. Callaway Nuclear Power Plant

On June 14, 2006, Union Electric Company (the licensee) notified the NRC of elevated tritium levels along the blowdown discharge pipeline at the Callaway Plant, near Fulton, Missouri. The licensee believes that the radioactive material leaked from air-relief valves during routine radiological releases through the discharge pipeline. The licensee detected radioactive cobalt and cesium in the soil inside the manholes, which are located on the licensee's property. The licensee also sampled and analyzed the well water and found no evidence of radioactive contamination in the drinking water.

4. Dresden Nuclear Power Station

On February 11, 2006, Exelon Generation Company LLC (the licensee) at the Dresden Nuclear Power Station, near Morris, Illinois, found that a sample from a monitoring well near the condensate storage tanks indicated an increase in tritium concentration. The licensee had installed this monitoring well following previous leaks in underground piping from these tanks, with the most recent leakage identified in 2004. The licensee isolated the piping and realigned the system to bypass the leaking section of pipe. Although the leak location has not been fully identified, the licensee is replacing the suspect piping and continuing its evaluation and onsite monitoring. No migration of detectable tritium has occurred offsite.

5. Haddam Neck Station

The Haddam Neck Station ceased operations about 10 years ago and is being decommissioned under an approved NRC license termination plan. The monitoring programs of the Connecticut Yankee Atomic Power Company (the licensee) have not identified any offsite ground water contamination associated with plant operations.

In December of 2005, the licensee began its 18-month groundwater monitoring for its License Termination Plan. The licensee initially identified tritium, cobalt-60, cesium-137, and strontium-90 in the onsite ground water and/or soil samples. The licensee has removed a large amount of soil and bedrock and has backfilled the excavated areas with clean fill (uncontaminated soil). Although the licensee has substantially reduced residual contamination levels, recent ground water sampling results have identified residual radioactive contamination. The licensee has completed dose assessments for the existing onsite ground water contamination in accordance with the license termination plan.

6. Indian Point Nuclear Generating Station, Units 1, 2, and 3

In September 2005, Entergy Nuclear Operations (the licensee) identified contaminated water leaking from cracks in the Unit 2 spent fuel pool (SFP) at the Indian Point Nuclear Power Plant (near Buchanan, New York). It subsequently discovered tritium-contaminated ground water in a monitoring well located on site in the Unit 2 transformer yard. Upon discovery of this condition, the licensee initiated extensive efforts to characterize the nature and source of the ground water contamination. The licensee installed a series of instrumented monitoring wells, performed a comprehensive hydrological and geophysical assessment of the site, and enhanced onsite and offsite radiological environmental monitoring. In an effort to reduce Unit 2 SFP leakage, the licensee has inspected the SFP and carried out repairs at locations where there were indications of leakage.

In addition to tritium, the licensee detected the radionuclides nickel-63, cesium-137, strontium-90, and cobalt-60 in the onsite ground water. The licensee suspects that the presence of these isotopes is the result of leakage from the Unit 1 SFP, which resulted in the contamination of ground water locally. Even though Unit 1 has been permanently shut down since 1974, its SFP still contains expended fuel and radioactive water. Currently, the licensee operates a filter/demineralizer system in the SFP to reduce the concentration of radioactive material that may continue to leak from the Unit 1 facility until the fuel is removed in 2008.

7. Palo Verde Nuclear Generating Station

On March 1, 2006, the Arizona Public Service Company (the licensee) identified tritium above the EPA drinking water standard in a water sample collected from on onsite test hole at the Palo Verde Nuclear Generating Station, Unit 3, near Phoenix, Arizona. The licensee concluded that most of the tritium contamination was the result of past operational practices in which the licensee had performed batch releases from the evaporator system during rainy days. The rain condensed these releases of gaseous tritiated vapor, and the resulting onsite water runoff was absorbed into the ground and also ran into the storm drain system.

The licensee determined that the tritiated water at elevated levels was confined on site. It found no elevated levels in wells located outside the protected area and no evidence of an offsite release of the radioactive water.

8. Perry Nuclear Power Plant

On March 28, 2006, a quarterly sample taken from a manhole in the underdrain system at the Perry Nuclear Power Plant, near Painesville, Ohio, indicated increased concentrations of tritium. FirstEnergy Nuclear Operating Company (the licensee) attributed the tritium to a leaking flange in the feedwater system venturi. The leak occurred within the plant boundary, and the leakage was diverted to the licensee's normal effluent release pathway, without any apparent abnormal release to the environment. The licensee has repaired the leaking flange, and tritium concentrations have decreased.

9. Three Mile Island Nuclear Power Plant

On May 17, 2006, personnel at the Three Mile Island Nuclear Power Plant, near Harrisburg, Pennsylvania, identified water coming from a utility access manway in the owner-controlled parking lot. The licensee initially determined the source of the water to be a leak in a domestic water line since it was the only known source of water in the area. The AmerGen Energy Company LLC (the licensee) subsequently pumped out 2000 gallons of water from the asphalt parking lot.

On June 1, 2006, the licensee sampled and analyzed the water from the manway and identified elevated concentrations of tritium. Samples taken from four nearby ground water monitoring wells indicated no elevated tritium in the surrounding ground water. The licensee repaired the source of leakage, continued enhanced monitoring of ground water wells, and verified that no tritiated water had left the owner-controlled area via the underground cable conduit.

APPENDIX D
REVISED ABNORMAL OCCURRENCE CRITERIA AND GUIDELINES FOR OTHER EVENTS OF INTEREST

The following criteria which became effective on October 12, 2006 will be used to determine whether to consider events for reporting as AOs for FY 2007:

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 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 other than the lens of the eye, the 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 of 1 Sv (100 rem) or more; or a committed dose equivalent to the gonads of 2,500 mSv (250 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 which results in 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). This criterion does not apply to transportation events.

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach[1,2]

1. Any unrecovered lost, stolen, or abandoned sources that exceed the values listed in Appendix P to Part 110, "Category 1 and 2 Radioactive Material." 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 while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.

2. A substantiated[3] case of actual theft or diversion of licensed, risk-significant radioactive sources or a formula quantity[4] of special nuclear material; or act that results in radiological sabotage[5].

3. Any substantiated[3] loss of a formula quantity[4] of special nuclear material or a substantiated[3] inventory discrepancy of a formula quantity[4] of special nuclear material that is judged to be caused by theft or diversion or by a substantial breakdown[6] of the accountability system.

4. Any substantial breakdown[6] of physical security or material control (i.e., access control containment or accountability systems) that

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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 ERA of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

2 Due to increased terrorist activities worldwide, the AO report would not disclose specific classified information and sensitive information, the details of which are considered useful to a potential terrorist. Classified information is defined as information that would harm national security if disclosed in an unauthorized manner.

3 "Substantiated" means a situation where an indication of loss, theft, or unlawful diversion such as: an allegation of diversion, report of lost or stolen material, statistical processing difference, or other indication of loss of material control or accountability cannot be refuted following an investigation; and requires further action on the part of the Agency or other proper authorities.

4 A formula quantity of special nuclear material is defined in 10 CFR 70.4.

5 Radiological sabotage is defined in 10 CFR 73.2.

6 A substantial breakdown is defined as a red finding in the security inspection program, or any plant or facility determined to have overall unacceptable performance, or in a shutdown condition (inimical to the effective functioning of the Nation's critical infrastructure) as a result of significant performance problems and/or operational events.

significantly weakened the protection against theft, diversion, or sabotage.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that harms the public health and safety.

D. Initiation of High-Level NRC Team Inspections.[7]

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 drive mechanism).

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[7] Initiation of any Incident Investigation Teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any Accident Review Groups, as described in MD 8.9, "Accident Investigation."

C. Any reactor events or conditions that are determined to be of high safety significance.[8]

D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s).[9]

III. Events at Facilities Other than Nuclear Power Plants and all Transportation Events

A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, 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 that require immediate remedial action.

3. A serious safety-significant deficiency in management or procedural controls.

4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

B. For Fuel Cycle Facilities

1. Absence or failure of all safety-related or security-related controls (engineered and human) for an NRC-regulated lethal hazard (radiological or chemical) while the lethal hazard is present.

2. An NRC-ordered safety-related or security-related immediate remedial action.

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8 The NRC Reactor Oversight Process (ROP) uses four colors to describe the safety significance of licensee performance. As defined in NRC Management Directive 8.13, "Reactor Oversight Process," green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered Abnormal Occurrences. Additionally, Criterion II.C also includes any events or conditions evaluated by the NRC Accident Sequence Precursor (ASP) program to have a conditional core damage probability (CCDP) or change in core damage probability (ΔCDP) of greater than $1x10^{-3}$.

9 Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

C. For Medical Licensees

A medical event that:

1. Results in a dose that is

   a. equal to or greater than 1Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or
   b. equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and

2. Represents either
   a. a dose or dosage that is at least 50 percent greater than that prescribed, or
   b. a prescribed dose or dosage that
      (i) uses the wrong radiopharmaceutical or unsealed byproduct material; 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; or
      (vi) is delivered to the wrong individual or human research subject.

IV. Other Events of Interest

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as “Other Events of Interest.” Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.