REPORT TO CONGRESS

ON

ABNORMAL OCCURRENCES

FISCAL YEAR 2011

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 report AOs to Congress annually.

This report describes five events that the NRC identified as AOs during fiscal year (FY) 2011 based on the criteria defined in this report's Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." The first event at an NRC-licensed facility involved radiation exposure to an embryo/fetus, and the second was an event of high safety significance at a commercial nuclear power plant. The other three events occurred at NRC-licensed or NRC-regulated medical institutions and are medical events, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material."

In addition, this report describes 19 events that Agreement States identified as AOs during FY 2011, based on the criteria in Appendix A to this report. 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 37 Agreement States. The first Agreement State event involved radiation exposure to an embryo/fetus, the second event involved an exposure to the extremities of a radiographer, and the third event involved a stolen radiography camera. The other 16 Agreement State events were medical events, as defined in 10 CFR Part 35.

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, "Updates of Previously Reported Abnormal Occurrences," provides updated information for one event reported in the FY 2010 "Report to Congress on Abnormal Occurrences" regarding the medical event at Providence Hospital in Novi, Michigan. During FY 2011, three items were identified as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest." These three events occurred at nuclear power plants. Appendix D, "Glossary," presents definitions of terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

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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 report AOs to Congress annually.

This report describes those events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 2011, based on the criteria defined in this report's Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." 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. The NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described here meet the criteria for being reported as AOs. For each AO, this report documents 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, "Updates of Previously Reported Abnormal Occurrences," provides updated information for one event reported in NUREG-0090 Volume 33, "Report to Congress on Abnormal Occurrences-FY 2010," issued June 2011. The update involves the medical event at Providence Hospital in Novi, Michigan. During FY 2011, the NRC identified three items as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest." These three events occurred at nuclear power plants. Appendix D, "Glossary," presents definitions of terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

THE LICENSING AND 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 agency's regulatory process, consistent with the NRC's "Strategic Plan for FY 2008–2013" (NUREG-1614, Volume 4, issued February 2008). The NRC regularly conducts licensing reviews, inspections, enforcement, investigations, operating experience evaluations, incident response, and confirmatory research. The NRC also maintains programs to establish standards and issue technical reviews and studies. In addition, the NRC involves the public as an essential element in the regulatory process.

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, operation, and quality assurance criteria appropriate for the various activities regulated by the NRC. Licensing, inspection, investigations, and enforcement programs provide a regulatory framework to ensure compliance with the regulations. In

addition, the NRC is striving to make the regulatory system more risk informed and performance-based, where appropriate.

REPORTABLE EVENTS

The NRC initially promulgated the AO criteria in a Commission policy statement published in the *Federal Register* on February 24, 1977 (42 FR 10950), followed by several revisions in subsequent years. The most recent revision to the AO criteria was published in the *Federal Register* on October 12, 2006, (71 FR 60198), and became effective on that date. That revision established the criteria presented in Appendix A, used by the NRC to define AOs for the report.

Review of and responses to operating experience are essential to ensure that licensed activities are conducted safely. Toward that end, the regulations require that licensees 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. The NRC responds to risk-significant issues through licensing reviews, inspections, and enhancements to regulations. In addition, the agency maintains operational data in computer-based data files for more effective collection, storage, retrieval, and evaluation.

The NRC also routinely disseminates (to the public, industry, and other interested stakeholders) publicly available information and records regarding reportable events at licensed or regulated facilities. The agency achieves this dissemination through public announcements and special notifications to licensees and other stakeholders. To widely disseminate information to the public, the NRC also issues a *Federal Register* notice describing AOs that occurred in the previous fiscal year at facilities licensed or otherwise regulated by the NRC or Agreement States. In addition, the NRC routinely informs Congress of significant events, including AOs, that occur at licensed or regulated facilities.

AGREEMENT STATES

Section 274 of the AEA, 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 sufficient to form a critical mass. States that enter into such agreements with the NRC 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 2011, there were 37 Agreement States.

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," which the agency published in the *Federal Register* on September 2, 1997 (62 FR 46517). The NRC has also developed and implemented procedures for evaluating materials events to identify those that should be reported as AOs. Toward that end, the NRC uniformly applies the AO criteria (in Appendix A to this report) to events at licensees regulated by either the NRC or the Agreement States. In addition, in early 1977, the Commission determined that the annual report to Congress also should include events that meet the criteria for AOs at

licensees regulated by Agreement States. The *Federal Register* notice that the NRC issues to disseminate AO-related information to the public includes those Agreement State AOs.

FOREIGN INFORMATION

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

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC provides updates of previously reported AOs if significant new information becomes available. Appendix B provides updated information for one event reported in the FY 2010 "Report to Congress on Abnormal Occurrences" regarding the medical event at Providence Hospital in Novi, Michigan.

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. During FY 2011, the NRC identified three other events of interest as meeting the guidelines for inclusion in Appendix C. These three events occurred at nuclear power plants.

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ABBREVIATIONS

AEA	Atomic Energy Act
AO	abnormal occurrence
AS	Agreement State
CFR	*Code of Federal Regulations*
cGy	centigray
Ci	curie
cm	centimeter
cm^3	cubic centimeter
CT	computed tomography
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel
Gy	gray
HDR	high dose rate
IEMA	Illinois Emergency Management Agency
LPCI	low-pressure coolant injection
MBq	megabecquerel
mCi	millicurie
MDH	Minnesota Department of Health
mm	millimeter
mrem	millirem
mSv	millisievert
NMCP	Naval Medical Center in Portsmouth, Virginia
NOV	Notice of Violation
NRC	U.S. Nuclear Regulatory Commission
ODH	Ohio Department of Health
RHR	residual heat removal
SPECT	single photon emission computed tomography
Sv	sievert
TBq	terabecquerel
TVA	Tennessee Valley Authority
UCLA	University of California, Los Angeles
VA	Department of Veterans Affairs

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ABNORMAL OCCURRENCES IN FISCAL YEAR 2011

The following briefly explains the numbering system used in this section of the report. Appendix A provides the specific criteria for determining when an event is an abnormal occurrence (AO) and provides the guidelines for reporting other events of interest which may not meet the AO criteria, but which the Commission has determined should be in this report. Appendix A contains four major categories: I. All Licensees, II. Commercial Nuclear Power Plant Licensees, III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events, and IV. Other Events of Interest. Category IV events are discussed in Appendix C to this report, and Categories I, II, and III are discussed in this section. Categories I and II contain significant subelements labeled A, B, C, and D, and Category III addresses Subelement C. This section of the report discusses only the specific subelement in Categories I, II, and III for which an AO was reported. The identification number for all Agreement State AO reports starts with "AS." Similarly, the identification number for all U.S. Nuclear Regulatory Commission (NRC) AO reports starts with "NRC."

I. ALL LICENSEES

During this reporting period, one event at NRC-licensed or NRC-regulated facilities and three events at Agreement-State-licensed facilities were significant enough to be reported as AOs based on the criteria in Appendix A to this report. Although two of these events occurred at a medical facility, they involved unintended exposures of individuals who were not the patient. Therefore, these events belong under the Criteria I.A, "All Licensees" category, as opposed to the Criteria III.C, "Medical Licensees" category.

NRC11-01 Human Exposure to Radiation at Portsmouth Naval Medical Center in Portsmouth, Virginia

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

Date and Place – January 12, 2011, Portsmouth, Virginia

Nature and Probable Consequences – The Department of the Navy (the licensee) reported that a female patient at the Naval Medical Center in Portsmouth, Virginia (NMCP), received 3,630 MBq (98 mCi) of iodine-131 for thyroid ablation therapy. On the day of the treatment the patient informed NMCP staff that she was not pregnant and NMCP staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, NMCP staff administered iodine-131 to the patient.

On January 27, 2011, the patient became aware that she was pregnant and informed the physician who had administered the treatment. An obstetrician estimated that conception had occurred somewhere around January 7-10, 2011, and that a pregnancy test administered on January 12, 2011, would not have been sensitive enough to produce a positive result. NMCP estimated the dose to the embryo to be 21.3 cGy (21.3 rem) and notified the Naval Radiation Safety Committee that the patient may have been pregnant before the therapy. NMCP staff

estimated a slight increased risk of early pregnancy failure and this was discussed with the patient. NMCP staff subsequently refined the dose estimate to 24.7 cGy (24.7 rem). The NRC contracted with a medical consultant who estimated a fetal/embryo dose of 27 cGy (27 rem) and stated that embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, the tissue had not yet formed at the time of the treatment. The medical consultant concluded that there was a low possibility of carcinogenesis or malformations. The pregnancy progressed normally and both the mother and child are doing well.

Cause(s) – The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test result, to the administration of the iodine-131.

Actions Taken to Prevent Recurrence

Licensee – NMCP revised the initial consultation procedures for the prescribing physician to stress the importance of discussing with the patient the need for sexual abstinence at least 10 days before therapeutic dose administration.

NRC – The NRC conducted an inspection on February 2, 2011 through June 2, 2011, and there were no violations of NRC requirements associated with this event.

This event is closed for the purpose of this report.

AS11-01 Human Exposure to Radiation at Montefiore Medical Center in New York City, New York

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

Date and Place – September 22, 2006 (reported on April 27, 2011), New York City, New York

Nature and Probable Consequences – Montefiore Medical Center (the licensee) reported that a female patient received 3,519 MBq (95 mCi) of iodine-131 for thyroid ablation therapy. Before the treatment, the licensee interviewed the patient and ascertained that she was not pregnant. The licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, the licensee administered iodine-131 to the patient.

On December 22, 2006, the patient returned to the licensee for a followup visit. Following that visit, the nuclear medicine department staff was informed by another section of the medical center that the patient was pregnant. The licensee confirmed the pregnancy with the patient's obstetrician/gynecologist (OB/GYN). The ultrasound performed by the patient's obstetrician/gynecologist revealed that the patient was approximately 2-3 weeks pregnant at the time of the iodine-131 treatment. The licensee estimated that the fetus received about 25 cGy (25 rem) of radiation exposure and stated that embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, this tissue had not yet fully formed at the time of the treatment. The patient was advised to see a genetic specialist to discuss the possible consequences to the fetus from this exposure. Although the licensee claimed that it had originally reported the event to the New York City Office of Radiological Health in 2006, the office had no record of the report. The New York City Office of Radiological Health identified the missing report in April 2011, and subsequently notified the NRC on June 15, 2011. The licensee reported that the child, now 5 years old, is normal and meeting all developmental milestones.

Cause(s) – The cause of this event was the close proximity of conception to the iodine-131 treatment and a false negative result on a pregnancy test done before the administration of the treatment.

Actions Taken to Prevent Recurrence

Licensee – The licensee's corrective actions included additions to its Safety Precaution Form stressing the necessity of sexual abstinence before the treatment and recommending that patients also take precautions to avoid getting pregnant for 6 months after the treatment.

State – The New York City Office of Radiological Health conducted an inspection on June 16, 2011, and determined that the licensee had followed acceptable protocols before the administration of iodine-131. Consequently no civil penalties or enforcement action for this event are warranted.

This event is closed for the purpose of this report.

AS11-02 Human Exposure to Radiation at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to an adult resulting in an annual shallow dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more shall be considered for reporting as an AO.

Date and Place – September 12, 2011, Port Lavaca, Texas

Nature and Probable Consequences – Caribbean Inspection & NDT Services Inc. (the licensee) reported that a radiographer trainee received an overexposure to his right hand and was seeking medical attention. The radiographer trainee stated that on September 12, 2011, while conducting radiography operations in the field, he removed a radiography camera guide tube from the Amersham 660 D radiography camera. The radiographer trainee stated that he noticed the 2.7 TBq (73 Ci) iridium-192 source was not fully retracted and protruding from the camera about 2 inches. The radiographer trainee stated that he may have brushed the source with his hand when he removed the guide tube.

On September 19, 2011, the radiographer trainee presented himself to a Houston, Texas hospital with observable deterministic effects, which included blistering of the thumb, index and middle fingers. These types of effects correspond to an exposure range of 20 - 40 Sv (2000 to 4000 rem) to the extremities. His doctors initially conferred with the Radiation Emergency Assistance Center/Training Site regarding his medical treatment. The trainee is continuing his treatment at the Houston, Texas hospital as an out-patient. The licensee stated that the results of the trainee's dosimeter indicated that he received 14.1 mSv (1.41 rem) whole body exposure based on the film badge he was wearing at the time of the event.

Cause(s) – The State of Texas is currently investigating the cause of this event.

Actions Taken to Prevent Recurrence

Licensee – The licensee is conducting an investigation to determine the exact nature and cause of this event. Pending the results of this investigation the licensee will determine corrective action and inform the State of the circumstances of the event and the corrective actions.

State –Texas Department of State Health Services, Radiation Control Program is currently investigating this incident, which includes collecting information from the physicians, the licensee, and the individuals involved in the event. Pending the results of this investigation and the depositions performed through the General Counsel, the Texas Department of State Health Services will determine the probable causes of the event and review the licensee's corrective actions and consider what, if any, civil penalties and enforcement actions to pursue.

This event is open for the purpose of this report.

AS11-03 Stolen Radiography Camera at Acuren Inspection, Inc., in La Porte, Texas

Criterion I.C.2, "Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach" of Appendix A to this report provides, in part, that any substantiated case of actual theft or diversion of licensed, risk-significant radioactive sources, shall be considered for reporting as an AO.

Date and Place – July 19, 2011, La Porte, Texas

Nature and Probable Consequences – Acuren Inspections Inc. (the licensee) reported the theft of a radiography camera containing 1.25 GBq (33.7 Ci) of iridium-192. On July 19, 2011, the licensee discovered that their radiography truck had been broken into, and the radiography camera, associated equipment, and portable generator had been stolen. The alarm system on the truck was then tested and determined to be operational; however, the alarm had not been set at the time of the theft. Attempts to locate the camera included the use of portable radiation detection equipment on vehicles, Austin Police Department/6 Civil Support Team (APD/6CST) helicopter flyovers of the area, and a Department of Energy fly-over survey between the cities of Austin and San Antonio, using a fixed wing plane.

It should be noted that at the time this event was reported to the NRC, the radioactive material in the camera was at a level considered to be risk-significant. However, as of October 1, 2011, the radioactive material had decayed to a level considered to not be risk-significant. The radioactive source has not been recovered at the time of this report.

Cause(s) – Licensee failure to use the vehicle alarm system.

Actions Taken to Prevent Recurrence

Licensee – The licensee conducted a company-wide review of the incident with all employees, inspected all their trucks to verify the alarm systems were operating, and required all employees to view a video that showed the proper way to lock and secure radioactive material.

State – The Texas Department of State Health Services conducted an inspection on July 21, 2011 and determined that radiographer had failed to activate the alarm system on the truck containing the radiography camera. The licensee and the radiographers involved were cited for the violation.

This event is closed for the purpose of this report.

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, one event at commercial nuclear power plants in the United States was significant enough to be reported as an AO based on the criteria in Appendix A to this report.

NRC11-02 Commercial Nuclear Power Plant Event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama

Criterion II.C, "For Commercial Nuclear Power Plant Licensees," of Appendix A to this report provides, in part, that a commercial nuclear power plant event shall be considered for reporting as an AO if it results in any reactor conditions or performance indicators that are determined to be of high safety significance (red findings).

Date and Place – October 23, 2010, Athens, Alabama

Nature and Probable Consequences – The Tennessee Valley Authority (TVA) (the licensee) reported a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, a boiling-water reactor designed by General Electric. On October 23, 2010 during a refueling outage, it was discovered that a residual heat removal (RHR) low pressure coolant injection (LPCI) flow control valve failed while the licensee was attempting to establish shutdown cooling. The flow control portion of the valve, called the disc, was found stuck in the seat of the valve. The disc had become separated from the valve stem and could no longer be controlled by the valve motor operator. The RHR system is primarily used for LPCI during accident conditions and for cooling while the reactor is shut down. As a result of the flow control valve failure, Loop II of the RHR system could not have performed its safe shutdown functions and was declared inoperable. The licensee promptly placed the other loop of the RHR system (Loop I) into service and, as a result, the failure of the flow control valve did not involve an actual safety consequence or impact the health and safety of the public.

However, the NRC reviewed this event under its significance determination process and determined that the licensee's history with regards to this valve performance issue represented a finding of high safety significance (red finding). The basis for this finding was that the flow control valve's failure (condition) caused a weakness in the licensee's fire mitigation strategy, resulting in a significant increase in the core damage frequency. The licensee's fire mitigation strategy limits the availability of alternative sources of reactor coolant inventory makeup and both loops of LPCI could potentially be unavailable in some accident scenarios. Automatic valve function was lost, as well as the ability of plant operators to manually use this loop of the RHR system.

The public was never actually endangered because no event requiring use of the RHR system occurred. However, the RHR system is counted on for core cooling during certain accident scenarios, and the flow control valve failure left it inoperable, which could have led to core damage had an accident involving a series of unlikely events occurred. The NRC determined that this event did not represent an immediate safety concern, because the licensee staff had, as part of its immediate corrective actions, implemented repairs and modifications in accordance with design requirements that returned the flow control valve to an operational condition (the red finding was for licensee performance deficiencies resulting in a past inoperability).

Cause(s) – The immediate cause for this condition was separation of the valve disc from the

stem/skirt, with the disc wedged into the seat in the closed position. The licensee determined that part of the root cause was a valve manufacturing defect that resulted in undersized disc skirt threads at the disc connection to the valve stem. In addition, the NRC identified several other performance deficiencies on the part of the licensee. Specifically, the NRC determined that the licensee's failure to establish adequate programs to ensure that motor-operated valves continue to be capable of performing their design-basis safety functions was a performance deficiency. The NRC also concluded that TVA should have foreseen the results of not including these valves within the scope of the program described in Generic Letter 89-10, "Safety-Related Motor-Operated Valve Testing and Surveillance," dated June 28, 1989, and should have corrected the problem. This failure to effectively maintain and inspect these valves within the program contributed to the performance deficiency. The licensee's corrective action program and root cause evaluation also did not appear to address the broader issues associated with programs to ensure the continued capability of motor-operated valves to perform their design-basis safety function.

Actions Taken to Prevent Recurrence

Licensee – TVA reported this condition under 10 CFR 50.73, "Licensee Event Reporting System," and under 10 CFR Part 21, "Reporting of Defects and Noncompliance Process." In addition, TVA has presented corrective actions related to the flow control valve failure and corrective actions that are planned to address long-term fire strategies at the Browns Ferry Nuclear Power Station. The flow control valve was repaired promptly, and inspections were performed on all similar valves for Units 1, 2, and 3 to verify their functional capability. TVA informed the NRC of plans to reduce operator manual actions; implement procedural changes related to fire strategy; install modifications as a result of its review of National Fire Protection Association Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," and continue to reduce fire risk at the station.

NRC – The NRC assessed the performance of Browns Ferry Nuclear Power Station, Unit 1, to be in the Multiple/Repetitive Degraded Cornerstone Column of the NRC's Action Matrix beginning in the fourth quarter of calendar year 2010. This finding resulted in increased NRC oversight at Browns Ferry Nuclear Power Station, including a supplemental inspection to evaluate safety, organizational, and programmatic issues at the plant. NRC staff initiated the supplemental inspection at the Browns Ferry Nuclear Power Station beginning on September 12, 2011. This inspection is being conducted in accordance with inspection procedures, and will include extensive reviews of programs and processes not inspected as part of the NRC's baseline inspection program. The inspection will also include an assessment of the Browns Ferry Nuclear Power Station's safety culture. Part 1 of this supplemental inspection was completed and an inspection report was issued on November 17, 2011 (available at Agencywide Documents Access and Management System (ADAMS) Accession No. ML113210602). The results of this inspection will be combined with the results from Parts 2 and 3 of the Browns Ferry Inspection Procedure (IP) 95003 (available at ADAMS Accession No. ML102020551), and will assist the NRC in determining the breadth and depth of safety, organizational, and programmatic issues at Browns Ferry Nuclear Power Station. The NRC will report on the final supplemental inspection results as part of the FY 2012 AO report to Congress.

This event is open for the purpose of this report.

III. EVENTS AT FACILITIES OTHER THAN NUCLEAR POWER PLANTS AND ALL TRANSPORTATION EVENTS

During this reporting period, 3 events at NRC-licensed or NRC-regulated facilities and 16 events at Agreement-State-licensed facilities were significant enough to be reported as AOs, based on the criteria in Appendix A to this report.

AS11-04 Medical Event at Western Pennsylvania Hospital in Allegheny, Pennsylvania

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – February 23, 2009, Allegheny, Pennsylvania

Nature and Probable Consequences – Western Pennsylvania Hospital (the licensee) reported that a medical event occurred associated with a high-dose-rate (HDR) mammosite treatment for breast cancer; the treatment consisted of 184.2 GBq (4.9 Ci) of iridium-192. The patient was prescribed to receive 34 Gy (3,400 rad) in 10 fractionated doses, but instead, received a dose of 50 Gy (5,000 rad) to the skin tissue around the catheter entry point (wrong treatment site). The patient's physicist notified the patient and the referring physician of this event.

Before starting the treatment on February 23, 2009, the licensee performed a check to verify the catheter length and treatment calculations. In addition, the treatment procedure required daily CT scans to verify the treatment site. On February 27, 2009, a different therapy physicist identified a potential error in the patient's chart and contacted the patient's physicist. On March 3, 2009, the patient's physicist checked the other therapy physicist's findings and discovered there had been a 3 cm error in the placement of the source during treatment. This incorrect distance resulted in the intended site receiving only 30 percent of the intended dose and the skin tissue receiving the full dose. The patient received followup care for erythema of the skin tissue and the licensee concluded that this medical event would not have a significant medical effect on the patient.

Cause(s) – The medical event was caused by human error in the placement of the source during treatment.

Actions Taken to Prevent Recurrence

Licensee – The licensee revised all mammosite policies and procedures to strengthen the accuracy of measurement, planning, treatment, and quality control. Specifically, the licensee modified the mammosite worksheet to add the expected catheter length beside the block where the measured catheter length is recorded, and required that the catheter measurement wire be kept in place during CT simulation following catheter measurement.

State – The Pennsylvania Department of Environmental Protection investigated the incident on March 18, 2009 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on November 14, 2011.

This event is closed for the purpose of this report.

AS11-05 Medical Event at the University of Pennsylvania in Philadelphia, Pennsylvania

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – January 21 2010, Philadelphia, Pennsylvania

Nature and Probable Consequences – University of Pennsylvania (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 65 iodine-125 seeds. Instead, the seeds were inadvertently placed outside the intended treatment site (wrong treatment site). The patient received an approximate dose of 161 Gy (16,100 rad) to the penile bulb (glans) (wrong treatment site). The patient and referring physician were informed of this event.

On January 21, 2010 the iodine-125 seeds were implanted in the patient's prostate using real time dosimetry under ultrasonic guidance. The written directive called for a therapeutic radiation dose of 145 Gy (14,500 rad) to the prostate volume, plus 5 mm of margin. On February 23, 2010, the patient returned for a 30 day post implant CT scan, which revealed that the implanted seeds were "in an appropriate pattern," but outside the intended target volume, which resulted in unintended dose to the penile bulb (glans). The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause(s) – The medical event is presumed to have been caused by misuse of a new ultrasound unit.

Actions Taken to Prevent Recurrence

Licensee – The licensee's Radiation Oncology Department suspended all prostate brachytherapy treatments pending an additional quality assurance review. Upon completion of the quality assurance review, the licensee modified its prostate brachytherapy treatment procedures. As of January 2012, the licensee has not yet recommenced prostate brachytherapy treatments after implementation of these modified procedures.

State – The Pennsylvania Department of Environmental Protection investigated the incident on April 15, 2010 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on November 14, 2011.

This event is closed for the purpose of this report.

AS11-06 Medical Event at University Community Hospital in Tampa, Florida

Criteria III.C.1.b, III.C.2.a and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads), and represents a dose or dosage that is at least 50 percent greater than that prescribed or is delivered to the wrong treatment site.

Date and Place – February 14, 2010, Tampa, Florida

Nature and Probable Consequences – University Community Hospital (the licensee) reported that two patients were prescribed single-channel HDR brachytherapy treatments of 34 Gy (3,400 rad). The actual average dose of 17 Gy (1,700 rad) to the first patient, and 26 Gy (2,600 rad) to the second patient, were delivered to the target area of the breast in which some parts of the planned volume received greater than 700 percent (first patient) and 220 percent (second patient) of the prescribed dose. In addition, other areas of the breast not in the target region received up to 136 Gy (13,600 rad) in the first patient and 75 Gy (7,500 rad) in the second patient. The maximum skin dose was calculated to be 42.5 Gy (4,250 rad) to the first patient and 75 Gy (7,500 rad) to the second patient. The patients and their referring physicians were informed of the events.

On February 14, 2010, the licensee noted that the mammosite catheter was erroneously positioned approximately 2 to 2.5 cm away from the tumor. This was the result of the operator entering the wrong dwell position into the planning system. The licensee concluded that no significant adverse health effects to the patients are expected.

Cause(s) – The cause of the medical events was human error involving entering the wrong position of the reference end of the catheter into the planning system.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions included implementing various quality assurance steps to ensure that the correct treatment calculations and data are used for future treatments. Additional procedural guidance will be created with detailed instructions.

State – The Florida Bureau of Radiation Control initiated an inspection on February 18, 2010. The State completed the inspection on March 1, 2010, and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on February 1, 2011.

This event is closed for the purpose of this report.

AS11-07 Medical Event at Coral Springs Clinic in Coral Springs, Florida

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place – March 11, 2010, Coral Springs, Florida

Nature and Probable Consequences – Coral Springs Clinic (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for basal cell carcinoma of the ear; the treatment consisted of 210.9 GBq (5.7 Ci) of iridium-192. The patient was prescribed 14 fractionated doses of 2.5 Gy (250 rad) to the ear, but instead, the patient received 22.5 Gy (2,250 rad) on the second fractionated treatment dose. The patient and referring physician were informed of this event.

On March 11, 2010, the patient being treated for basal cell carcinoma of the ear was to receive the second fractionated dose 2.5 Gy (250 rad); however, while starting the treatment the radiation therapist accidentally pushed the incorrect button on the HDR device, which was the "auto radiography" button rather than the "treatment" button on the machine control console. This resulted in the patient receiving approximately 9 times the intended dose for that fraction of the treatment. Further treatments were canceled. The patient and doctor were notified of the incident. The licensee concluded that no significant health effects to the patient are expected as a result of this incorrect dose.

Cause(s) – The medical event was caused by human error in that the licensee failed to push the correct button on the HDR device.

Actions Taken to Prevent Recurrence

Licensee – The licensee immediately disabled the autoradiograph function on the HDR and other similar devices. The licensee modified its procedures to include the use of an independent mechanical timer and provided additional training to its entire clinical staff.

State – The Florida Bureau of Radiation Control initiated an inspection on April 27, 2010 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on October 10, 2011.

This event is closed for the purpose of this report.

AS11-08 Medical Event at Rhode Island Hospital in Providence, Rhode Island

Criteria III.C.1.b and III.C.2.b(i), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that uses the wrong radiopharmaceutical.

Date and Place – April 23, 2010, Providence, Rhode Island

Nature and Probable Consequences – Rhode Island Hospital (the licensee) reported that a medical event occurred during a thyroid diagnostic uptake scan. The patient was prescribed to receive 7.4 MBq (200 uCi) of iodine-123, but was administered 148 MBq (4 mCi) of iodine-131. The administration resulted in a dose of approximately 3,108 cGy (3,108 rad) to the patient's thyroid, rather than the estimated 7 cGy (7 rad) that would have resulted from the iodine-123 administration. The patient and referring physician were informed of this event.

The patient's physician handed the patient a written prescription for the iodine-123 scan, but the physician's office faxed an order to the hospital for an iodine-131 scan. On April 23, 2010, the patient presented the correct written prescription slip, for the iodine-123, to the licensee's admitting receptionist. The receptionist refused the written prescription, because she thought the hospital already had the correct prescription in its records. The patient was administered the iodine-131, and the whole body scan was performed. The nuclear medicine technologist noticed something was wrong based on the scan results. The impact of this event on the patient was not reported by the licensee.

Cause(s) – The cause of this medical event was human error and failure of the licensee staff to follow existing written procedures and protocols.

Actions Taken to Prevent Recurrence

Licensee – The licensee reviewed existing written protocols and training procedures used for the nuclear medicine technologists. The licensee's corrective actions included modifying the procedures and conducting refresher training for the nuclear medicine technologists. In addition, the licensee developed a thyroid interview and patient assessment history sheet and now requires a pathology report for all thyroid cancer patients before iodine-131 doses are administered.

State – The Rhode Island Department of Health, Radiation Control Program, conducted an investigation of this medical event on April 30 through May 20, 2010, and issued a Notice of Violation (NOV) to the licensee. The Rhode Island Department of Health also issued a regulatory citation regarding the licensee's failure to follow established procedures and forwarded the final update of the event to the NRC in September 2011.

This event is closed for the purpose of this report.

AS11-09 Medical Event at Lovelace Medical Clinic in Albuquerque, New Mexico

Criteria III.C.1.b, and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and is a prescribed dose delivered to the wrong treatment site.

Date and Place – May 4, 2010, Albuquerque, New Mexico

Nature and Probable Consequences – The Lovelace Medical Clinic (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for endometrial carcinoma; the treatment consisted of 129.7 GBq (3.5 Ci) of iridium-192. The patient was prescribed to receive a total dose of 21 Gy (2,100 rad) in three fractionated doses to the vaginal cuff, but instead, the skin tissue on the patient's thigh received 30.6 Gy (3,060 rad). The patient and referring physician were informed of this event.

On May 4, 2010, the patient received the third fractionated dose of 7 Gy (700 rad) and, 1 week later, noticed the appearance of two somewhat painful dark spots on the skin of her thigh. On May 18, 2010 the patient notified the licensee of the appearance of the spots on her skin and was examined by the prescribing physician the next day. The prescribing physician did not diagnose the spots as radiation erythema at this time, but asked the patient to return for a followup examination approximately a week later. On May 26, 2010, the physician identified two circular areas with a diameter of approximately 1 cm, which were determined to be radiation erythema. The average skin dose to the patient's thigh was calculated to be 30.6 Gy (3,060 rad) and the thigh dose at a depth of 2.5 cm was calculated to be 4.08 Gy (408 rad). The licensee concluded that no long-term medical effects are expected for the patient.

Cause(s) – The medical event was caused by either improper placement or workers inadvertently moving the catheter while adjusting the patient for better alignment with the treatment device.

Actions Taken to Prevent Recurrence

Licensee – The licensee revised its procedures to ensure that the catheter is correctly positioned before the start of the treatment. In addition, the licensee required staff training to address the procedure updates.

State – The New Mexico Radiation Control Bureau is conducting a long-term investigation of the event and the licensee's corrective actions and is still considering what, if any, enforcement actions to pursue.

This event is open for the purpose of this report.

AS11-10 Medical Event at Lancaster General Hospital in Lancaster, Pennsylvania

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – June 3, 2010, Lancaster, Pennsylvania

Nature and Probable Consequences – Lancaster General Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for ovarian cancer; the treatment consisted of 310.8 GBq (8.4 Ci) iridium-192. The patient was prescribed to receive 7.2 Gy (720 rad) in five fractionated doses, but instead during one of the fractionated treatments received a dose of 19 Gy (1,900 rad) to the small bowel (wrong treatment site). The patient and referring physician were informed of this event.

On June 15, 2010, before starting the second treatment, the licensee noted that an incorrect target area had been previously entered into the HDR device for the first treatment on June 3, 2010. The licensee noted that the intended treatment area in the written directive differed from the actual area treated by approximately 3 cm. This error in treatment area resulted in a dose of 19 Gy (1,900 rad) to the small bowel. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause(s) – The medical event was caused by human error in that the licensee entered the incorrect target area into the HDR device.

Actions Taken to Prevent Recurrence

Licensee – The licensee implemented corrective measures including procedure modifications to discontinue using the part of the HDR software that allows for treatment offsets to occur.

State – The Pennsylvania Department of Environmental Protection investigated the incident on June 21, 2010 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on November 14, 2011.

This event is closed for the purpose of this report.

AS11-11 Medical Event at the Greater Baltimore Medical Center in Baltimore, Maryland

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – July 9, 2010, Baltimore, Maryland

Nature and Probable Consequences – The Greater Baltimore Medical Center (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for cervical cancer. The patient was prescribed to receive 35 Gy (3,500 rad) to the cervix over the course of 73 hours using 1.635 GBq (44.2 mCi) of cesium-137. While the sources were being inserted into the patient, one of the cesium-137 sources fell out of the Fletcher-Suit applicator and into the patient's hospital gown. Consequently, the skin tissue on the patient's buttocks received a dose of 10.5 Gy (1,050 rad) from the errant source. The patient and referring physician were informed of this event.

Sometime after the sources had been inserted into the patient, the patient removed the hospital gown, folded it, placed it with the trash, and donned a clean gown. On July 9, 2010, the oncologist and medical physicist removed the sources from the patient and discovered that one of the six sources was missing. The oncologist and radiation safety officer subsequently located the source wrapped in the soiled hospital gown in a bag designated for radioactive waste. The source was retrieved and transported back to the Radiation Oncology Department's source storage room. The licensee noticed no erythema of the patient's skin and concluded that no clinically significant side effects would be expected from the radiation exposure to the skin.

Cause(s) – The cause of the medical event was the failure of the source attachment to the applicator, coupled with failure of the licensee to establish appropriate procedures to prevent the occurrence of the medical event.

Actions Taken to Prevent Recurrence

Licensee – The licensee plans to discontinue the use of the Fletcher-Suit applicator used during this treatment and exclusively use the Fletcher-Suit-Delclos applicator. The licensee also plans to revise procedures for brachytherapy applicators and provide improved training to the staff.

State – The Maryland Department of the Environment, Radiological Health Program conducted an investigation on July 27, 2010 and August 18, 2010. On October 18, 2010, the Department issued a letter and NOV to the licensee and forwarded the final update of the event to the NRC in July 2011.

This event is closed for the purpose of this report.

NRC11-03 Medical Event at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – August 4, 2008 (reported on September 8, 2010), Jackson, Mississippi

Nature and Probable Consequences – The U.S. Department of Veterans Affairs (the licensee) reported that a medical event involving prostate cancer brachytherapy seed implants occurred at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 104 iodine-125 seeds. However, the seed placement resulted in an approximate dose of 233 Gy (23,300 rad) to the patient's rectum (wrong treatment site). The patient and referring physician were informed of this event.

In September 2010, the licensee completed a followup comprehensive external review and reanalysis of posttreatment dose parameters for all prostate seed implants performed at the G.V. (Sonny) Montgomery VA Medical Center for the period between February 2005 and August 2008. Upon an evaluation of the updated dose information generated by external review, medical center staff, working with the National Health Physics Program, discovered this event. No adverse effect to the patient is expected from the implant procedure, and the licensee continues to monitor the progress of the patient.

Cause(s) – The cause of the medical event was an anatomical anomaly of the patient. The patient had an unusually thin tissue layer between the prostate gland and rectum, which resulted in a small area of the rectum receiving a higher than expected dose.

Actions Taken to Prevent Recurrence

Licensee – The U.S. Department of Veterans Affairs, working with the National Health Physics Program and the medical center's staff, performed an initial review of all prostate brachytherapy seed implant procedures for the period between February 2005 and August 2008. The initial review of this program resulted in the suspension of and eventual termination of the medical center's prostate brachytherapy implant program in August 2009. The followup comprehensive external review and reanalysis of the program identified this event, which the medical center reported to the licensee and the NRC.

NRC – In August 2010, the NRC issued an NOV and Proposed Imposition of Civil Penalties to the licensee, based on the results of the initial evaluation and analysis of the licensee's prostate brachytherapy implant program. The licensee was cited for failure to have adequate written procedures and failure to verify that the administered doses were in accordance with written directives. The NRC has not taken any additional actions based on the identification of this event.

This event is closed for the purpose of this report.

NRC11-04 Medical Event at Community Hospitals of Indiana in Indianapolis, Indiana

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – October 6, 2010, Indianapolis, Indiana

Nature and Probable Consequences – Community Hospitals of Indiana (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for breast cancer; the treatment consisted of 340.4 GBq (9.2 Ci) of iridium-192. The patient was prescribed to receive a total dose of 34 Gy (3,400 rad) in 10 fractionated doses to the postsurgical cavity in the left breast following excision of a cancerous tumor (treatment site). It was determined that the first eight treatment fractions resulted in a portion of the treatment site receiving a dose of 266 Gy (26,600 rad). In addition, a portion of the patient's skin on the left breast and the chest muscle tissue (tissue other than the treatment site) received doses of 105 Gy (10,500 rad) and 1,002 Gy (100,200 rad), respectively. The patient and referring physician were informed of this event.

On October 6, 2010, following the eighth fractionated treatment dose, an error was discovered in the treatment plan by the medical physicist who remembered that he had not changed a default entry in the treatment planning system. This error caused the source placement to be flipped 180 degrees along the applicator's long axis which resulted in a portion of the treatment site at the tip end of the applicator receiving less than the prescribed dose, and a portion of the treatment site at the connector end of the applicator receiving more than the prescribed dose. The licensee concluded that no long-term medical effects are expected for the patient. The NRC contracted with a medical consultant who determined that the overall impact to the patient is minimal.

Cause(s) – The medical event was caused by human error in that the medical physicist failed to change a default entry in the treatment planning system as required by the licensee's procedure.

Actions Taken to Prevent Recurrence

Licensee – The licensee revised its written directive form to remind staff to change the default entry in the treatment planning system as applicable, added a step to its procedure for multicatheter HDR breast treatments to verify that the default was changed as applicable, and trained its staff on the revised written directive form. In addition, the licensee evaluated all of the other HDR breast treatments that were conducted in 2010 to verify that the applicators were accurately reconstructed in the treatment planning computer.

NRC – The NRC conducted a reactive inspection on October 18-20, 2010, with continued in-office review through January 18, 2011, and issued two NOVs to the licensee on March 1, 2011 and April 20, 2011 respectively.

This event is closed for the purpose of this report.

AS11-12 Medical Event at Cleveland Clinic Foundation in Cleveland, Ohio

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – October 26, 2010, Cleveland, Ohio

Nature and Probable Consequences – The Cleveland Clinic Foundation (the licensee) reported, to the Ohio Department of Health (ODH) that a medical event occurred associated with a radioembolization brachytherapy treatment for liver cancer; the treatment consisted of 3.96 GBq (107 mCi) of yttrium-90. A postprocedure scan of the patient identified significant undesired activity in the duodenum (wrong treatment site). The licensee estimated that approximately 0.37 GBq (10 mCi) of activity was present in the duodenum, with a dose to the duodenum of approximately 90 Gy (9,000 rad). The patient and physician were informed of this event.

Approximately 3 weeks before the therapy, the patient was scanned for extra hepatic shunting by injecting technetium-99m into the hepatic artery. No shunting to the duodenum was identified during this procedure. On October 26, 2010, the interventional radiologist correctly inserted the catheter into the patient and its placement was confirmed by a second interventional radiologist. During the radioembolization treatment, the patient complained of pain, which resulted in the licensee performing a postprocedure SPECT/CT scan of the patient. The SPECT/CT scan identified undesired yttrium-90 activity in the duodenum. The patient was hospitalized for observation and possible intervention as a result of the dose to the duodenum. Some ulceration of the duodenum bulb was observed, but no evidence of perforation or bleeding was detected. The licensee is continuing to monitor the patient for health effects from the radiation exposure.

Cause(s) – The licensee believes that the cause of the medical event was that some collateral blood vessels became dominant and blood was shunted through them to the duodenum, allowing movement of the yttrium-90 microspheres. Although the licensee has not seen this relatively uncommon occurrence in the past 3 years, it has been noted in other treatment cases.

Actions Taken to Prevent Recurrence

Licensee: – The licensee modified its radioembolization therapy procedure to include posttreatment imaging of yttrium-90 distribution. This will allow the licensee to respond appropriately in the event of a recurrence. The licensee's rate of occurrence is approximately 10 times less than is reported in medical literature; therefore, no specific action to prevent a reoccurrence is proposed.

State: – On November 3, 2010, ODH performed an onsite investigation of the event. ODH reviewed and approved the licensee's corrective actions and took no enforcement action.

This event is closed for the purpose of this report.

AS11-13 Medical Event at Rush University Medical Center in Chicago, Illinois

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – November 23, 2010, Chicago, Illinois

Nature and Probable Consequences – Rush University Medical Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 102 iodine-125 seeds. Instead, the seeds were placed 4-5 cm inferior of the treatment plan (wrong treatment site). The patient received an approximate dose of 273.5 Gy (27,350 rad), 112 Gy (11, 200 rad) and 183 Gy (18,300 rad) to the urethra, perineum and penile bulb (glans), respectively. The patient and referring physician were informed of this event.

During the treatment, the iodine-125 seeds were manually inserted into the prostate needle template via ultrasound imaging. Visualization of the seed placement in the postimplantation scan was problematic for the licensee's staff; however, the staff's initial estimate of seed placement was that the seeds may have been inferior to the ideal placement, but still in an acceptable location. An additional posttreatment scan at the 4-week posttreatment mark indicated that the seeds were placed 4-5 cm inferior to the planned treatment site. The licensee surmised that the geometry of the template against the patient's perineum shifted during the procedure, and pulled away from the patient, perhaps due to leg movement or coughing. This placement resulted in an elevated dose to the patient's urethra, perineum and penile bulb (glans). The licensee concluded that there were no observed medical effects to the patient, and no long-term significant complications are expected.

Cause(s) – The cause of the medical event was the engorgement of the prostate gland and surrounding tissue, which made the visualization and placement of the seeds difficult during the implantation procedure.

Actions Taken to Prevent Recurrence

Licensee – The licensee has indicated that these procedures will now be conducted only where fluoroscopic imaging can be performed to provide better "real time" imaging of seed placement, in addition to transrectal ultrasound. Needle unloading procedures have been modified, and ultrasound equipment quality assurance tests have been added before each procedure.

State – The Illinois Emergency Management Agency (IEMA) conducted an onsite investigation. IEMA reviewed the event and other similar treatment procedures at the facility and determined that this event was an isolated incident. IEMA approved the licensee's corrective actions, and issued no citations or enforcement actions at the conclusion of the investigation.

This event is closed for the purpose of this report.

AS11-14 Medical Event at the University of Texas Southwestern Medical Center in Dallas, Texas

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place – July 30, 2010 and September 16, 2010 (reported on February 15, 2011), Dallas, Texas

Nature and Probable Consequences – The University of Texas Southwestern Medical Center (the licensee) reported the occurrence of two medical events to two young adult patients prescribed colloidal phosphorus-32 (ranging from 7.4 MBq (0.2 mCi) and 92.5 MBq (2.5 mCi) of activity) for treatment of cranial cysts. The patients were prescribed to receive a total dose of 300 Gy (30,000 rad) and 200 Gy (20,000 rad) respectively, but instead the patients received an approximate dose of 565 Gy (56,500 rad) and 506 Gy (50,600 rad) to the cysts. These dosages were 88 and 153 percent greater than the prescribed dosages. The patients and referring physicians were informed of these events.

On February 15, 2011, the licensee discovered that two young adult patients were administered doses of phosphorus-32 greater than 50 percent of the prescribed doses. The incidents were discovered when the authorized user noticed an area of inflammation surrounding the cysts and along the track of the drainage catheter. The authorized user discussed these findings with the staff medical physicist who reviewed the colloidal phosphorus-32 doses supplied by the nuclear pharmacy. The licensee determined that for both cases, the labels had the correct total activity, but the incorrect volume and activity per unit volume. Therefore, the doses were incorrectly labeled, and the concentration was approximately 60 percent higher than indicated on the labels. The licensee subsequently calculated the doses to the target and surrounding tissues and does not expect any patient impact or unfavorable outcomes as a result of these events.

Cause(s) – The cause of the medical event was that the two colloidal phosphorus-32 prescriptions provided by the vendor's nuclear pharmacy were incorrectly diluted and labeled. In addition, the licensee did not perform a verification assay of the doses before their administration.

Actions Taken to Prevent Recurrence

Licensee – To prevent recurrence, the licensee will obtain future doses that have been calibrated to a National Institute of Standards and Technology traceable standard. The licensee also will perform a verification assay at its facility and will assess the dose volume for calculating the specific activity.

State – On March 1, 2011, the Texas Department of State Health Services conducted an inspection and reviewed the causes and the licensee's corrective actions. The licensee was cited for a violation for failing to perform a direct measurement of the dosage taken from a bulk quantity for medical purposes.

This event is closed for the purpose of this report.

NRC11-05 Medical Event at the University of Michigan Hospital in Ann Arbor, Michigan

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place – March 9, 2011, Ann Arbor, Michigan

Nature and Probable Consequences – The University of Michigan Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer; the treatment consisted of 2.24 GBq (60.5 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 74.4 Gy (7,440 rad) to the left lobe of the liver, but instead, the patient received an approximate dose of 159.4 Gy (15,940 rad). This dosage was in excess of 100 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On March 9, 2011, before the treatment, the licensee's medical physicist calculated the activity needed for the dose to the left lobe of the liver. The medical physicist's calculations used the liver segment volumes for the right lobe and medial segment combined, instead of the much smaller left lobe. As a result of the volume calculation error, the dose to the left lobe of the liver was 159.4 Gy (15,940 rad), which was in excess of 100 percent of the prescribed dose. The licensee concluded that the elevated radiation dose to the patient's liver will not result in permanent medical damage or loss of function. The NRC contracted with a medical consultant who concluded that the administered dose is unlikely to result in any significant adverse effects.

Cause(s) – The NRC determined that the root cause of the medical event was a lack of communication between licensee personnel which resulted in an inaccurate written directive and subsequent medical event.

Actions Taken to Prevent Recurrence

Licensee – The licensee modified procedures by adding reviews of treatment plans to ensure that written directives properly reflect the treatment plan.

NRC – The NRC conducted an inspection on March 15 and 16, 2011, and reviewed the licensee's corrective actions. On January 6, 2012, NRC issued an NOV for failure to possess adequate procedures resulting in the medical event.

This event is closed for the purpose of this report.

AS11-15 Medical Event at Abbott Northwestern Hospital in Minneapolis, Minnesota

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place – March 17, 2011, Minneapolis, Minnesota

Nature and Probable Consequences – Abbott Northwestern Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer; the treatment consisted of 1.11 GBq (29.97 mCi) yttrium-90. The patient was prescribed to receive a total dose of 30.8 Gy (3,080 rad) to the liver, but instead, the patient received an approximate dose of 46.1 Gy (4,610 rad). This delivered dosage was about 150 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On March 18, 2011, after reviewing the treatment procedure from the previous day, the licensee's radiation oncologist discovered that the dose delivered to the patient's liver was actually 150 percent of the prescribed dose. For further clarification, the radiation oncologist brought this error to the attention of the lead medical physicist responsible for the patient's treatment delivery. Upon investigation, it was deduced that the medical physicist had not read the patient's therapy written directive prescription correctly, resulting in a higher than intended dosage being administered to the patient's liver. The licensee's radiation oncologist and interventional radiologist concluded that this elevated dose would slightly increase the patient's risk of radiation-induced liver disease.

Cause(s) – The medical event is believed to have been caused by human error in failing to correctly read the therapy written directive prescription.

Actions Taken to Prevent Recurrence

Licensee – The licensee implemented corrective measures, including increasing the font and highlighting in a different color the final dose on the written directive. In addition, the final dose is now transferred automatically rather than manually to the spreadsheet workbook used to draw up the dose. Also, procedures now require a second individual to verify that the correct prescribed activity has been transferred to the worksheet used for drawing up the dose.

State – The Minnesota Department of Health (MDH) conducted an investigation on April 5, 2011. During the investigation, MDH met with the radiation safety officer, the medical physicist and both radiation oncologists involved with the incident, and several members of the licensee administrative team. In addition, MDH reviewed the corrective actions implemented by the licensee. MDH did not issue any violations or penalties associated with the event; however, MDH will evaluate the licensee's corrective actions at its next inspection.

This event is closed for the purpose of this report.

AS11-16 Medical Event at the University of California, Los Angeles in Los Angeles, California

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – April 4, 2011, Los Angeles, California

Nature and Probable Consequences – The University of California, Los Angeles (UCLA) (the licensee) reported the occurrence of a medical event associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a dose of 144 Gy (14,400 rad) to the prostate using 101 iodine-125 seeds. Instead, the iodine-125 seeds were implanted inferior to the target volume (wrong treatment site), resulting in a dose to this tissue of 144 Gy (14,400 rad). The patient and referring physician were informed of this event.

On May 3, 2011, the patient returned to the UCLA Department of Radiation Oncology for a routine postimplant CT scan to verify seed placement and final dosimetry endpoints. The routine postimplant CT scan indicated that of the 101 total seeds implanted, approximately 72 seeds had been placed inferior to the target volume. As a result of the seed misplacements, approximately 31 cm^3 of normal tissue inferior to the prostate received at least 144 Gy (14,400 rad) instead of the prostate tissue receiving that dose. Rectal and bladder doses were not significantly impacted by the seed misplacements and remained within typical doses for prostate implants. The licensee concluded that there was no harm to the patient from doses to the nontargeted tissue.

Cause(s) – The licensee believes that the cause of the medical event was movement of the prostate gland during the implantation procedure, coupled with insufficient ultrasound images needed to identify the movement of the prostate gland during the procedure.

Actions Taken to Prevent Recurrence

Licensee – The licensee temporarily placed the permanent prostate seed implantation program on hold pending a review of the procedures. Upon completion of the review the licensee changed the implant procedure to require the verification of the base prostate plane and needle placement using both axial and sagittal plane ultrasound views. The licensee also did an internal investigation to determine if any similar incidents of seed misplacements had occurred in the past and reported that postimplant CT had been performed for at least the previous 5 to 6 years without the detection of any significant seed misplacement events.

State – The California Radiation Control Program investigated the event and issued violations for failing to have adequate prostate seed implantation procedures, failing to report the medical event within 24 hours of discovery, failing to provide a written report with all of the required information for the medical event within 15 days, and failing to have procedures and to adequately train staff and authorized users for reporting of medical events.

This event is closed for the purpose of this report.

AS11-17 Medical Event at St. Vincent Hospital in Green Bay, Wisconsin

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – May 15, 2011, Green Bay, Wisconsin

Nature and Probable Consequences – St. Vincent Hospital (the licensee) reported that a medical event occurred associated with HDR brachytherapy treatment for breast cancer; the treatment consisted of 318.2 GBq (8.6 Ci) iridium-192. The patient was prescribed to receive a total dose of 34 Gy (3,400 rad) over 10 fractionated treatments. Instead, the patient received 8.84 Gy (884 rad) to the tumor site and a dose of 67.5 Gy (6,750 rad) to unintended skin tissue. The patient and referring physician were informed of this event.

On June 6, 2011, the licensee determined that the applicator catheter lengths measured using the check ruler were incorrect during the breast cancer treatment. The licensee ascertained that the incorrect measurement was the result of the wire being caught at the apex of the curved catheter, approximately 4.5 cm from of the end of the catheter. Members of the licensee's staff assumed that this measured length was accurate because they were not aware of the nominal catheter length. The Wisconsin Department of Health Services verified that the nominal catheter length was not provided in the manufacturer's written procedure, and the manufacturer determined that the check wire used by the licensee met all design specifications. The licensee concluded that there were no observed significant adverse effects to the patient, and no long-term significant complications are expected.

Cause(s) – The cause of the medical event was human error in the failure to identify that the check wire was not inserted to the end of the catheter's lumen and failure to identify an incorrect measurement length.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions include obtaining a new measurement wire which has the same flexible tip as the HDR dummy wire. The treatment protocol was changed to incorporate the manufacturer's expected applicator treatment distances. In addition, the licensee developed a new policy and procedure, which emphasizes the due diligence required by the staff before the first clinical use of new HDR treatment applicators and guide tubes.

State – Based on its investigation conducted on June 14, 2011, the Wisconsin Department of Health Services cited the licensee for failure to develop, implement, and maintain written procedures to ensure that each administration is performed according to the provisions of the written directive.

This event is closed for the purpose of this report.

AS11-18 Medical Event at the University of Wisconsin—Madison in Madison, Wisconsin

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – July 7, 2011, Madison, Wisconsin

Nature and Probable Consequences – The University of Wisconsin—Madison (the licensee) reported that a medical event occurred associated with radioembolization brachytherapy treatment for liver cancer; the treatment consisted of 1.05 GBq (28.4 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 120 Gy (12,000 rad) to the left lobe of the liver, but instead, the patient received an approximate dose of 41.8 Gy (4,180 rad) to the right lobe of the liver (wrong treatment site). The patient and referring physician were informed of this event.

On July 7, 2011, the patient was scheduled for treatment for multinodular hepatocellular carcinoma to the left lobe of the liver. The dosimetry for yttrium-90 radioembolization brachytherapy treatment was based on volume (mass) of the left lobe. The written directive specified the treatment of the left lobe of the liver; however, the right lobe of the liver was treated in error. The licensee concluded that the dose received was not medically significant to the patient.

Cause(s) – The cause of the medical event was human error in not correctly following the treatment plan as documented on the written directive. The interventional radiologist forgot that he had changed the initial target of the procedure after the dose had been ordered and did not communicate that change to the rest of the staff.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions include a series of checks developed to occur in the interventional radiology room before an administration. Checks include a verbal confirmation between the interventional radiologist and the medical physicist and confirmation of the patient name, target area, dose, and route of administration. This checklist is also compared to the written directive.

State – The Wisconsin Department of Health Services conducted a reactive inspection on August 12, 2011, and did not issue any violations to the licensee.

This event is closed for the purpose of this report.

AS11-19 Medical Event at the Swedish American Hospital in Rockford, Illinois

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place – September 13, 2011, Rockford, Illinois

Nature and Probable Consequences – The Swedish American Hospital (the licensee) reported a medical event involving brachytherapy seed implant treatment for prostate cancer. The patient was prescribed a dose of 145 Gy (14,500 rad) to the prostate using 71 iodine-125 seeds. Instead, 68 of the iodine-125 seeds were implanted in the large bowel, the small bowel, and the bladder. The licensee calculated that the dose to the prostate was less than 1 Gy (100 rad), but the unintended dose to the large bowel was 10.2 Gy (1,020 rad). The patient and referring physician were informed of this event.

On September 15, 2011, postimplant imaging of the patient revealed that only three seeds were properly located in the prostate (target site), indicating a dose significantly less than the prescribed amount in the written directive. Postimplant imaging also revealed that seven seeds were in the bladder; these seeds were immediately removed. Additional postoperative imaging indicated that a number of seeds had been placed in the bowel wall, bladder wall, and the lumen of the bowel. On October 3, 2011, surgery was performed to remove misplaced seeds. All but four seeds were removed from the patient. With the removal of the seeds that the licensee was able to remove, the licensee concluded that the medical event would not have a significant effect on the patient.

Cause(s) – The cause of the medical event was a deviation from protocol by not having a medical physicist present during the procedure and not using fluoroscopy during needle placement.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions include emphasizing strict adherence to prostate brachytherapy protocols.

State – IEMA conducted an investigation on September 26, 2011, and verified the root cause of the event as reported by the licensee. IEMA issued an NOV to the licensee regarding this failure to implement appropriate procedures.

This event is closed for the purpose of this report.

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

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

(1) moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission

(2) major degradation of essential safety-related equipment

(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 U.S. Nuclear Regulatory Commission (NRC) identified the following criteria for determining an AO and the guidelines for "other events of interest" in a policy statement published in the *Federal Register* on October 12, 2006 (71 FR 60198).

Abnormal Occurrence Criteria

The following presents the criteria, by types of events, used to determine which events will be considered for reporting as AOs.

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, "High Risk Radioactive Material, Category 2." 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

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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.

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 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 Inspection.[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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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.

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.

C. For Medical Licensees

A medical event that:

1. Results in a dose that is

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8 The NRC 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 ASP program to have a conditional core damage probability (CCDP) or change in core damage probability (ΔCDP) of greater than 1×10^{-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.

a. Equal to or greater than 1 Gy (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.

APPENDIX B
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, updated information became available for one abnormal occurrence (AO) event that the U.S. Nuclear Regulatory Commission (NRC) had previously reported in NUREG-0090, Volume 33, "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2010," issued June 2011, regarding the medical event at Providence Hospital in Novi, Michigan.

Medical Event at Providence Hospital in Novi Michigan (previously reported as NRC10-08 in NUREG-0090, Volume 33)

Date and Place – August 30, 2010, Providence Hospital in Novi, Michigan

Background – Providence Hospital (the licensee) reported that a medical event occurred associated with an anal brachytherapy treatment using 32 seeds containing iodine-125. The intended dose was 90 Gy (9,000 rad) to the tumor. Instead, the patient's seminal vesicle received 19.79 Gy (1,979 rad) more than intended, and the bladder received 3.68 Gy (368 rad) more than intended. The licensee determined that the event was caused by not using tissue markers to confirm source placement and the insertion needle, which resulted in the placement of the sources at an incorrect depth. Corrective actions taken by the licensee include modifications of procedures used to administer sources as prescribed in the written directive and training of licensee staff on the event and modified procedures. The NRC conducted an onsite inspection and hired an independent medical consultant to review the event. The FY 2010 AO report discusses the full details of the event under NRC10-08.

Update on Actions Taken To Prevent Recurrence

NRC – NRC Region III reviewed and concurred on the licensee's corrective actions. The NRC obtained the services of a medical expert consultant who determined that the patient had no clinical adversity from the implant and that the radiation from the sources in the pelvis was not likely to manifest any clinical effects, either acute or chronic. On May 17, 2011, the NRC issued a violation regarding the licensee's failure to develop written procedures to provide high confidence that each brachytherapy treatment is in accordance with the written directive.

This event is closed for the purpose of this report.

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 U.S. Nuclear Regulatory Commission (NRC) to increase its attention to or oversight of a program area. These include a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

EOI-01 International Nuclear and Radiological Events Scale Level 7 "Major Accident": Fukushima Dai-ichi Site (Japan) Nuclear Accident

This event is included in this report because it received significant world-wide media coverage and was of high health and safety significance in Japan. On March 11, 2011, a magnitude 9.0 earthquake occurred at a depth of approximately 25 kilometers (15 miles), 130 kilometers (81 miles) east of Sendai and 372 kilometers (231 miles) northeast of Tokyo off the coast of Honshu Island. This earthquake resulted in the automatic shutdown of 11 nuclear power plants at four sites along the northeast coast of Japan (Onagawa 1, 2, and 3; Fukushima Dai-ichi 1, 2, and 3; Fukushima Dai-ni 1, 2, 3, and 4; and Tokai 2). The earthquake precipitated a large tsunami that is estimated to have exceeded 14 meters (45 feet) in height at the Fukushima Dai-ichi Nuclear Power Plant site. The earthquake and tsunami produced widespread devastation across northeastern Japan, resulting in approximately 20,000 people dead or missing, displacing many tens of thousands of people, and significantly impacting the infrastructure and industry in the northeastern coastal areas of Japan.

On March 12, 2011, the Nuclear and Industrial Safety Agency (NISA) of Japan provided the first provisional rating as a Level 3 (serious incident) on the International Atomic Energy Agency's International Nuclear and Radiological Event Scale (INES). As conditions of the multiple reactors became known, both NISA and the Japanese Nuclear Safety Commission, in cooperation with the Japan Atomic Energy Agency, revised their initial provisional rating based on the radiation monitoring data and aerial dispersion analysis and, on April 12, 2011, issued the final rating as a Level 7 (major accident) on the INES. This final INES rating considers the events that occurred at Fukushima Dai-ichi Units 1, 2, and 3 as a single event on the INES. NISA notes that while an INES rating of 7 is the same as the rating for the Chernobyl accident, this is the first time INES has been used during a declared emergency, and the radioactive materials released in this case are only about 10 percent of the estimated amount released from the 1986 Chernobyl accident.

The Tokyo Electric Power Company and NISA reported that as a result of the earthquake, the operating reactors at all of the operating units appeared to experience a normal reactor trip within the capability of the design specifications of the plants. The ensuing tsunami resulted in extensive damage to site facilities and a complete loss of alternating current electrical power at Units 1 through 5, a condition known as "station blackout." Unit 6 retained the function of one of its diesel generators. Despite the actions of the operators following the earthquake and tsunami, cooling was lost to the fuel in the Unit 1 reactor after several hours, the Unit 2 reactor after about 71 hours, and the Unit 3 reactor after about 36 hours, resulting in damage to the nuclear fuel shortly after the loss of cooling. Units 1, 2, and 3 experienced explosions caused by the buildup of hydrogen gas within primary containment, which was produced during fuel

damage in the reactor and the subsequent movement of that hydrogen gas from the drywell into the secondary containment. Fukushima Dai-ichi Units 1, 2, and 3 experienced severe core damage; the Unit 4 core had been offloaded to a spent fuel pool before the earthquake. The source of the explosive gases causing the Unit 4 explosion remains unclear, but may have been caused by leakage of hydrogen from unit 3. On December 16, 2011 the Japanese government and TEPCO announced that all of the reactors had achieved a state of cold shutdown.

On March 11, 2011, the NRC fully staffed its 24-7 Operations Center with technical experts and liaison staff, in order to evaluate potential impacts, if any, on U.S. nuclear facilities from the tsunami, and monitor and analyze events at the nuclear plants in Japan. At the request of the Japanese government and through the U.S. Agency for International Development, the NRC sent a team of its technical experts to provide on-the-ground support to the Japanese government and U.S. Ambassador. As events at the Fukushima Dai-ichi site became relatively static over a period of time, the NRC reduced the staffing levels for the Operations Center. The NRC continued to provide a small technical staff to the U.S. Ambassador in Japan until February 2012, as well as maintains a cadre of key technical competent staff members at NRC Headquarters to answer requests from the onsite technical support staff (see http://www.nrc.gov/japan/japan-info.html).

In response to these events in Japan, as well as questions about the safety and survivability of similarly designed U.S. plants, the Commission directed the Executive Director for Operations to establish a senior-level task force to conduct both a short- and long-term analysis of the lessons that can be learned from the situation in Japan. In addition, the NRC inspected all U.S. commercial nuclear power plants to evaluate the industry's readiness for a similar event and to aid in determining whether additional regulatory actions by the NRC are warranted. These inspections were intended to be a high-level examination of the industry's preparedness for events that may exceed the design basis of a plant. The senior-level task force reviewed the results of these inspections.

The NRC's Japan Near-Term Task Force conducted a systematic and methodical review of NRC processes and regulations to determine whether the agency should make additional improvements to its regulatory system and to make recommendations to the Commission for its policy direction, in light of the accident at the Fukushima Dai-ichi Nuclear Power Plant. In examining the Fukushima Dai-ichi accident for insights for reactors in the United States, the Task Force addressed protecting against accidents resulting from natural phenomena, mitigating the consequences of such accidents, and ensuring adequate emergency preparedness. Therefore, continued operation of the operating nuclear power plants and continued licensing activities do not pose an imminent threat to public health and safety. The Task Force found that the Commission's longstanding defense-in-depth philosophy, supported and modified as necessary by state-of-the-art probabilistic risk assessment techniques, should continue to serve as the primary organizing principle of its regulatory framework. The result of the Task Force's work is a set of 12 recommendations that take a balanced approach to defense-in-depth as applied to low-likelihood, high-consequence events such as prolonged station blackout resulting from severe natural phenomena. These recommendations, taken together, are intended to clarify and strengthen the regulatory framework for protection against natural disasters, mitigation, and emergency preparedness, and to improve the effectiveness of the NRC's programs. The Task Force concluded that the application of the defense-in-depth philosophy can be strengthened by including explicit requirements for beyond-design-basis events. The Task Force completed its report to the Commission, SECY-11-0093, "The Near-Term Task Force Review of Insights from the Fukushima Dai-ichi Accident," on July 12, 2011. For more details on the Task Force's report, see the NRC Web page "Recommendations of the

Japan Task Force," available at http://pbadupws.nrc.gov/docs/ML1118/ML111861807.pdf.

On October 3, 2011, the NRC staff proposed to the Commission recommendations for the prioritization of the Japan Near-Term Task Force recommendations in SECY-11-0137, "Prioritization of Recommended Actions to be Taken in Response to Fukushima Lessons Learned," available at http://www.nrc.gov/japan/japan-activities.html. The Commission approved the staff's proposed prioritization of the Japan Near-Term Task Force recommendations as detailed in the Staff Requirements Memorandum (SRM) to SECY-11-0137, "Staff Requirements – SECY-11-0137 – Prioritization of Recommended Actions to be Taken in Response to Fukushima Lessons Learned," dated December 15, 2011, available at http://www.nrc.gov/japan/japan-activities.html. Additionally, the NRC maintains a public webpage providing updated details related to the Japan earthquake/tsunami reactor events available at: http://www.nrc.gov/japan/japan-info.html.

EOI-02 Fort Calhoun Station, Unit 1, Nuclear Power Plant: Unusual Event Due to High River Level

This event is included in this report because it received significant media coverage and public attention. Local and national media also perceived it to be of high health and safety significance. However, as described below, the 2011 flooding of the Missouri River and the subsequent high water levels surrounding the Fort Calhoun Station (FCS) did not directly impact safety-related equipment. Additionally, the Omaha Public Power District (OPPD) (the licensee) maintained plant safety, and the NRC maintained oversight of licensee response.

FCS, located approximately 19 miles north of Omaha, NE on the Missouri River, consists of a single pressurized-water reactor (PWR) designed by Combustion Engineering. On June 6, 2011, FCS declared a Notification of Unusual Event (NOUE) in anticipation that the Missouri River level at the plant would reach 1,004 feet mean sea level (MSL). By design, the plant is protected to a river level elevation of 1,014 feet MSL. Record snowfall totals during the winter, followed by a rapid snowpack melt and significant rainfall during the spring caused this rise in the Missouri River System. FCS had been shut down since April 9, 2011 for a planned refueling outage and remained shut down during the entire period of flooding. Although some plant equipment was impacted by the flooding, FCS maintained their emergency response capability and the physical security of the plant. The NRC also established 24-hour onsite inspector coverage during a significant portion of the event.

FCS personnel implemented many steps in advance of high water conditions including use of a large water-filled tube (water berm) around the facility to protect additional plant assets. They also erected additional earthen berms and other structures to protect specific plant structures and systems. On June 26, 2011, OPPD reported the failure of the water berm. The failure of the water berm flooded open areas of the plant's Protected Area to a depth of approximately 2.5 feet and allowed floodwaters to surround the concrete dams of the main electrical transformers, prompting OPPD to take the precautionary measure of temporarily transferring from offsite power to onsite emergency diesel generators (EDGs). Reactor shutdown cooling and spent fuel pool cooling were unaffected during the transfer of power to the onsite EDGs. The NRC entered the Monitoring Mode of agency response for four days with the Region IV Incident Response Center having the response lead. On August 29, 2011, the licensee terminated the NOUE for flooding when the Missouri River level receded to less than 1,004 feet MSL. The highest river level reported at FCS was 1,006 feet, 10 inches MSL on June 25, 2011.

On August 10, 2011, OPPD provided the NRC with a Post-Flooding Recovery Action Plan, which called for extensive reviews of plant systems, structures, and components to assess the impact of the floodwaters (available at Agencywide Documents Access and Management System (ADAMS) Accession No. ML112231755). The NRC issued a confirmatory action letter (CAL 4-11-003) on September 2, 2011 (available at ADAMS Accession No. ML112490164), which described various commitments made by OPPD for site restoration, plant systems and equipment status, equipment reliability, design and licensing basis, emergency planning and security impacts, and the recovery actions that would occur before the unit proceeds to startup. NRC review and approval in accordance with CAL 4-11-003 are required before startup of the FCS reactor.

In addition, some of the media attention related to this FCS flooding issue referenced an earlier NRC inspection finding issued to FCS that involved flooding issues. On October 6, 2010, the NRC issued a final finding of substantial safety significance (yellow finding), which was identified during a 2009 NRC inspection (available at ADAMS Accession No. ML102800342). The NRC

team identified deficiencies in the licensee's flooding coping strategies for protecting areas vital to plant safety between 1,009.5 and 1,014 feet MSL. By identifying and having the licensee address this issue earlier and before the flooding began, the NRC enhanced the safety of the site. At no time was the health and safety of the public compromised by the actual flooding that occurred on and subsequent to June 26, 2011.

Other plant performance issues have been identified and are currently under evaluation by the NRC staff. For example, on June 7, 2011, FCS experienced a fire in a safety-related breaker and switchgear. The fire resulted in FCS declaring an Alert because the fire impacted safety related equipment. These plant performance issues and their continuing review have resulted in FCS's extended plant shutdown continuation after termination of the flooding condition. Additionally as described in NRC letter dated December 13, 2011 (available at ADAMS Accession No. ML113470721), NRC decided to transition to FCS oversight under inspection manual chapter 0350, "Oversight of Reactor Facilities in a Shutdown Condition due to Significant Performance and/or Operational Concerns."

At this time, the NRC staff continues to evaluate plant performance issues under the NRC's Accident Sequence Precursor (ASP) Program and Significance Determination Process (SDP). The ASP Program provides an integrated risk analysis of all deficiencies, equipment failures, and degraded conditions that were observed during the event. The inspection program separately assesses the risk associated with each performance deficiency. Therefore, for events involving multiple licensee performance deficiencies and equipment failures, as in the FCS event, it is not unexpected that the ASP and inspection programs would assign different risk-significance levels. As such, the integrated approach used by the ASP Program complements the inspection program.

If the NRC evaluation for the plant performance issues at FCS result in a SDP finding of high safety significance (red finding) or if the final ASP analysis of these events result in its identification as a significant precursor, the NRC will report this event in Section II, "Commercial Nuclear Power Plant Licensees," of the next fiscal year's AO report and in the FY 2012 "Performance and Accountability Report to Congress."

EOI-03 North Anna Power Station: Alert Due to Seismically Induced Loss of Offsite Power with Emergency Diesel Generator Failure

On August 23, 2011, a magnitude 5.8 earthquake occurred in the United States, with its epicenter located in Mineral, VA, at a depth of 3.7 miles and approximately 11 miles south-southeast from the North Anna Power Station (NAPS). This event received significant local and national media coverage and caused the NRC to increase its attention to and oversight of a program area. Additionally, the Virginia Electric and Power Company (VEPCO) (the licensee) maintained plant safety, and the NRC maintained oversight of licensee response.

NAPS is located on Lake Anna in Louisa, VA, and consists of two Westinghouse-designed three-loop PWRs. VEPCO declared an Alert (the next to lowest NRC emergency classification for plant events) at NAPS because of significant seismic activity on site with the loss of offsite power. The NRC entered monitoring mode. The two PWRs experienced automatic reactor trips from 100 percent power, and the facility experienced a loss of offsite power. The station's four EDGs automatically started, loaded, and provided power to the emergency buses. While NAPS was receiving power from the EDGs, one EDG experienced a coolant leak and was subsequently shut down. All control rods were inserted into the core during the reactor trips, and plant decay heat was removed via the steam dumps to the atmosphere. The station's three remaining EDGs continued to provide power to the station's safety systems until offsite power was restored approximately 3 hours later.

On August 24, 2011, NAPS downgraded the Alert to an NOUE based on equipment alignments and safety equipment inspection results. Later that same day, NAPS completed walkdowns and plant inspections and subsequently exited the NOUE. The NRC exited monitoring mode based on its understanding of the event and the licensee's priorities. The NRC's resident inspectors at the facility observed the licensee's activities and provided firsthand information to the agency. On August 29, 2011, the NRC dispatched a seismic expert and another structural expert to assist the agency's resident inspectors on site. Further reviews indicated that additional inspections were warranted, and the NRC inspection team was officially classified as an Augmented Inspection Team (AIT).

On September 8, 2011, the licensee provided the NRC with a detailed presentation about the event (available at ADAMS Accession No. ML11252A006). The licensee reported that the operating-basis earthquake and design-basis earthquake criteria were exceeded; however, the cumulative absolute velocity, a concept used by the Electric Power Research Institute to address exceedance calculations for the operating-basis earthquake, indicates that significant damage would not be expected. The licensee undertook extensive actions to inspect, evaluate, test, and repair, if necessary, any systems, structures, or components to ensure that they are capable of performing their required design-basis functions. The licensee reported that no significant equipment damage to safety-related systems (including Class I structures) has been identified through site walkdowns, nor had equipment degradation been detected through plant performance and surveillance testing following the earthquake. In addition, the Lake Anna Dam was also inspected with no damage noted. On September 30, 2011, NRC issued Confirmatory Action Letter (CAL) No. 2-2011-001, "Confirmatory Action Letter – North Anna Power Station Unit Nos. 1 and 2, Commitments to Address Exceeding Design Bases Seismic Event (TAC Nos. ME7050 and ME7051)," to VEPCO (available at ADAMS Accession No. ML11273A078), confirming NAPS' commitment that, Units 1 and 2, will not enter Modes 1-4 (as defined in the facility technical specifications), until the Commission has completed its review of the request for restart, performed confirmatory inspections, and completed its safety evaluation review.

On October 3, 2011, a public meeting was held at NAPS to discuss the preliminary results of the AIT (available at ADAMS Accession No. ML11276A024). Subsequently, the NRC released the final report of the AIT on October 31, 2011 (available at ADAMS Accession No. ML113040031). The NRC and VEPCO conducted a public meeting in Mineral, Virginia on November 1, 2011, regarding the units' restart readiness inspection findings and the NRC staff's technical review, available at http://www.nrc.gov/about-nrc/emerg-preparedness/virginia-quake-info.html. On November 7, 2011, VEPCO submitted its plans for the seismic evaluation of future plant modifications, including new and replacement equipment. In that letter, VEPCO committed to include the seismic ground acceleration and derived in-structure response spectra from both the existing design-basis earthquake and the August 23, 2011, earthquake in any future seismic analysis to determine the maximum bounding design values for future modifications. Additionally, VEPCO committed to including the maximum bounding design values in the NAPS Updated Final Safety Analysis Report.

On November 11, 2011, the NRC issued its Technical Evaluation Related to Plant Restart after the Occurrence of an Earthquake Exceeding the Level of the Operating Basis and Design Basis Earthquakes (available at ADAMS Accession No. ML11308B406). In that document, the NRC staff concluded that VEPCO had acceptably demonstrated that no functional damage occurred to those features necessary for continued operation, and that NAPS could be operated, without undue risk to the health and safety of the public. Also on November 11, 2011, NRC informed VEPCO that its commitment for future plant modifications was reasonable and acceptable (available at ADAMS Accession No. ML11308B406) and issued VEPCO a Confirmatory Action Letter (CAL) (ADAMS Accession No. ML11311A201), confirming VEPCO's commitments to take long term actions in response to the August 23, 2011 earthquake. The CAL requires VEPCO to inform the NRC when it has fulfilled its commitments and to inform the NRC if any commitments will not be fulfilled.

NAPS Unit 1 was restarted on November 14, 2011 and restored to full power operation on November 18, 2011. NAPS Unit 2 was restarted on November 20, 2011 and restored full power operation on November 25, 2011. On December 1, 2011, NRC submitted a finalized INES rating of a below-scale event that received domestic and international attention to the International Atomic Energy Agency. The Event Rating Form is publicly available at http://www-news.iaea.org/ErfView.aspx?mId=24a176aa-6b4c-40ea-9262-e3927eed56db. NRC's participation in the INES is described in Information Notice 2009-27, dated November 13, 2009 (available at ADAMS Accession No. ML092510055).

APPENDIX D
GLOSSARY

Act – the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto.

Authorized User – as defined in 10 CFR 35.2, "Definitions," a physician, dentist, or podiatrist who (1) meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or (2) is identified as an authorized user on (i) a Commission or Agreement State license that authorizes the medical use of byproduct material; (ii) a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; (iii) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or (iv) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Brachytherapy – as defined in 10 CFR 35.2, a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy Source – as defined in 10 CFR 35.2, a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

[1]**Catheter** – a tubular medical device for insertion into canals, vessels, passageways, or body cavities, for diagnostic or therapeutic purposes, to permit injection or withdrawal of fluids or to keep a passage open.

[1]**Computed Tomography (CT)** – radiography in which a three-dimensional image of a body structure is constructed by a computer from a series of cross-sectional images made along an axis.

Dose Equivalent (H_T) – as defined in 10 CFR 20.1003, the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest; the units of dose equivalent are the rem and sievert.

[1]**Duodenum** – the first, shortest, and widest part of the small intestine that in humans is about 25 centimeters (10 inches) long and that extends from the pylorus to the undersurface of the liver where it descends for a variable distance and receives the bile and pancreatic ducts and then bends to the left and finally upward to join the jejunum near the second lumbar vertebra.

Effective Dose Equivalent (H_E) – as defined in 10 CFR 20.1003, the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma\, w_T\, H_T$).

[1] These terms are not defined in 10 CFR, a management directive, an inspection procedure, or an NRC policy statement. Rather, they are defined based on definitions in Merriam-Webster's "MedlinePlus Online Medical Dictionary." MedlinePlus is a service of the U.S. National Library of Medicine and the National Institutes of Health (http://www.nlm.nih.gov/medlineplus/mplusdictionary.html).

[2]**Embolization** – a treatment that clogs small blood vessels and blocks the flow of blood, such as to a tumor.

[1]**Endometrial Carcinoma** – a cancer that starts in the endometrium, the lining of the uterus (womb).

Exposure – as defined in 10 CFR 20.1003, being exposed to ionizing radiation or to radioactive material.

External Dose – as defined in 10 CFR 20.1003, that portion of the dose equivalent received from radiation sources outside the body.

[2]**Glans (Bulb of Penis)** – the rounded head of the penis.

Gray (Gy) – as defined in 10 CFR 20.1004, the international system's unit of absorbed dose; one gray is equal to an absorbed dose of 1 joule/kilogram (100 rad).

[2]**Hepatocellular Carcinoma** – a tumor in which the cancer starts during adulthood in cells in the liver. Also called adult primary liver cancer.

[1]**Interstitial** – situated within but not restricted to or characteristic of a particular organ or tissue, used especially of fibrous tissue.

[1]**Lumen** – the bore of a tube (as of a hollow needle or catheter).

[3]**Mammosite Treatment** – a minimally invasive radiation therapy technique used to treat breast cancer. This technique uses brachytherapy to deliver radiation directly to the site of the tumor bed from inside the body. A soft balloon, attached to a thin catheter, is inserted into the cavity where the tumor was removed. The balloon is inflated and a computer-controlled machine delivers the radiation down the catheter into the balloon, where it irradiates the tumor bed.

Manual Brachytherapy – as defined in 10 CFR 35.2, a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are close to a treatment site or directly into the tissue volume.

Medical Event – as defined in 10 CFR 35.2, an event that meets the criteria in 10 CFR 35.3045(a) or (b). 10 CFR 35.3045(a) states that a licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in (1) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin and (i) the total dose delivered differs from the prescribed dose by 20 percent or more, (ii) the total dosage delivered differs from the prescribed

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[2] These terms are not defined in 10 CFR, a management directive, an inspection procedure, or an NRC policy statement. Rather, they are defined based on definitions in MedicineNet's "Online MedTerms Medical Dictionary." MedicineNet is an online service part of WebMD (http://www.medterms.com).

[3] This term is not defined in 10 CFR, a management directive, an inspection procedure, or an NRC policy statement. Rather, this term is defined based on the definitions in the online WebMD (http://www.webmd.com).

dosage by 20 percent or more or falls outside the prescribed dosage range, or (iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; (2) a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following (i) an administration of a wrong radioactive drug containing byproduct material, (ii) an administration of a radioactive drug containing byproduct material by the wrong route of administration, (iii) an administration of a dose or dosage to the wrong individual or human research subject, (iv) an administration of a dose or dosage delivered by the wrong mode of treatment, or (v) a leaking sealed source; (3) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site). 10 CFR 35.3045(b) states that a licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Member of the Public – as defined in 10 CFR 20.1003, any individual except when that individual is receiving an occupational dose.

Occupational Dose – as defined in 10 CFR 20.1003, the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," from voluntary participation in medical research programs, or as a member of the public.

[2]**Perineum** – the area between the anus and the scrotum in the male and between the anus and the vulva (the labial opening to the vagina) in the female.

Prescribed Dosage – as defined in 10 CFR 35.2, the specified activity or range of activity of unsealed byproduct material as documented (1) in a written directive or (2) in accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR 35.100, "Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required," and 10 CFR 35.200, "Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required."

Prescribed Dose – as defined in 10 CFR 35.2, (1) for gamma stereotactic radiosurgery, the total dose as documented in the written directive, (2) for teletherapy, the total dose and dose per fraction as documented in the written directive, (3) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive, or (4) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

[2]**Prostate Gland** – a gland within the male reproductive system that is located just below the bladder.

Rad – as defined in 10 CFR 20.1004, the special unit of absorbed dose; 1 rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

Radiation (Ionizing Radiation) – as defined in 10 CFR 20.1003, alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions; radiation, as used in 10 CFR Part 20, "Standards for Protection against Radiation," does not include non-ionizing radiation, such as radiowaves or microwaves, or visible, infrared, or ultraviolet light.

Radiation Safety Officer (RSO) – as defined in 10 CFR 35.2, an individual who (1) meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59, "Recentness of Training"; or (2) is identified as a radiation safety officer on (i) a specific medical use license issued by the Commission or Agreement State; or (ii) a medical use permit issued by a Commission master material licensee.

[2]**Radiation Oncologist** – a specialist in the use of radiation therapy as a treatment for cancer.

[2]**Radiation Therapy (Radiotherapy)** – treatment in which high-energy rays are used to damage cancer cells and stop them from growing and dividing. A specialist in radiation therapy is called a "radiation oncologist."

[2]**Radioembolization** – a combination of radiation therapy and a procedure called embolization to treat cancer of the liver. A type of selective internal radiation therapy, which is also called intra-arterial brachytherapy.

[2]**Radiologist** – a physician specialized in radiology, the branch of medicine that uses ionizing and non-ionizing radiation for the diagnosis and treatment of disease.

Reactive Inspection – as defined in NRC Inspection Procedure 43003, "Reactive Inspections of Nuclear Vendors," an inspection performed for the purpose of obtaining additional information and/or verifying adequate corrective actions on reported problems or deficiencies.

Rem – as defined in 10 CFR 20.1004, the special unit of any of the quantities expressed as dose equivalent; the dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

[2]**Seminal Vesicle** – a structure in the male that is about 5 centimeters (2 inches) long and is located behind the bladder and above the prostate gland. The seminal vesicles contribute fluid to the ejaculate.

Shallow Dose Equivalent (H_S) – as defined in 10 CFR 20.1003, which applies to the external exposure of the skin of the whole body or the skin of an extremity, the dose equivalent at a tissue depth of 0.007 centimeter (7 milligrams/square centimeter).

Sievert (Sv) – as defined in 10 CFR 20.1004, the international system's unit of any of the quantities expressed as dose equivalent; the dose equivalent in sieverts is equal to the absorbed dose in Gy multiplied by the quality factor (1 Sv = 100 rem).

Source Material – as defined in 10 CFR 40.4, (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores that contain by weight one-twentieth of one percent (0.05 percent) or more of: (i) uranium, (ii) thorium, or (iii) any combination thereof.

Source material does not include special nuclear material.

Special Nuclear Material – as defined in 10 CFR 70.4, (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act, determines to be special nuclear material, but not including source material; or (2) any material artificially enriched by any of the foregoing but not including source material.

Teletherapy – as defined in 10 CFR 35.2, a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Therapeutic Dose – as defined in 10 CFR 35.2, a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Treatment Site – as defined in 10 CFR 35.2, the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

[2]Urethra – the transport tube leading from the bladder to discharge urine outside the body.

Whole Body – as defined in 10 CFR 20.1003, for purposes of external exposure, includes the head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Written Directive – as defined in 10 CFR 35.2, an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40, "Written Directives."

APPENDIX E
CONVERSION TABLE

Radioactivity and Ionizing Radiation

QUANTITY	FROM METRIC UNITS	TO NON-SI UNITS	DIVIDE BY
(Radionuclide) Activity	MBq	Curie (Ci)	37,000
	TBq	Ci	0.037
	GBq	Ci	37
Absorbed dose	Gy (gray)	rad	0.01
	cGy	rad	1.0
Dose equivalent	Sv (sievert)	rem	0.01
	cSv	rem	1.0
	mSv	rem	10
	mSv	mrem	0.01
	µSv	mrem	10