UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SECRETARY

April 11, 2012

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0032

TITLE: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2011

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 11, 2012.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-12-0032

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACZKO	X					3/13/12
COMR. SVINICKI	X				X	3/20/12
COMR. APOSTOLAKIS	X				X	312/12
COMR. MAGWOOD	X				X	3/26/12
COMR. OSTENDORFF	X				X	3/20/12

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Gregory B. Jaczko

SUBJECT: SECY-12-0032 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2011

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached ___ None __X__

SIGNATURE

3/13/12

DATE

Entered on "STARS" Yes _x_ No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-12-0032 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2011

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below XX Attached XX None ___

I approve the proposed FY 2011 AO report to Congress, subject to the attached edits.

SIGNATURE

03/28/12

DATE

Entered on "STARS" Yes ✓ No ___

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.

EXECUTIVE SUMMARY

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 (Updated)" (NUREG-1614, Volume 45, issued February ~~2008~~2012). 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 certain quantities of 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

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 an NRC-licensed ~~or NRC-regulated facilities~~ facility 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 in Oak Ridge, TN 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 a 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.

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~~ resumed 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 source within 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 radiation therapist~~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 incorrect 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.

AS11-12 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~~ medical staff 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~~ reported 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.

AS11-14 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~~ a medical event~~s~~ 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.

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~~ reported 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~~ that 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.

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. In addition, the NRC ~~as well as~~ still maintains a cadre of key technical ~~competent~~ staff members at NRC Headquarters to answer requests ~~from the onsite~~for technical support or information about actions in response to the Japan nuclear accident~~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. The Task Force determined that the current regulatory approach, and more importantly, the resultant plant capabilities allow them to conclude that a sequence of events like the Fukushima accident is unlikely to occur in the United States and some appropriate mitigation measures have been implemented, reducing the likelihood of core damage and radiological releases. 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 also 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,

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 to 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 results in a SDP finding of high safety significance (red finding) or if the final ASP analysis of these events results 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."

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 to 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).

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-12-0032 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2011

Approved X **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

3/12/12
DATE

Entered on "STARS" Yes ✓ No ___

EXECUTIVE SUMMARY

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 to ensure openness in the agency's regulatory process, consistent with the NRC's "Strategic Plan for FY 2008–2013" (NUREG-1614, Volume 5 issued February 2012). 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~~ conducts technical reviews and studies. In addition, the NRC involves the public as an essential element in the regulatory process.

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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 certain regulatory authority over byproduct, source, and special nuclear materials. 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.

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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

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 a NRC-regulated facility 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.

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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.~~

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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.~~

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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.

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 operator 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.

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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.

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 source within 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.

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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 radiation therapist failed to push the correct button on the HDR device.

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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.

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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.

AS11-10 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 operator/radiation therapist noted that an incorrect target area had been previously entered into the HDR device for the first treatment on June 3, 2010. The operator/radiation therapist 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.

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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.

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 medical center staff 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.

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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.

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 medical staff 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.

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Cause(s) – The licensee reported 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.

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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.

AS11-16 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 reported 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.

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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.

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 tens of thousands of people, and significantly impacting the infrastructure and industry in the northeastern coastal areas of Japan.

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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 maintain a cadre of key technical staff members at NRC Headquarters to answer requests from the onsite technical support staff (see http://www.nrc.gov/japan/japan-info.html).

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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 protection against accidents resulting from natural phenomena, mitigation of the consequences of such accidents, and emergency preparedness. The Task Force found that the current regulatory approach and the resultant plant capabilities let to a conclusion that a sequence of events like the Fukushima accident is unlikely to occur in the U.S. and some appropriate mitigation measures have been implemented, reducing the likelihood of core damage and radiological releases. 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

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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."

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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 were capable of performing their required design-basis functions. The licensee reported that no significant equipment damage to safety-related systems (including Class I structures) had 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, would not enter Modes 1-4 (as defined in the facility technical specifications), until the Commission had completed its review of the request for restart, performed confirmatory inspections, and completed its safety evaluation review.

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Commissioner Apostolakis' edits SECY-12-0032

The Honorable John Boehner
Speaker of the United States
House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am forwarding the enclosed "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2011." This submission is in accordance with Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) and the Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66), which require the NRC to identify and report abnormal occurrences (AOs) to Congress on an annual basis. An AO is an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety.

~~The NRC initially promulgated the AO criteria in a policy statement that the Commission published in the *Federal Register* on February 24, 1977, followed by several revisions in subsequent years. The most recent revision to the AO criteria, published in the *Federal Register* on October 12, 2006, established the criteria that the NRC uses to define AOs for the purpose of the enclosed report, as set forth in Appendix A to that report.~~

The enclosed AO report for FY 2011 describes 5 events at NRC-regulated facilities and 19 events at Agreement-State-licensed facilities. The first event at an NRC-licensed facility involved radiation exposure to an embryo/fetus, and the second involved an incident of high safety significance at a commercial nuclear power plant. The other three NRC-licensed events were medical events as defined in NRC regulations. The first Agreement-State-licensed 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-licensed events were medical events as defined in NRC regulations. Additionally three events occurred at nuclear power plants that are not AOs but have received significant attention by Congress or the public, these events can be found in an Appendix C to the AO report

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Sincerely,

Gregory B. Jaczko

Enclosure:
As stated

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-12-0032 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2011

Approved X **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** ___ **Attached** X **None** ___

SIGNATURE

26 March 2012

DATE

Entered on "STARS" Yes X **No** ___

EXECUTIVE SUMMARY

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 5, issued February ~~2008~~ 2012). 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

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.

AS11-07 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~~ radiation therapist 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.

AS11-12 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~~ medical staff 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~~ reported 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.

AS11-16 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~~ reportedthat 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.

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).

Following the nuclear accident at Fukushima, the NRC chartered a Near-Term Task Force (NTTF) to review insights from the event and provide recommendations for enhancing reactor safety in the United States. On July 12, 2011, the NTTF issued its report, entitled, "Near-Term Report and Recommendations for Agency Actions Following the Events in Japan." This report is available in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. ML11186A950. The NTTF concluded that continued U.S. plant operation and NRC licensing activities present no imminent risk to public health and safety. While the NTTF also concluded that the current regulatory system has served the Commission and the public well, it found that enhancements to safety and emergency preparedness are warranted and made a dozen general recommendations for Commission consideration.

On October 3, 2011, the NRC staff proposed to the Commission a three-tiered prioritization of the NTTF recommendations (ADAMS Accession No. ML11272A111). The Tier 1 recommendations are those actions that should be implemented without unnecessary delay. The Tier 2 recommendations are those actions that need further technical assessment or critical skill sets to implement. The Tier 3 recommendations are longer-term actions that depend on the completion of a shorter-term action or need additional study to support a regulatory action. On December 15, 2011, the Commission approved the staff's recommended prioritization (ADAMS Accession No. ML113490055).

The Conference Report on the Fiscal Year (FY) 2012 Energy and Water Development Appropriations Act (P.L. 112-74), signed by the President on December 23, 2011, states in part:

> The conferees recognize the progress that the Nuclear Regulatory Commission has made on the recommendations of the Near Term Task Force. Commission staff has proposed a prioritized list of the Task Force recommendations that reflects the order regulatory actions are to be taken. The conferees direct the Commission to implement these recommendations consistent with, or more expeditiously than, the "schedules and milestones" proposed by NRC staff on October 3, 2011.

In response to the conferees' request and the input it received from stakeholders, the NRC

accelerated the schedule originally proposed in its October 3, 2011, paper. On February 17, 2012, the NRC staff proposed orders and a request for information to the Commission in SECY-12-0025, "Proposed Orders and Requests for Information in Response to Lessons Learned From Japan's March 11, 2011, Great Tōhoku Earthquake and Tsunami" (ADAMS Accession No. ML12039A103). SECY-12-0025 also discussed the disposition of recommendations from the Commission's Advisory Committee on Reactor Safeguards (ACRS), as well as six additional recommendations identified after the NTTF report was issued, that the NRC staff has determined may also warrant additional action.

On March 12, 2012, the NRC issued three immediately effective orders and the request for information. These regulatory actions are discussed in more specific detail in the following section.

To ensure the NRC made well-informed decisions on the Tier 1 regulatory actions, the NRC staff conducted over a dozen public meetings with stakeholders to better understand the public's point of view, as well as the industry's views on the NRC's proposed actions. The staff also established an e-mail box so that members of the public could send input on the NRC's resolution of the Tier 1 recommendations. The NRC staff considered this input when developing the orders and request for information.

By letter dated December 16, 2011 (ADAMS Accession No. ML11353A008), the Nuclear Energy Institute, the policy organization for the nuclear industry, presented its plans to respond to Fukushima-like events. The industry developed a concept of a diverse and flexible mitigation capability called "FLEX." The NRC staff has considered this industry approach and is generally encouraged by the actions the industry is taking in this area. The NRC staff envisions that many elements of FLEX may satisfy the requirements of the order to mitigate challenges to key safety functions resulting from beyond-design-basis natural phenomena hazards.

On March 12, 2012, the NRC issued three immediately effective orders. The first two orders were issued to all power reactor licensees, including holders of construction permits and combined licenses. The third order was issued to licensees operating boiling water reactors (BWRs) with Mark I and Mark II containment designs. The following is a summary of each of the orders:

1. Licensees are ordered to develop strategies to mitigate the effects of beyond-design-basis natural phenomena that address both multiunit events and reasonable protection of equipment identified to implement such strategies.

   This order requires development of strategies to deal with beyond-design-basis external events resulting in simultaneous loss of all alternating current (ac) power and loss of normal access to the ultimate heat sink. The strategies and guidance developed and implemented by licensees in response to the requirements imposed by this order will provide the necessary capabilities to supplement those of the permanently installed plant structures, systems, and components that could be unavailable following beyond-design-basis external events. These strategies and guidance will enhance the safety and preparedness capabilities established following the events of September 11, 2001, and codified in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.54(hh)(2). To address the potential for more widespread effects of beyond-design-basis external events, this order requires licensees to have increased capabilities to implement multiple strategies concurrently at multiple units on a site. The strategies shall be developed to add multiple ways to maintain or

restore core cooling, containment and spent fuel pool (SFP) cooling capabilities in order to improve the defense in depth of licensed nuclear power reactors. The order also requires that the equipment needed to implement the strategies be reasonably protected.

2. Licensees are ordered to install enhanced SFP instrumentation.

   This order requires enhanced, reliable SFP instrumentation. During the events at Fukushima, responders were without reliable instrumentation to determine the water level in the SFP. This caused concerns that the pool may have boiled dry, resulting in fuel damage, but in fact the spent fuel had remained covered at all times. Fukushima demonstrated that confusion and misapplication of resources may result from beyond-design-basis external events when adequate instrumentation is not available. The instrumentation installed at U.S. nuclear power plants is typically only for a narrow range of SFP level and, therefore, only capable of monitoring normal and slightly off-normal conditions in the pool. Although the likelihood of a catastrophic event affecting U.S. nuclear power plants and their associated SFPs remains very low, beyond-design-basis external events could challenge the ability of existing SFP instrumentation to provide emergency responders with reliable information on the condition of SFPs. Reliable and available indication is essential to ensure that plant personnel can effectively prioritize emergency actions.

3. Licensees with BWR Mark I and Mark II containments are ordered to have reliable, hardened vents.

   This order requires reliable, hardened vents in BWR Mark I and Mark II containments. At Fukushima, limitations in time and the unpredictable conditions associated with the accident significantly challenged the attempts by responders to preclude core damage and containment failure. In particular, the operators were unable to successfully operate the containment venting system. The inability to reduce containment pressure inhibited efforts to cool the reactor core. Had additional backup or alternate sources of power been available to operate the containment venting system remotely, or had certain valves been more accessible to allow manual operation, the operators at Fukushima might have been able to depressurize the containment earlier. This, in turn, could have allowed operators to implement strategies using low-pressure water sources. Thus, the events at Fukushima demonstrate that reliable hardened vents at BWR facilities with Mark I and Mark II containment designs are important to maintain core and containment cooling.

The NRC has concluded that the orders on mitigation strategies and reliable, hardened vents are necessary to ensure adequate protection of public health and safety under the provisions of the backfit rule, 10 CFR 50.109(a)(4)(ii). The NRC has concluded that the order on SFP instrumentation represents a significant enhancement to the protection of public health and safety and is an appropriate response to the insights from the Fukushima Dai-ichi accident. The NRC believes that continued operation under existing regulations does not pose an imminent threat to public health and safety but that the events at Fukushima highlighted the need for these additional capabilities to mitigate the effects of beyond-design-basis external events.

The NRC plans to prepare guidance for implementation of the technical requirements of the orders by August 2012. Licensees will then be required, by February 28, 2013, to submit to the

Commission an integrated plan, including a description of how compliance with the orders will be achieved. After reviewing the licensee submittals, the NRC plans to issue facility-specific orders, as necessary, imposing license conditions that address the requirements of the orders. Each licensee will be required to achieve full compliance within two refueling outages after submittal of its integrated plan, or by December 31, 2016, whichever comes first.

On March 12, 2012, the NRC issued a request for information to power reactor licensees pursuant to 10 CFR 50.54(f), which requires a written response. The request for information asked licensees to do the following:

- Reevaluate seismic and flooding hazards at each site using present-day information, guidance, and methodologies.
- Perform seismic and flooding walkdowns to identify and address plant-specific degraded, nonconforming, or unanalyzed conditions.
- Assess current communication systems and equipment under conditions of onsite and offsite damage and prolonged station blackout (SBO).
- Perform a staffing study to determine the number and qualifications of staff required to fill all necessary positions to respond to a multiunit event.

Protection from natural phenomena is critical for continued safe operation of nuclear power plants. Given that new information has been developed on natural phenomena hazards since the licensing basis of currently operating plants was established, the NRC found it necessary to confirm the adequacy of the hazard assumptions for U.S. plants, and their ability to protect against them. These hazards include earthquakes, local intense precipitation, floods of streams and rivers, storm surges, seiches, tsunamis, and dam failures. Further, the NRC found that the accident at Fukushima highlighted a need to verify the adequacy of emergency planning, including communications infrastructure and staffing levels of response personnel, to address a prolonged SBO and multiunit event.

The NRC will evaluate each licensee's response to the request for information and take additional regulatory action, if necessary.

The NRC staff's October 3, 2011, paper included two Tier 1 recommendations that were not addressed by the orders or request for information. One was a recommendation to enhance SBO mitigation capability, and the other was to strengthen and integrate onsite emergency response procedures, training, and exercises. Both of these recommendations remain Tier 1 priority issues and are being actively implemented through the NRC's rulemaking process. The NRC expects to complete the SBO rule in 2014 and the emergency response enhancements rule in 2016. The NRC will publish an advance notice of its proposed rulemaking on SBO in March 2012.

The Conference Report on the Consolidated Appropriations Act, 2012 (P.L. 112-74), stated in part:

> The conferees direct the Commission to maintain an implementation schedule such that the remaining recommendations (not identified as Tier I priorities) will be evaluated and acted upon as expeditiously as practicable.

The NRC will address Tier 2 recommendations consistent with the milestone schedule set forth in its October 3, 2011, paper. The NRC staff is developing a Commission paper, currently scheduled for July 2012, where it will propose schedules and milestones for Tier 3 recommendations. Furthermore, the NRC has established a process to assess additional issues as they are identified, applying the same three-tiered prioritization process used for the NTTF recommendations. In its October 3, 2011, paper, the NRC staff identified six additional issues with a clear connection to the Fukushima event that may warrant regulatory action but were not included with the original NTTF recommendations. The detailed assessment can be found in Enclosure 2 to SECY-12-0025 (ADAMS Accession No. ML12039A118).

In accordance with Section 402 of the Consolidated Appropriations Act, 2012, the NRC will also consider external natural phenomena hazards. The request for information issued on March 12, 2012, addresses seismic, tsunami, and flooding hazards, which the NRC believes will encompass the dominant, albeit low, risks to operating plants. The NRC intends to address other external hazards, such as wind and missile loads from tornadoes and hurricanes, and snow and ice loads from winter weather, as a Tier 2 activity that will be initiated as soon as sufficient resources become available.

On October 13, 2011, and on November 8, 2011, the ACRS provided recommendations to the Commission based on its review of the NRC staff's prioritization of the NTTF recommendations (ADAMS Accession Nos. ML11284A136 and ML11311A264, respectively). The NRC staff's evaluation of the ACRS recommendations can be found in Enclosure 3 to SECY-12-0025 (ADAMS Accession No. ML12039A121). By letter dated February 15, 2012, the ACRS provided a third letter (ADAMS Accession No. ML12046A145).

The NRC staff continues to evaluate ongoing stakeholder recommendations, and it plans to make the results available on the NRC's public website.

~~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 protection against accidents resulting from natural phenomena, mitigation of the consequences of such accidents, and ensuring adequate emergency preparedness. The Task Force found that the current regulatory approach and the resultant plant capabilities led to a conclusion that a sequence of events like the Fukushima~~

accident is unlikely to occur in the U.S. and some appropriate mitigation measures have been implemented reducing the likelihood of core damage and radiological releases. 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.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-12-0032 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2011

Approved _X_ **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** _X_ **Attached** _X_ **None** ___

I approve submitting to Congress the "Report to Congress on Abnormal Occurrences: Fiscal Year 2011" subject to the attached edits. I also support the edits of Commissioner Apostolakis and Commissioner Svinicki except as indicated by the attached edits.

_____
SIGNATURE

3/20/12
DATE

Entered on "STARS" **Yes** _X_ **No** ___

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 certain quantities of 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

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 contains ~~addresses~~ s~~S~~ubelements labeled A, B, and 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 an ~~NRC-licensed or~~ NRC-regulated facilit~~y~~~~ies~~ 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

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, one event at a 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

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~~ An 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, and ~~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.

AS11-11 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 a~~n HDR~~ manual 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 several events associated with 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.

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~~ to 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.

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 perceived to be 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 U~~u~~nit 3. The Unit 4 spent fuel remained intact and was covered with water during the entire accident, contrary to media reports that the spent fuel pool had gone dry. 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. Shortly after March 11, 2011, the NRC concluded that there was no significant risk to U.S facilities and minimal health risk to citizens in the United States. 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 t~~The Task Force~~'s work is a set of~~provided 12 overarching 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 plant safety~~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 provide ease of access for site personnel and to protect additional plant assets beyond what was necessary for plant safety.~~.~~ 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, and other plant safety systems 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~~ supplements 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 ~~the~~ earthquake was beyond what the plant was designed for in certain earthquake vibration frequencies, but only minor damage was anticipated based on substantial safety margin in the plant's design ~~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