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

April 1, 2014

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-14-0022

TITLE: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2013

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 1, 2014.

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 Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

SECY Note: This Voting Record will be released to the public five working days after dispatch of the report to Congress

VOTING SUMMARY - SECY-14-0022

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	3/21/14
COMR. SVINICKI	X				X	3/24/14
COMR. APOSTOLAKIS	X				X	3/10/14
COMR. MAGWOOD	X				X	3/27/14
COMR. OSTENDORFF	X				X	3/13/14

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison M. Macfarlane

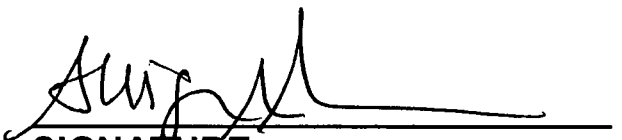
SUBJECT: SECY-14-0022 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2013

Approved __X___ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X__ None ___

I approve the proposed FY 2013 AO report subject to Commissioners Apostolakis' and Ostendorff's comments in addition to the attached edits.



SIGNATURE

3/21/14

DATE

Entered on "STARS" Yes X No ___

AS13-02 Human Exposure to Radiation at Baptist Medical Center-Princeton in Birmingham, Alabama

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—March 26, 2013, Birmingham, Alabama

Nature and Probable Consequences—Baptist Medical Center-Princeton (the licensee) reported that a pregnant patient received 1.85 GBq (50 mCi) of iodine-131 for thyroid ablation therapy.

On March 1, 2013, the patient had a thyroidectomy to treat thyroid cancer. Following surgery on March 6, 2013, the patient had general lab work that included a negative pregnancy test. On March 26, 2013, the patient returned for a 50 mCi iodine-131 treatment on the remaining thyroid tissue and had another pregnancy test performed prior to the dosing that yielded positive results. The second pregnancy test was ordered based on discussions between the nurse and the patient about her menstrual cycle. The administering technician was not informed of the second pregnancy test and did not speak with the floor nurse before administration of the iodine-131. An ultrasound revealed that the patient was 4 to 5 weeks pregnant at the time of the iodine-131 treatment. The licensee estimated a fetal/embryo dose of 126 mSv (12.6 rem). The patient and referring physician were informed of this event. A low possibility of carcinogenesis or malformations of the fetus is expected based on the age of the fetus at the time of the treatment.

Cause(s)—The cause of the medical event was determined to be inadequate communication between the floor nurse and the nuclear medicine technologist. The floor nurse did not communicate to the nuclear medicine technologist that a second pregnancy test had been ordered for the patient and was positive nor did the nuclear medicine technologist seek this information from the nurse prior to the radiopharmaceutical administration.

Actions Taken To Prevent Recurrence

Licensee—The licensee implemented new procedures to include improving communications between the nursing staff and nuclear medicine staff. The department developed a "Pre-iodine-131 Therapy" checklist that requires a signature from the nurse and technologist. The licensee conducted training on these changes for all nuclear medicine department staff.

State—The Alabama Department of State Health Services conducted an inspection on April 17, 2013, and focused on implementation of new procedures and communication with hospital management. Alabama found the licensee's corrective actions acceptable.

This event is closed for the purpose of this report.

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, no events at commercial nuclear power plants in the United States were significant enough to be reported as AO's based on the criteria in Appendix A to this report.

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

During this reporting period, eight events at facilities licensed by Agreement States were significant enough to be reported as AOs. There were no AO events ~~at~~ involving NRC licensees, based on the criteria in Appendix A to this report.

AS13-03 Medical Event at an Unspecified Licensee in New York State

Criteria III.C.1.b, III C.2.a, 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads), and represents either a dose or dosage that is at least 50 percent greater than that prescribed, or uses the wrong radiopharmaceutical.

Date and Place—December 29, 2008 (reported on March 13, 2009), Unspecified City, New York

Nature and Probable Consequences—The unspecified licensee reported a medical event to the New York (NY) Department of Health (DOH). The DOH reported the event and provided the NRC with all of the required information for ~~this~~ the report. The DOH does not specify the name of the licensee for medical events in accordance with a NY state law designed to protect the privacy of the patient. This event occurred during radioiodine treatment of a patient for hyperthyroidism. The patient was prescribed 11.1 MBq (300 µCi) of iodine-123, but instead was administered 72.5 MBq (1.96 mCi) of iodine-131 for a whole body scan (wrong radiopharmaceutical and wrong dose). The dose estimate to the patient's thyroid was approximately 25 Gy (2,500 rad). The patient and referring physician were informed of this event. The patient was subsequently treated with a therapeutic dose of iodine-131 in accordance with the written directive.

A referring physician requested that the patient receive an iodine-123 uptake study and scan to be followed by an iodine-131 therapy for hyperthyroidism. On December 29, 2008, the authorized user (AU) directed the secretary to schedule the uptake study using iodine-123; however, the secretary scheduled the patient for a whole body scan using iodine-131. The nuclear medicine technologist reviewed the patient's history, which included the fact that the patient still had a thyroid, but failed to seek clarification from the AU on the correct treatment. Additionally, the nuclear medicine technologist did not review the AU's written directive/approval for the treatment. The AU discovered the error after the administration of the iodine-131 and the uptake study of the patient revealed hyperthyroidism. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause(s)—The cause of the medical event was human error in that the secretary did not schedule the patient's treatment correctly coupled with the failure of the medical technologist to seek clarification and review the physician's order.

Medical Event at Carolina East in New Bern, North Carolina (previously reported as AS12-16 in NUREG-0090, Volume 35, Revision 1)

Date and Place—May 29, 2012, New Bern, North Carolina

Nature and Probable Consequences—Carolina East Medical Center (the licensee) reported that a medical event occurred associated with a manual brachytherapy treatment for prostate cancer. The treatment consisted of 27 needles containing 65 pre-stranded seeds of iodine-125 with each seed containing 12.6 megabecquerel (MBq) [0.34 millicurie (mCi)]. The physician prescribed a total dose of 145 Gy (14,500 rad) to the prostate; however, it was determined during post implant seed count that all the seeds were implanted in the penile bulb (glans) (wrong treatment site). The resulting dose to the penile bulb was 145 Gy (14,500 rad). The patient and referring physician were informed of this event.

On May 29, 2012, after completion of the implantation procedure, the licensee performed a computed tomography (CT) scan of the patient to verify the placement of the implanted seeds. The licensee confirmed that all the seeds were improperly implanted in the penile bulb. The patient was informed the following day, since he had been under general anesthesia during and after the procedure. The patient and his family were counseled at length by the authorized user (AU) within a week of the occurrence of the medical event. The AU reported that anticipated side effects from this event will be similar to the anticipated side effects from a typical permanent prostate brachytherapy implant. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause(s)—The cause of the medical event was the incorrect identification of the prostate during ultrasound imaging resulting in the improper placement of the brachytherapy seeds.

Update on Actions Taken to Prevent Recurrence

Licensee—The AU compiled a report and discussed corrective actions with the urologist and the authorized medical physicist. The licensee revised the procedures to include a mandatory "time-out" period during implant procedures, and a quality assurance procedure for preplan ultrasounds. Additional licensee corrective actions include using single shot fluoroscopy, in addition to ultrasound, to verify placement of the brachytherapy seed needle at the base of the prostate. Contrast and other additional enhancements may be used in conjunction with the fluoroscopy to ensure more accurate imaging results.

State—The North Carolina Division of Radiation Protection conducted an investigation on June 12, 2012. Two items of noncompliance were noted: (1) the licensee failed to have documented procedures to ensure that a therapy is administered in accordance with the written directive; and (2) the licensee failed to have a program commensurate with licensed activities. The State did not take any enforcement action and the NRC received the information regarding final enforcement determination in mid-2013.

This event is closed for the purpose of this report.

Commercial Nuclear Power Plant Event at Fort Calhoun Station, Unit 1, in Fort Calhoun, Nebraska (previously reported as NRC12-01 in NUREG-0090, Volume 35, Revision 1)

Date and Place—June 7, 2011, Fort Calhoun, Nebraska

Background—The Omaha Public Power District (OPPD) (the licensee) reported a commercial nuclear power plant fire event at Fort Calhoun Station (FCS), Unit 1 on June 7, 2011. The fire resulted in the declaration of an Alert emergency condition. An Alert is the second of four NRC emergency classification levels in ascending order of severity. The fire started in a recently replaced safety-related electrical breaker in an electrical switchgear room at the plant. The failure of the replacement breaker and subsequent fire generated a large quantity of soot and smoke. The soot and smoke were sufficiently conductive that arcing occurred and the feeder breaker for the redundant train of electrical switchgear tripped. The event resulted in the loss of the spent fuel pool cooling function and could have resulted in the loss of a safety function or multiple failures in systems used to mitigate an event had the event occurred at power (the unit was shut down at the time of the event).

The NRC designates inspection findings as green, white, yellow, or red representing a greater degree of safety significance and therefore, greater regulatory attention. NRC determined that the FCS fire event represented a finding of high safety significance (~~Red~~ red finding). The basis for this determination was the high fire frequency given the short period of time that the replacement breaker had been in service, the significant damage caused by the failure, and the fact that the event affected both trains of safety equipment. The direct cause of the fire was the high electrical resistance of the replacement breaker and the lack of proper cleaning and tightening of the electrical switchgear. Additionally, the area of the electrical connection was found to be full of hardened grease and copper oxide because of poor electrical maintenance practices by the licensee.

In response to this event and other performance issues in the areas of flood protection and maintenance of the reactor protection system, the NRC transitioned FCS oversight to that described in Inspection Manual Chapter (IMC) 0350, "Oversight of Reactor Facilities in a Shutdown Condition due to Significant Performance and/or Operational Concerns." On February 26, 2013, the NRC issued a revised Confirmatory Action Letter (Enforcement Action (EA)-13-020) "Confirmatory Action Letter-Fort Calhoun Station," (ADAMS Accession No. ML13057A287) for the purpose of confirming those actions that the NRC determined will need review or inspection before the restart of the plant. This revision supplemented two previously issued confirmatory action letters (ADAMS Accession No. ML112490164 and ML12163A287) that confirmed actions that were to be completed prior to restart.

Update on Inspection Activities and Closure—On November 13, 2012, the NRC issued the "U.S. Nuclear Regulatory Commission Manual Chapter 0350 Panel Fort Calhoun Station Restart Checklist Basis Document" (ADAMS Accession No. ML12318A319), which was developed consistent with the guidance in NRC IMC 0350. This document provided details and clarification of the scope and breadth of the Restart Checklist items and the actions, at a minimum, that the NRC planned to take to verify that FCS had adequately addressed the specific items in the Confirmatory Action Letter. The NRC issued revisions to the Restart Checklist Basis Document on March 7, 2013 (ADAMS Accession No. ML13066A877), September 19, 2013 (ADAMS Accession No. ML13262A371), and on November 15, 2013 (ADAMS Accession No. ML13319B251). These revisions superseded the earlier basis documents and confirmatory action letters. The breaker fire event was identified as "Item 1.c

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-14-0022 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2013

Approved XX **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** XX **Attached** XX **None** ___

I approve the Report to Congress on Abnormal Occurrences, subject to the attached edits.

SIGNATURE

03/24/14

DATE

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

ABSTRACT

Section 208 of the Energy Reorganization Act of 1974, as amended (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 10 events that Agreement States identified as AOs during fiscal year (FY) 2013 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 of 1954 (AEA) (Public Law 83-703), to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 37 Agreement States. Two events involved radiation exposure to an embryo/fetus and the other eight events were medical events, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material." During this reporting period, no events at NRC-licensed facilities including commercial nuclear power plants, were significant enough to be reported as AOs based on the criteria defined in Appendix A.

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 three events reported or updated in the FY 2012 "Report to Congress on Abnormal Occurrences." The updates includes a radiation exposure event at Caribbean Inspection & Nondestructive Testing (NDT) Services, Inc., in Port Lavaca, Texas; a medical event at Carolina East in New Bern, North Carolina; and a commercial nuclear power plant event at Fort Calhoun Station, Unit 1, in Fort Calhoun, Nebraska. During FY 2013, the NRC identified three commercial operating reactor events and one nuclear fuel facility event as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest," either as an update to previously reported information, or as a new event that received significant public interest. 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) 2013, 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 of 1954 (AEA) (Public Law 83-703), 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 in this request 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.

It should be noted that three of the 10 AOs included in this report occurred in previous fiscal years. The NRC completed its evaluation of these AOs in FY 2013. NRC requires that information about AOs be complete, to allow for adequate evaluation. Occasionally, all the required information is not available in time to report an AO in the fiscal year of its occurrence.

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 three events reported or updated in NUREG-0090, Volume 35, Revision 1, "Report to Congress on Abnormal Occurrences—FY 2012," dated August 2013 (the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML13198A165). The updates includes a radiation exposure event at Caribbean Inspection & Nondestructive Testing (NDT) Services, Inc., in Port Lavaca, Texas; a medical event at Carolina East in New Bern, North Carolina; and a commercial nuclear power plant event at Fort Calhoun Station, Unit 1, in Fort Calhoun, Nebraska. During FY 2013, the NRC identified three commercial operating reactor events and one nuclear fuel facility event as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest," either as an update to previously reported information, or as a new event that received significant public interest. 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 that the NRC uses to carry out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations*. The agency informs and involves stakeholders to ensure openness in the agency's regulatory process, consistent with the NRC's "Strategic Plan: Fiscal Years 2008–2013 (Updated)," (NUREG-1614, Volume 5, dated February 2012). The NRC regularly conducts licensing reviews, inspections, enforcement, investigations, operating experience evaluations, incident response, and confirmatory research. In addition, the agency involves the public 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. The agency normally achieves and maintains these levels 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 issued 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 of this report, which the NRC used to define AOs for this report.

Review of and responses to operating experience are essential to ensure that licensees conduct their activities 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 its licensees 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 routinely makes information and records on reportable events at licensed facilities available to the public. The agency also disseminates information through public announcements and special notifications to licensees and other stakeholders. The NRC 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 certain quantities of 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 2013, 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 also has implemented procedures for evaluating materials events to

identify those that meet the AO criteria. 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 1977, the Commission determined that the annual report to Congress should include events that meet the criteria for AOs at licensees regulated by Agreement States. The *Federal Register* notice that the NRC issues to disseminate AO-related information to the public includes those AOs that occurred at licensees regulated by the Agreement States.

FOREIGN INFORMATION

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

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC provides updates of previously reported AOs if significant new information becomes available. Appendix B provides updated information for three events reported or updated in NUREG-0090, Volume 35, Revision 1, "Report to Congress on Abnormal Occurrences—FY 2012," dated August 2013 (ADAMS Accession No. ML13198A165). The updates includes a radiation exposure event at Caribbean Inspection & Nondestructive Testing (NDT) Services, Inc., in Port Lavaca, Texas; a medical event at Carolina East in New Bern, North Carolina; and a commercial nuclear power plant event at Fort Calhoun Station, Unit 1, in Fort Calhoun, Nebraska.

OTHER EVENTS OF INTEREST

The NRC provides information concerning events that are not reportable to Congress as AOs but are included in this report based on the Commission's guidelines, listed in Appendix A for other events of interest. During FY 2013, the NRC identified three commercial operating reactor events and one nuclear fuel facility event as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest", either as an update to previously reported information, or as a new event that received significant public interest.

ABNORMAL OCCURRENCES IN FISCAL YEAR 2013

Appendix A provides the specific criteria for determining whether an event is an abnormal occurrence (AO) and provides the guidelines for reporting other events of interest that 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. Categories I, II, and III are discussed in this section and Category IV events are discussed in Appendix C to this report.

I. ALL LICENSEES

During this reporting period, two events involving organizations licensed by Agreement States were reported as AOs based on criteria in Appendix A, Criterion I to this report. Both of these events occurred at medical facilities and involved unintended exposure of an individual who was not the patient. Therefore, both of the events belong under the Criterion I.A, "All Licensees," category, as opposed to the Criterion III.C, "Medical Licensees," category.

AS13-01 Human Exposure to Radiation at Radiological Associates of Sacramento in Sacramento, California

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 millisieverts (mSv) [5 roentgen equivalent man (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—February 20, 2013, Sacramento, California

Nature and Probable Consequences—Radiological Associates of Sacramento (the licensee) reported that a pregnant patient received 6.55 gigabecquerels (GBq) [176.9 millicuries (mCi)] of iodine-131 for thyroid ablation therapy.

On February 18, 2013, prior to the treatment, the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result and the licensee administered iodine-131 to the patient.

On April 22, 2013, the patient's physician informed the patient that she was pregnant, and that she became pregnant very close to the therapy time. An ultrasound evaluation determined that the embryo/fetus would have been approximately two weeks old at the time of iodine-131 administration. The dose to the embryo/fetus was determined to be 470 mSv (47 rem). The embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, this tissue had not yet formed at the time of the treatment. However, the medical consultant concluded that, based on the National Council on Radiation Protection and Measurements Report #54, there is a risk of fetal malformation at doses greater than 15 rem. The licensee indicated that the patient will receive ongoing medical evaluations and genetic counseling.

Cause(s)—The cause of this event was the inability of the pregnancy test to provide a positive determination of pregnancy in close proximity to conception.

AS13-04 Medical Event at Adventist Health System/Sunbelt, Inc., in Altamonte Springs, Florida

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, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—November 7-18, 2011 (reported on May 10, 2012), Altamonte Springs, Florida

Nature and Probable Consequences—Adventist Health System/Sunbelt, Inc. (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) brachytherapy treatment for uterine cancer, containing approximately 314.5 GBq (8.5 curies (Ci)) of iridium-192. The patient was prescribed a total dose of 25 Gy (2,500 rad) to the uterine area in five fractionated doses; however, the patient received a dose of approximately 60 Gy (6,000 rad) to the skin of the inner thighs (wrong treatment site). The patient and referring physician were informed of this event.

The medical event was not identified until April 2012, when the patient informed a physician at another medical institution that she exhibited signs of delayed necrosis in the thigh area. The physician determined that this injury was consistent with a radiation burn and informed the licensee about the injury. The licensee determined that the necrosis most likely occurred during the last treatment fraction.

Cause(s)—The cause of the medical event was not conclusively determined but was most likely due to a malfunction of the applicator that dislodged the source from the vaginal cylinder and subsequently deposited the source in the guide tube between the patient's thighs.

Actions Taken To Prevent Recurrence

Licensee—The licensee modified its clinical procedure to require the therapist, physicist, and radiation oncologist to verify the applicator assembly and positioning. In addition, the procedure now requires a measurement of the flex tube to verify that it extends to the exact position beyond the end of the guide tube and also requires verification that the compression screw is tight.

State—The State of Florida conducted an inspection ~~on~~ during May 14, 17, and 21, 2012. Based on the results of the inspection and additional information provided by the licensee, no enforcement action was taken, and the State forwarded the final update of the event to the NRC in April 2013.

This event is closed for the purpose of this report.

AS13-06 Medical Event at the University of Toledo in Toledo, 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, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—November 27, 2012, Toledo, Ohio

Nature and Probable Consequences—The University of Toledo (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 160 Gy (16,000 rad) to the prostate using 88 iodine-125 seeds, but instead, the patient received an approximate dose of 10 Gy (1,000 rad) to the perineum (wrong treatment site). The patient and referring physician were informed of this event.

On December 10, 2012, the licensee performed a CT scan of the patient to verify the placement of the implanted seeds. The licensee initially confirmed that 16 of the 88 seeds were improperly implanted outside the prostate in the perineum. After additional review, on December 21, 2012, the licensee determined that only six seeds were in the perineum, yielding a dose of 10 Gy (1,000 rad) to the perineum. The licensee concluded that the medical event would not have a significant medical effect on the patient. Due to an unrelated medical condition, the licensee has discontinued any further treatment of the patient's prostate.

Cause(s)—The causes of the medical event was the incorrect identification of the prostate during ultrasound imaging resulting in the improper placement of the brachytherapy seeds. Contributing to the error was an improperly supervised trainee (urology resident) and the trainee's lack of familiarity with the tensioning adjustments on the applicator.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included revising procedures to preclude a recurrence of the event. The revisions to the procedures included: (1) the authorized user will provide heightened oversight of trainees, and (2) additional confirmatory measurements will be performed to verify the distance the needle is withdrawn from the applicator prior to placing the seeds.

State—The Ohio Department of Health conducted an inspection on December 19, 2012, to review the incident and initial reports. The Department did not cite the licensee for any violations.

This event is closed for the purpose of this report.

NRC designates inspection findings as green, white, yellow, or red representing a greater degree of safety significance and therefore, greater regulatory attention. NRC preliminarily determined that the inadequate computer modeling in the design of the steam generators in SONGS Unit 3 was a white finding of low to moderate safety significance. A green finding was issued for SONGS Unit 2 because its steam generator tubes did not leak.

In a letter dated October 21, 2013 (ADAMS Accession No. ML13296A018), SCE responded to the NRC staff preliminary determination regarding the Unit 3 finding, which included their agreement that the finding has low-to-moderate safety significance and is, therefore, appropriately characterized as a white finding. The white finding is based upon failure of the licensee to comply with SONGS Technical Specification requirements for maintenance of steam generator tube integrity and leakage control, and upon an apparent violation of the requirements of 10 CFR Part 50, Appendix B, Criterion III regarding design control.

The NRC also issued a notice of nonconformance to Mitsubishi Heavy Industries (MHI) for problems associated with the design of the SONGS steam generators. MHI, in its October 17, 2013, response to the staff, did not contest the nonconformance and stated they took corrective actions to prevent recurrence (ADAMS Accession No. ML13291A359). MHI also stated that the reasons for the nonconformance were, "inadequate design interface control between the MHI Steam Generator Designing Section and the MHI Takasago Research & Development Center (MHI Takasago R&D) related to the thermal-hydraulic and vibration analyses used for aspects of the San Onofre Nuclear Generating Station, Unit 2 and Unit 3 replacement steam generator design."

On December 23, 2013, the NRC issued the final white finding and violation (ADAMS Accession No. ML13357A058) to SCE for inadequate computer modeling in the design of the steam generators in SONGS Unit 3 as described in the September 20, 2013 report. SCE ~~is required to~~ will respond in writing to the violation to address how the cause(s) of the violation may impact decommissioning activities, and any associated corrective actions that SCE has taken or will take to address those potential impacts.

This event is closed for the purpose of this report.

responses to this event. The NRC investigated the reactor safety related part of the accident. OSHA pursued its own investigation and enforcement of the worker safety issues related to the stator drop for all the companies involved and issued citations to four entities in September 2013.

This event is closed for the purpose of this report.

EOI-04 Honeywell Metropolis Works: Vulnerability of Feed Materials Building Process Equipment to Seismic or Tornado Events and Inadequacy of Emergency Response Plan (previously reported as EOI-08 in NUREG-0090, Volume 35, Revision 1)}

The NRC included this event in this report because updated information became available since it was previously reported in NUREG-0090, Volume 35, Revision 1, "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2012, dated August 2013 (the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML13198A165).

Date and Place—May 21, 2012, Metropolis, Illinois

Background—From May 21 to 24, 2012, as part of NRC's response to the 2011 Japan Fukushima Daiichi nuclear plant accident, the NRC conducted an inspection at Honeywell Metropolis Works (MTW) using Temporary Instruction 2600/015, "Evaluation of Licensee Strategies for the prevention and/or Mitigation of Emergencies at Fuel Facilities" (ADAMS Accession No. ML111030453). The NRC determined that the site Emergency Response Plan (ERP) underestimated the amount of uranium hexafluoride (UF_6) and hydrogen fluoride (HF) that could potentially be released during credible seismic events or tornadoes. Specifically, the inspection identified that the process equipment in the licensee's Feed Materials Building (FMB) lacked seismic restraints, supports, and bracing that would ensure process equipment integrity during certain credible seismic events or tornadoes. The results of the inspection are documented in TI 2600/015 Inspection Report 40-3392/2012-006 (ADAMS Accession No. ML12222A163). At the time of the inspection, the Honeywell MTW facility had been shut down for a planned maintenance outage since May 9, 2012, therefore, there was no immediate safety concern.

On July 13, 2012, the NRC issued a Confirmatory Action Letter (ADAMS Accession No. ML12195A212), acknowledging that the licensee voluntarily suspended all NRC-licensed operations involving a phase change of solid UF_6 or quantities of liquid UF_6 beyond the amount used as the bases for its ERP. The NRC concluded that significant actions by Honeywell were necessary to provide reasonable assurance of public health and safety prior to resuming operations. On October 15, 2012, the NRC issued a Confirmatory Order (ADAMS Accession No. ML12289A863) outlining the actions that Honeywell must complete before it may resume uranium conversion operations. On November 30, 2012, the licensee responded to the Confirmatory Order by providing its safety basis and corrective action plan, and NRC accepted Honeywell's submittal for detailed review.

Updated Information—On July 2, 2013, after a thorough evaluation and inspection of plant modifications, the NRC authorized Honeywell to resume full licensed operations (ADAMS Accession No. ML13183A336). The NRC held two public meetings in Metropolis, IL: one on November 29, 2012, prior to the submittal of Honeywell's corrective action plan; the other on July 9, 2013, prior to the resumption of licensed operations. At each of these meetings, the NRC discussed the staff's evaluation and inspection of Honeywell's analysis and plant modifications. The meetings provided a forum for the NRC to present its technical evaluations and inspections and interact with interested members of the public.

On July 10, 2013, Honeywell resumed full licensed operations. Since then, there have not been any events at the MTW facility of significance to the NRC, nor have NRC inspectors identified issues at the MTW facility. As required by the Confirmatory Order, by letter dated October 28, 2013, the licensee submitted a revised Integrated Safety Analysis Summary that included

updated evaluations of the potential impacts of seismic and tornado events for the FMB and the associated component structural modifications. The NRC staff is currently ~~revising~~ reviewing these ~~elevations~~ evaluations.

This event is closed for the purpose of this report.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

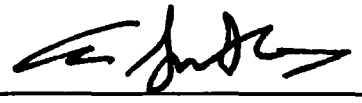
SUBJECT: SECY-14-0022 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2013

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

Not Participating _____

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

I approve the proposed FY2013 Abnormal Occurrence report to Congress subject to revising the last sentence on page C-7 as follows: "The NRC staff is currently reviewing these evaluations."



SIGNATURE

10 March 2014

DATE

Entered on "STARS" Yes ✓ No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-14-0022 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2013

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

27 March 2014
DATE

Entered on "STARS" Yes ___ No ___

ABNORMAL OCCURRENCES IN FISCAL YEAR 2013

Appendix A provides the specific criteria for determining whether an event is an abnormal occurrence (AO) and provides the guidelines for reporting other events of interest that 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. Categories I, II, and III are discussed in this section and Category IV events are discussed in Appendix C to this report.

I. ALL LICENSEES

During this reporting period, there were two events involving organizations licensed by Agreement States which are reported as AOs based on criteria in Appendix A, Criterion I to this report. Both of these events occurred at medical facilities and involved unintended exposure of an individual who was not the patient. Therefore, both of the events belong under the Criterion I.A, "All Licensees," category, as opposed to the Criterion III.C, "Medical Licensees," category.

AS13-01 Human Exposure to Radiation at Radiological Associates of Sacramento in Sacramento, California

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 millisieverts (mSv) [5 roentgen equivalent man (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—February 20, 2013, Sacramento, California

Nature and Probable Consequences—Radiological Associates of Sacramento (the licensee) reported that a pregnant patient received 6.55 gigabecquerels (GBq) [176.9 millicuries (mCi)] of iodine-131 for thyroid ablation therapy.

On February 18, 2013, prior to the treatment, the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result and the licensee administered iodine-131 to the patient.

On April 22, 2013, the patient's physician informed the patient that she was pregnant, and that she became pregnant very close to the therapy time. An ultrasound evaluation determined that the embryo/fetus would have been approximately two weeks old at the time of iodine-131 administration. The dose to the embryo/fetus was determined to be 470 mSv (47 rem). The embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, this tissue had not yet formed at the time of the treatment. However, the medical consultant concluded that, based on the National Council on Radiation Protection and Measurements Report #54, there is a risk of fetal malformation at doses greater than 15 rem. The licensee indicated that the patient will receive ongoing medical evaluations and genetic counseling.

Cause(s)—The cause of this event was the inability of the pregnancy test to provide a positive

determination of pregnancy in close proximity to conception.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included adding a declaration for female patients stating that they have not had unprotected intercourse within three to four weeks prior to treatment.

State—The California Radiologic Health Branch conducted an inspection of Radiological Associates on May 2, 2013. A violation was issued for failing to report the medical event within 24 hours of discovery.

This event is closed for the purpose of this report.

AS13-02 Human Exposure to Radiation at Baptist Medical Center-Princeton in Birmingham, Alabama

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—March 26, 2013, Birmingham, Alabama

Nature and Probable Consequences—Baptist Medical Center-Princeton (the licensee) reported that a pregnant patient received 1.85 GBq (50 mCi) of iodine-131 for thyroid ablation therapy.

On March 1, 2013, the patient had a thyroidectomy to treat thyroid cancer. ~~Following surgery~~ On March 6, 2013, the patient had general lab work that included a negative pregnancy test. On March 26, 2013, the patient returned for a 50 mCi iodine-131 treatment on the remaining thyroid tissue and had another pregnancy test performed prior to the dosing that yielded positive results. The second pregnancy test was ordered based on discussions between the nurse and the patient about her menstrual cycle. The administering technician was not informed of the second pregnancy test and did not speak with the floor nurse before administration of the iodine-131. An ultrasound revealed that the patient was 4 to 5 weeks pregnant at the time of the iodine-131 treatment. The licensee estimated a fetal/embryo dose of 126 mSv (12.6 rem). The patient and referring physician were informed of this event. A low possibility of carcinogenesis or malformations of the fetus is expected based on the age of the fetus at the time of the treatment.

Cause(s)—The cause of the medical event was determined to be inadequate communication between the floor nurse and the nuclear medicine technologist. The floor nurse did not communicate to the nuclear medicine technologist that a second pregnancy test had been ordered for the patient and was positive nor did the nuclear medicine technologist seek this information from the nurse prior to the radiopharmaceutical administration.

Actions Taken To Prevent Recurrence

Licensee—The licensee implemented new procedures to include improving communications between the nursing staff and nuclear medicine staff. The department developed a "Pre-iodine-131 Therapy" checklist that requires a signature from the nurse and technologist. The licensee conducted training on these changes for all nuclear medicine department staff.

State—The Alabama Department of State Health Services conducted an inspection on April 17, 2013, and focused on implementation of new procedures and communication with hospital management. Alabama found the licensee's corrective actions acceptable.

This event is closed for the purpose of this report.

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, no events at commercial nuclear power plants in the United States were significant enough to be reported as AO's based on the criteria in Appendix A to this report.

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

During this reporting period, eight events at facilities licensed by Agreement States were significant enough to be reported as AOs. There were no AO events ~~at~~ involving NRC licensees, based on the criteria in Appendix A to this report.

AS13-03 Medical Event at an Unspecified Licensee in New York State

Criteria III.C.1.b, III C.2.a, 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads), and represents either a dose or dosage that is at least 50 percent greater than that prescribed, or uses the wrong radiopharmaceutical or unsealed byproduct material.

Date and Place—December 29, 2008 (reported on March 13, 2009), Unspecified City, New York

Nature and Probable Consequences—The unspecified licensee reported a medical event to the New York (NY) Department of Health (DOH). The DOH reported the event and provided the NRC with all of the required information for this report. The DOH does not specify the name of the licensee for medical events in accordance with a NY state law designed to protect the privacy of the patient. This event occurred during radioiodine treatment of a patient for hyperthyroidism. The patient was prescribed 11.1 MBq (300 µCi) of iodine-123, but instead was administered 72.5 MBq (1.96 mCi) of iodine-131 for a whole body scan (wrong radiopharmaceutical and wrong dose). The dose estimate to the patient's thyroid was approximately 25 Gy (2,500 rad). The patient and referring physician were informed of this event. The patient was subsequently treated with a therapeutic dose of iodine-131 in accordance with the written directive.

A referring physician requested that the patient receive an iodine-123 uptake study and scan to be followed by an iodine-131 therapy for hyperthyroidism. On December 29, 2008, the authorized user (AU) directed the secretary to schedule the uptake study using iodine-123; however, the secretary scheduled the patient for a whole body scan using iodine-131. The nuclear medicine technologist reviewed the patient's history, which included the fact that the patient still had a thyroid, but failed to seek clarification from the AU on the correct treatment. Additionally, the nuclear medicine technologist did not review the AU's written directive/approval for the treatment. The AU discovered the error after the administration of the iodine-131 and the uptake study of the patient revealed hyperthyroidism. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause(s)—The cause of the medical event was human error in that the secretary did not schedule the patient's treatment correctly coupled with the failure of the medical technologist to seek clarification and review the physician's order.

AS13-04 Medical Event at Adventist Health System/Sunbelt, Inc., in Altamonte Springs, Florida

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, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—November 7-18, 2011 (reported on May 10, 2012), Altamonte Springs, Florida

Nature and Probable Consequences—Adventist Health System/Sunbelt, Inc. (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) brachytherapy treatment for uterine cancer, containing approximately 314.5 GBq (8.5 curies (Ci)) of iridium-192. The patient was prescribed a total dose of 25 Gy (2,500 rad) to the uterine area in five fractionated doses; however, the patient received a dose of approximately 60 Gy (6,000 rad) to the skin of the inner thighs (wrong treatment site). The patient and referring physician were informed of this event.

The medical event was not identified until April 2012, when the patient informed a physician at another medical institution that she exhibited signs of delayed necrosis in the thigh area. The physician determined that this injury was consistent with a radiation burn and informed the licensee about the injury. The licensee determined that the necrosis most likely occurred during the last treatment fraction.

Cause(s)—The cause of the medical event was not conclusively determined but was most likely due to a malfunction of the applicator that dislodged the source from the vaginal cylinder and subsequently deposed the source in the guide tube between the patient's thighs.

Actions Taken To Prevent Recurrence

Licensee—The licensee modified its clinical procedure to require the therapist, physicist, and radiation oncologist to verify the applicator assembly and positioning. In addition, the procedure now requires a measurement of the flex tube to verify that it extends to the exact position beyond the end of the guide tube and also requires verification that the compression screw is tight.

State—The State of Florida conducted ~~an~~ inspections on May 14, 17, and 21, 2012. Based on the results of the inspection and additional information provided by the licensee, no enforcement action was taken, and the State forwarded the final update of the event to the NRC in April 2013.

This event is closed for the purpose of this report.

AS13-05 Medical Event at University of Minnesota in Minneapolis, Minnesota

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, 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 20, 2012, Minneapolis, Minnesota

Nature and Probable Consequences—The University of Minnesota (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) brachytherapy unit, during a cervical cancer treatment. The HDR unit utilized a 233.1 GBq (6.3 Ci) iridium-192 source.

The patient was prescribed a total dose of 25 Gy (2,500 rad), given in five fractions, to the target area in the uterus. The uterus received 19.5 Gy (1,950 rad) and an excessive dose of 15 Gy (1500 rad) was delivered to the inner thigh (wrong treatment site).

The event was discovered on May 26, 2013, during a transfer of electronic treatment planning records to a new system. Records showed that the tips and ends of the treatment catheters had been inverted in the planning system by an auto-locate tool whose function was to automatically detect catheters. The deficiency resulted in some source dwell positions that either were below the target area or completely outside the patient. The referring physician notified the patient of the event on May 27, 2013. The patient showed significant treatment response with no evidence of residual cervical tumor; however, the patient also experienced rectal wall thickening, urethral stricture, and ulceration of the anterior rectal wall, as confirmed by a colonoscopy performed on June 3, 2013.

Cause(s)—The causes of the medical event were determined to be a deficiency in the treatment planning system equipment and human error. The auto-locate tool did not detect that the tips and ends of the catheters were inverted. During the course of treatment, the dosimetry planner and three plan checkers also failed to notice the labeling at the proximal (shallow) ends of the catheters indicating that the catheters were inverted. Because the equipment was unable to self-identify the error, a generic concern is possible; however there is no evidence supporting a generic concern as there have been no reports of similar occurrences from other facilities.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included ending use of the auto-locate tool, augmenting dosimetry planner and checker training, conducting an external audit of previous interstitial cases, and changing the written directive and treatment day checklist. At the time of the event, the manufacturer, Nucletron, was contacted. Nucletron investigated the incident, but did not report any related incidents.

State—The Minnesota Department of Health conducted an onsite inspection on June 18, 2013. The investigation focused on clarification of the conditions surrounding the error, treatment planning software transfer to treatment control computer, and potential for additional unnoticed cases. The State accepted the licensee's analysis and corrective actions for this incident and issued no violations.

This event is closed for the purpose of this report.

AS13-06 Medical Event at the University of Toledo in Toledo, 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, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and Place—November 27, 2012, Toledo, Ohio

Nature and Probable Consequences—The University of Toledo (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 160 Gy (16,000 rad) to the prostate using 88 iodine-125 seeds, but instead, the patient received an approximate dose of 10 Gy (1,000 rad) to the perineum (wrong treatment site). The patient and referring physician were informed of this event.

On December 10, 2012, the licensee performed a CT scan of the patient to verify the placement of the implanted seeds. The licensee initially confirmed that 16 of the 88 seeds were improperly implanted outside the prostate in the perineum. After additional review, on December 21, 2012, the licensee determined that only six seeds were in the perineum, yielding a dose of 10 Gy (1,000 rad) to the perineum. The licensee concluded that the medical event would not have a significant medical effect on the patient. Due to an unrelated medical condition, the licensee has discontinued any further treatment of the patient's prostate.

Cause(s)—The causes of the medical event ~~was~~ were the incorrect identification of the prostate during ultrasound imaging resulting in the improper placement of the brachytherapy seeds. Also ~~C~~contributing to the error was an improperly supervised trainee (urology resident) and the trainee's lack of familiarity with the tensioning adjustments on the applicator.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included revising procedures to preclude a recurrence of the event. The revisions to the procedures included: (1) the authorized user will provide heightened oversight of trainees, and (2) additional confirmatory measurements will be performed to verify the distance the needle is withdrawn from the applicator prior to placing the seeds.

State—The Ohio Department of Health conducted an inspection on December 19, 2012, to review the incident and initial reports. The Department did not cite the licensee for any violations.

This event is closed for the purpose of this report.

AS13-07 Medical Event at Rosa of North Dallas in Dallas, Texas

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, 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—March 27, 2013, Dallas, Texas

Nature and Probable Consequences—Rosa of North Dallas (the licensee) reported that a medical event occurred associated with 253.3 GBq (6.846 Ci) iridium-192 HDR brachytherapy treatment for cervical cancer. The patient was prescribed to receive a total dose of 51.39 Gy (5,139 rad) in four fractionated doses. However, the patient's urethra (wrong treatment site) received a dose of 16.07 Gy (1,607 rad) and the patient's anterior vagina (wrong treatment site) received a dose of 15.49 Gy (1,549 rad) for the four fractions. It was determined that the physicist selected the incorrect guide tube length size for treatment delivery. The event was not discovered until after the third fraction. As a result of the exposure to the unintended site, the patient experienced radiation burns. The patient has undergone medical treatment for the radiation burns and has responded well. There are a few small areas that have not healed that will be removed surgically. The physician expects these areas to heal after the surgery. The patient and referring physician were informed of this event.

Cause(s)—The cause of the medical event was human error in that the physician inadvertently used a 132 centimeter (cm) tube for the treatment delivery for three out of four fractions but planned the patient's procedure with the treatment length of 119.9 cm. This resulted in the source being positioned 12 cm short of the intended treatment site.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included suspension of all HDR treatments pending appropriate review of its process and procedures. In addition to this action, the licensee changed its operating procedures to require the measurement of the treatment guide-tube prior to a treatment. The forms used have been changed to record the type of guide tube used for each fraction. Pictures of the different guide tubes were taken and the lengths of the tube printed on them. Labels were placed on each guide tube indicating its length. A "time-out" is now required prior to each treatment to confirm that the correct size guide tube is in place for the treatment. Additional training will be provided to physicists unfamiliar with the device and its procedures.

State—The Texas Department of State Health Services conducted an onsite inspection on May 8, 2013. The Agency reviewed the licensee's corrective actions and confirmed that the stated changes to their program had been completed.

This event is closed for the purpose of this report.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-14-0022 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2013

Approved __X___ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: and edits Below ___ Attached _X_ None ___

_____
SIGNATURE

3/13/14
DATE

Entered on "STARS" Yes _X__ No ___

Commissioner Ostendorff's Comments on SECY-14-0022,
"Report to Congress on Abnormal Occurrences: Fiscal Year 2013"

I approve the report to Congress and the transmittal letters, subject to the comments below and the enclosed edits.

I applaud staff for providing the Abnormal Occurrences (AO) report in a timely fashion. I do, however, have a concern that we do not put the number of AOs in perspective. The staff's SECY paper notes that the number of identified AOs is small in comparison to the high number of medical procedures performed annually. I believe this statement provides valuable context and should be included in the report to Congress. Further, I believe it would be useful to provide an estimate of the number of medical procedures to emphasize the point.

I noted that the AO report for the State of New York, as directed by state law, did not provide the name of the licensee. I understand the need for patient confidentiality in these reports, but do not believe that redacting the name of the licensee is needed to protect patient confidentiality, as all other states include the licensee name. Staff should evaluate this issue in their next Integrated Materials Performance Evaluation Program review for New York.

ABSTRACT

Section 208 of the Energy Reorganization Act of 1974, as amended (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 10 events that Agreement States identified as AOs during fiscal year (FY) 2013 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 of 1954 (AEA) (Public Law 83-703), to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 37 Agreement States. Two events involved radiation exposure to an embryo/fetus and the other eight events were medical events, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material." During this reporting period, no events at NRC-licensed facilities including commercial nuclear power plants, were significant enough to be reported as AOs based on the criteria defined in Appendix A.

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 three events reported or updated in the FY 2012 "Report to Congress on Abnormal Occurrences." The updates includes a radiation exposure event at Caribbean Inspection & Nondestructive Testing (NDT) Services, Inc., in Port Lavaca, Texas; a medical event at Carolina East in New Bern, North Carolina; and a commercial nuclear power plant event at Fort Calhoun Station, Unit 1, in Fort Calhoun, Nebraska. During FY 2013, the NRC identified three commercial operating reactor events and one nuclear fuel facility event as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest," either as an update to previously reported information, or as a new event that received significant public interest. Appendix D, "Glossary," presents definitions of terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

The NRC adheres to the philosophy that the health and safety of the public are best ensured by establishing multiple levels of protection. The agency normally achieves and maintains these levels 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 issued 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 of this report, which the NRC used to define AOs for ~~the~~ this report.

Review of and responses to operating experience are essential to ensure that licensees conduct their activities 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 its licensees 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 routinely makes information and records on reportable events at licensed facilities available to the public. The agency also disseminates information through public announcements and special notifications to licensees and other stakeholders. The NRC 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 certain quantities of 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 2013, 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 also has implemented procedures for evaluating materials events to

ABNORMAL OCCURRENCES IN FISCAL YEAR 2013

Appendix A provides the specific criteria for determining whether an event is an abnormal occurrence (AO) and provides the guidelines for reporting other events of interest that 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. Categories I, II, and III are discussed in this section and Category IV events are discussed in Appendix C to this report.

I. ALL LICENSEES

During this reporting period, two events involving organizations licensed by Agreement States were reported as AOs based on criteria in Appendix A, Criterion I to this report. Both of these events occurred at medical facilities and involved unintended exposure of an individual who was not the patient. Therefore, both of the events belong under the Criterion I.A, "All Licensees," category, as opposed to the Criterion III.C, "Medical Licensees," category.

AS13-01 Human Exposure to Radiation at Radiological Associates of Sacramento in Sacramento, California

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 millisieverts (mSv) [5 roentgen equivalent man (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—February 20, 2013, Sacramento, California

Nature and Probable Consequences—Radiological Associates of Sacramento (the licensee) reported that a pregnant patient received 6.55 gigabecquerels (GBq) [176.9 millicuries (mCi)] of iodine-131 for thyroid ablation therapy.

On February 18, 2013, prior to the treatment, the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result and the licensee administered iodine-131 to the patient.

On April 22, 2013, the patient's physician informed the patient that she was pregnant, and that she became pregnant very close to the therapy time. An ultrasound evaluation determined that the embryo/fetus would have been approximately two weeks old at the time of iodine-131 administration. The dose to the embryo/fetus was determined to be 470 mSv (47 rem). The embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, this tissue had not yet formed at the time of the treatment. However, the medical consultant concluded that, based on the National Council on Radiation Protection and Measurements Report #54, there is a risk of fetal malformation at doses greater than 15 rem. The licensee indicated that the patient will receive ongoing medical evaluations and genetic counseling.

Cause(s)—The cause of this event was the inability of the pregnancy test to provide a positive determination of pregnancy in close proximity to conception.

APPENDIX D
GLOSSARY

Act—the Atomic Energy Act of 1954 (Public Law 83-703), including any amendments.

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

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

Brachytherapy Seed Implantation for Prostate ~~Cancer~~[2]Cancer[1]—Radioactive seed implants are a form of radiation therapy for prostate cancer. The radioactive seeds are loaded into the designated number of needles, in a specific order, each needle is inserted through the skin in the perineum and into the prostate using continuous ultrasound guidance. Once accurate needle placement is confirmed, the seeds in that needle are released. This process is continued until all of the radioactive seeds have been implanted.

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

Catheter[1]—[2]—a tubular medical device for insertion into canals, vessels, passageways, or body cavities for diagnostic or therapeutic purposes to permit injection or withdrawal of fluids or to keep a passage open.

Cervical ~~Cancer~~[1]Cancer[2]—cancer of the cervix, the narrow neck at the lower part of a woman's uterus, just above the vagina.

Dose Equivalent (H_T)—as defined in 10 CFR 20.1003, "Definitions," the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location

---

~~1~~

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

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

~~These~~

EOI-04 **Honeywell Metropolis Works: Vulnerability of Feed Materials Building Process Equipment to Seismic or Tornado Events and Inadequacy of Emergency Response Plan (previously reported as EOI-08 in NUREG-0090, Volume 35, Revision 1)}**

The NRC included this event in this report because updated information became available since it was previously reported in NUREG-0090, Volume 35, Revision 1, "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2012, dated August 2013 (the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML13198A165).

Date and Place—May 21, 2012, Metropolis, Illinois

Background—From May 21 to 24, 2012, as part of NRC's response to the 2011 Japan Fukushima Daiichi nuclear plant accident, the NRC conducted an inspection at Honeywell Metropolis Works (MTW) using Temporary Instruction 2600/015, "Evaluation of Licensee Strategies for the prevention and/or Mitigation of Emergencies at Fuel Facilities" (ADAMS Accession No. ML111030453). The NRC determined that the site Emergency Response Plan (ERP) underestimated the amount of uranium hexafluoride (UF_6) and hydrogen fluoride (HF) that could potentially be released during credible seismic events or tornadoes. Specifically, the inspection identified that the process equipment in the licensee's Feed Materials Building (FMB) lacked seismic restraints, supports, and bracing that would ensure process equipment integrity during certain credible seismic events or tornadoes. The results of the inspection are documented in TI 2600/015 Inspection Report 40-3392/2012-006 (ADAMS Accession No. ML12222A163). At the time of the inspection, the Honeywell MTW facility had been shut down for a planned maintenance outage since May 9, 2012, therefore, there was no immediate safety concern.

On July 13, 2012, the NRC issued a Confirmatory Action Letter (ADAMS Accession No. ML12195A212), acknowledging that the licensee voluntarily suspended all NRC-licensed operations involving a phase change of solid UF_6 or quantities of liquid UF_6 beyond the amount used as the bases for its ERP. The NRC concluded that significant actions by Honeywell were necessary to provide reasonable assurance of public health and safety prior to resuming operations. On October 15, 2012, the NRC issued a Confirmatory Order (ADAMS Accession No. ML12289A863) outlining the actions that Honeywell must complete before it may resume uranium conversion operations. On November 30, 2012, the licensee responded to the Confirmatory Order by providing its safety basis and corrective action plan, and NRC accepted Honeywell's submittal for detailed review.

Updated Information—On July 2, 2013, after a thorough evaluation and inspection of plant modifications, the NRC authorized Honeywell to resume full licensed operations (ADAMS Accession No. ML13183A336). The NRC held two public meetings in Metropolis, IL: one on November 29, 2012, prior to the submittal of Honeywell's corrective action plan; the other on July 9, 2013, prior to the resumption of licensed operations. At each of these meetings the NRC, discussed the staff's evaluation and inspection of Honeywell's analysis and plant modifications. The meetings provided a forum for the NRC to present its technical evaluations and inspections and interact with interested members of the public.

On July 10, 2013, Honeywell resumed full licensed operations. Since then, there have not been any events at the MTW facility of significance to the NRC, nor have NRC inspectors identified issues at the MTW facility. As required by the Confirmatory Order, by letter dated October 28, 2013, the licensee submitted a revised Integrated Safety Analysis Summary that included

updated evaluations of the potential impacts of seismic and tornado events for the FMB and the associated component structural modifications. The NRC staff is currently ~~revising~~ reviewing these elevations.