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Volume 36

Report to Congress on Abnormal Occurrences

Fiscal Year 2013

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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." It should be noted that 10 AOs is a small number, given the estimated 16 million medical procedures performed annually. 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 include 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.

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INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an "abnormal occurrence" (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that the NRC report AOs to Congress annually.

This report describes those events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 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 include 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 include 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.

ABBREVIATIONS

ADAMS	the NRC's Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AIT	augmented inspection team
AMP	authorized medical physicist
ANO	Arkansas Nuclear One
AO	abnormal occurrence
AS	Agreement State
AU	authorized user
CAL	confirmatory action letter
CFR	*Code of Federal Regulations*
Ci	curie
cm	centimeter
cm^3	cubic centimeter
CT	computed tomography
DOH	Department of Health
DRH	Division of Radiological Health
DSHS	Department of State Health Services
EA	enforcement action
ERP	emergency response plan
FMB	feed material building
FCS	Fort Calhoun Station
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel
gpd	gallons per day
Gy	gray
HDR	high dose rate
IMC	Inspection Manual Chapter
MBq	megabecquerel
MSL	mean sea level
µCi	microcurie
mCi	millicurie
MHI	Mitsubishi Heavy Industries
mSv	millisievert
MTW	Metropolis Works
NDT	Nondestructive Testing
NRC	U.S. Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
OPPD	Omaha Public Power District
REAC/TS	Radiation Emergency Assistance Center/Training Site
rem	roentgen equivalent man
SAR	safety analysis report
SCE	Southern California Edison
SG	steam generator
SIT	special inspection team
SONGS	San Onofre Nuclear Generating Station
Sv	sievert
TBq	terabecquerel

TEDE	total effective dose equivalent
TS	technical specification
UF_6	uranium hexafluoride

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.

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. 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 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 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.

Actions Taken To Prevent Recurrence

Licensee—The corrective action taken by the licensee included revising the treatment protocols to include a requirement for verification of the prescription by two nuclear medicine technologists and a consultation with the AU if there are any questions regarding the ordered written directive.

State— The DOH reviewed the licensee's root cause analysis and performed a reactive inspection on June 8 and 15, 2009. An additional follow-up inspection was performed on December 8, 2010. The licensee's corrective actions were found to be effective.

This event is closed for the purpose of this report.

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 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.

AS13-05 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 and 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 cause of the medical event was the incorrect identification of the prostate during ultrasound imaging resulting in the improper placement of the brachytherapy seeds. Also 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 include 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.

AS13-08 Medical Event at the Cleveland Clinic Foundation in Cleveland, Ohio

Criterion 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 —May 9, 2013, Cleveland, Ohio

Nature and Probable Consequences—The Cleveland Clinic Foundation (the licensee) reported that a medical event occurred associated with an yttrium-90 (Y-90) microsphere radioembolization procedure to treat liver metastases from colorectal cancer. The licensee prescribed a dose of 129.65 Gy (12,965 rad) to the left liver lobe tumor, and 127.94 Gy (12,794 rad) to the right liver lobe tumor. However, a dose of 62 Gy (6,200 rad) was delivered to the small intestine (wrong treatment site).

The consequence of the event is the generation of an intestinal ulcer caused by the radiation. The patient is being treated for pain management of the ulcer until it heals. The prognosis of the patient will be determined by the underlying cancer and spread of the tumors. The event was identified in September 2013 while treating the patient for the ulcer symptoms. The patient and referring physician were informed of this event.

Cause(s) —The cause of the medical event was most likely the development of collateral vessels around the tumor between the time of the initial patient treatment planning and delivery of the Y-90 microspheres. The licensee was not able to identify the small change of vasculature during routine checks at the time of the procedure.

Actions Taken To Prevent Recurrence

Licensee—The licensee did not identify corrective actions to add to its current procedures to preclude a recurrence of the event.

State—The Ohio Department of Health conducted an inspection on October 8, 2013, to review the incident and initial reports. The department concluded that the licensee made a conservative event determination and applied due diligence in performing the medical procedure. The department did not cite the licensee for any violations.

This event is closed for the purpose of this report.

AS13-09 Medical Event at Tufts Medical Center in Boston, Massachusetts

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—May 17, 2013, Boston, Massachusetts

Nature and Probable Consequences—On May 17, 2013, Tufts Medical Center (the licensee) reported that a medical event occurred associated with 82.8 terabecquerels (TBq) (2,231 Ci) cobalt-60 gamma knife radiosurgery procedure to treat the patient's brain for intense facial pain.

On May 17, 2013, a patient was prescribed to receive 7,500 centigray (cGy) (rad) from a single fraction gamma knife treatment to the left side of the brain, but instead received the intended dose to the right side of the brain (wrong treatment site). The radiation oncologist authorized user (AU) mistakenly selected the right trigeminal nerve on an image of the patient's brain in the planning computer, which disagreed with the diagnosis. The AU then printed the written directive and signed it. The authorized medical physicist (AMP) questioned the coordinates, suggesting the number should be higher, but the AU felt it was within the proper range. The written directive was signed by the AMP and the neurosurgeon.

The nurse and radiation therapist verified the site and side of the head with the patient prior to the treatment. However, during treatment it was not obvious to the oncology nurse and radiation therapist that they were treating the wrong side of the brain and the radiation dose was administered as prescribed in the written directive.

Later the same day, the AU realized the error while dictating the end-of-treatment notes. The licensee determined that the likely effect would be possible transient numbness to the right side of the patient's face. The patient and prescribing physician were informed of this event and no serious health effects to the patient are expected.

Cause(s)—The cause of the medical event was human error in the failure of the AU to confirm that the proper treatment site was selected in the planning computer. A contributing factor was the licensee's ineffective independent check of the planning computer treatment site coordinates prior to commencing the procedure.

Actions Taken To Prevent Recurrence

Licensee—The licensee corrective actions included increasing the number of "time-out" procedures, updating the Gamma Knife Safety Checklist, and training staff to identify potential erroneous coordinates.

State—The Commonwealth of Massachusetts conducted an inspection on June 12, 2013, approved the licensee's corrective actions, and did not issue any violations or penalties for this event.

This event is closed for the purpose of this report.

AS13-10 Medical Event at Abbott Northwestern Hospital 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—September 4, 2013, Minneapolis, Minnesota

Nature and Probable Consequences—Abbott Northwestern Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy unit. The HDR unit utilized a 237 GBq (6.4 Ci) iridium-192 source.

The patient was prescribed to receive six fractionated doses for a total dose of 24 Gy (2,400 rad) to a tumor in the prostate and bladder. Instead, the second of the six fractionated doses was 16 Gy (1,600 rad) and delivered to the small bowel near the bladder wall (wrong treatment site). The remaining fractions of the treatment were increased to compensate for the lack of tumor dose from the second fraction.

The patient and prescribing physician were informed of this event. No immediate adverse reaction to the increased dose was seen. The radiation oncologist and lead medical physicist performed a risk analysis and determined no long-term complication to the small bowel is expected.

Cause(s)—The cause of the medical event was due to an error in the catheter lengths entered into the treatment planning system. This was due to human error in that the medical physicists knew that the catheter lengths needed to be adjusted in the treatment plan, but did not properly communicate with each other on who would do it.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included procedure modifications that added verification of the catheter length to the daily HDR pre/post treatment checklist and universal "time-out" protocol. The licensee also added, and posted at the console, a procedure describing the verbal communication and verification to be used by the physics team and oncologist prior to the HDR treatment.

State—The Minnesota Department of Health conducted an onsite inspection on September 18, 2013, and reviewed the conditions of the treatment, the cause of the event and the effect on the patient. The State accepted the licensee's analysis and corrective actions. No violations or penalties were issued.

This event is closed for the purpose of this report.

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

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

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

(2) major degradation of essential safety-related equipment; and

(3) major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

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

Abnormal Occurrence Criteria

The NRC uses the following criteria to determine whether to consider events for reporting as AOs:

I. For All Licensees

A. Human Exposure to Radiation from Licensed Material

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) [25 roentgen equivalent man (rem)] or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye of 1 sievert (Sv) (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more; or a committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.

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

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

B. Discharge or dispersal of radioactive material from its intended place of confinement which results in the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to Part 20 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Standards for Protection against Radiation," unless the licensee has demonstrated compliance with 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," using 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2)(ii).

This criterion does not apply to transportation events.

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

1. Any unrecovered lost, stolen, or abandoned sources that exceed the values listed in Appendix P to 10 CFR Part 110, "Category 1 and 2 Radioactive Material." Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.

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

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

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

3 "Substantiated" means a situation where an indication of loss, theft, or unlawful diversion such as: an allegation of diversion, report of lost or stolen material, statistical processing difference, or other indication of

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

4. Any substantial breakdown[6] of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

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

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

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) [10 CFR 50.36(c)].

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

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100, “Reactor Site Criteria,” or 5 times the dose limits of 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix A, “General Design Criterion for Nuclear Power Plants,” General Design Criterion (GDC) 19, “Control Room,” could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

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

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loss of material control or accountability cannot be refuted following an investigation; and requires further action on the part of the agency or other proper authorities.

4 A formula quantity of special nuclear material is defined in 10 CFR 70.-4, “Definitions.”

5 Radiological sabotage is defined in 10 CFR 73.-2, “Definitions.”

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

7 Initiation of any Incident Investigation Teams, as described in NRC Management Directive (MD) 8.3, “NRC Incident Investigation Program,” or initiation of any accident review groups, as described in MD 8.9, “Accident Investigation.”

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

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

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

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

III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials

1. An accidental criticality [10 CFR 70.52(a)].

2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.

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

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

B. For Fuel Cycle Facilities

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

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

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

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

C. For Medical Licensees

A medical event that:

1. Results in a dose that is

   a. Equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or

   b. Equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and

2. Represents either

   a. A dose or dosage that is at least 50 percent greater than that prescribed, or

   b. A prescribed dose or dosage that

      (i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or
      (ii) Is delivered by the wrong route of administration; or
      (iii) Is delivered to the wrong treatment site; or
      (iv) Is delivered by the wrong treatment mode; or
      (v) Is from a leaking source or sources; or
      (vi) Is delivered to the wrong individual or human research subject.

IV. Other Events of Interest

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

APPENDIX B
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, updated information became available for three abnormal occurrence (AO) events that the U.S. Nuclear Regulatory Commission (NRC) had previously reported or updated 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). These events involved a human exposure to radiation event at Caribbean Inspection & Nondestructive Testing (NDT) Services, Inc., in Port Lavaca, Texas; a medical event at Carolina East Medical Center, in New Bern, North Carolina; and a commercial nuclear power plant event at Fort Calhoun Station, Unit 1, in Fort Calhoun, Nebraska.

Human Exposure to Radiation at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas (previously reported as AS11-02 in NUREG-0090, Volume 34, and updated in Appendix B in NUREG-0090, Volume 35, Revision 1)

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

Background—Caribbean Inspection & NDT Services Inc. (the licensee) reported that a radiographer trainee received an overexposure to his right hand. The radiographer trainee stated that while he was conducting radiography operations in the field, he removed a radiography camera guide tube from the radiography camera and noticed the 2.7 terabecquerels (TBq) (73 curies (Ci)) iridium-192 source was not fully retracted. Later, the radiographer trainee presented himself to a Houston, Texas, hospital with observable deterministic effects, which included blistering of the thumb, index and middle fingers, which correspond to an exposure range of 20–30 sieverts (Sv) (2000 to 3000 rem) to the extremities. The trainee's dosimeter indicated that he received 14.1 millisievert (mSv) (1.41 rem) whole body exposure. His doctors initially conferred with the Radiation Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, regarding his medical treatment. The trainee received medical care at an area hospital and was released. This event was previously closed in NUREG-0090, Volume 35, Revision 1; however, it is being reopened to report an update on the consequences as described below.

Update on Consequences—On June 13, 2013, the Texas Department of State Health Services (DSHS) was notified that on or about May 23, 2013, the index finger of the individual's right hand was amputated. The radiographer trainee stated he was also experiencing trouble with the thumb and middle finger of the right hand. Further treatment may be required.

This event is closed for the purpose of this report.

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 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

(Electrical bus modification and maintenance – Red Finding)" in the Restart Checklist due to its risk significance. This item was included in the Restart Checklist for the failure to adequately design, modify, and maintain the electrical power distribution system, resulting in a fire in the safety-related 480 volt electrical switchgear.

During fiscal year 2013, the NRC staff has performed inspection and assessment activities and has evaluated the adequacy, and where appropriate, the effectiveness of OPPD's actions to address the issues that resulted in the extended shutdown of FCS. The NRC assessment of OPPD's actions was based on inspections, supplemented by review and input from headquarters staff technical expertise. NRC inspections were performed individually and by teams, with results documented in reports that are publicly available. Based on the results of issue-specific inspection activities, the NRC determined that OPPD adequately evaluated the root and contributing causes for the breaker fire, and that the licensee conducted a thorough extent-of-condition review, and implemented appropriate corrective actions to resolve the associated performance deficiencies. Following completion of NRC inspection activities, on December 15, 2013, NRC staff involved in reviewing Restart Checklist Item 1.c conducted discussions and determined this item had been adequately addressed by OPPD and therefore the item was closed.

On December 2, 2013, OPPD submitted an "Integrated Report to Support Restart of Fort Calhoun Station and Post-Restart Commitments for Sustained Improvement." This report detailed the actions OPPD has taken to address CAL EA-13-020 dated February 26, 2013, and included the basis for closing the Restart Checklist item and the actions taken to close the CALs. Based on the NRC's review of OPPD's actions, the NRC determined that OPPD has satisfied the commitments in CAL EA-13-20. The NRC issued "Fort Calhoun Station Closure of Confirmatory Action Letter" on December 17, 2013 (ADAMS Accession No. ML13351A423). This CAL closeout letter stated that the NRC has not identified any issues that would preclude restart under the existing licensing basis, that all commitments contained in CAL EA-13-020 are closed, and that FCS is safe to restart.

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. This appendix includes updates to other events of interest reported in previous AO reports to Congress.

EOI-01 San Onofre Nuclear Generating Stations, Unit 3: Steam Generator Tube Leaks (previously reported as EOI-04 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—January 31, 2012, San Diego County, California

Background—On January 31, 2012, San Onofre Nuclear Generating Station (SONGS), Unit 3, was operating at full power when control room operators received a high radiation alarm for the condenser air ejector monitor. This indicated a tube leak in one of the two steam generators (SGs), and the operators entered the abnormal operating procedure for reactor coolant system leakage. Once the leak rate was determined to be greater than 75 gallons per day (gpd) with an increasing rate of leakage exceeding 30 gallons per hour, a rapid power reduction was commenced in accordance with plant procedures. Operators manually tripped the reactor from 35 percent power, as directed by procedure, and entered the emergency operating procedures for standard post-trip actions. This resulted in the identification of a SG tube leak. The licensee isolated the affected SG, and cooled down the plant.

SONGS, Units 2 and 3, have been shut down since January 2012. The NRC conducted an augmented inspection team (AIT) assessment of the circumstances surrounding the SG leak and the licensee's response. Although the SG issues at SONGS, Unit 3, were of regulatory significance, the Southern California Edison Company (the licensee) always maintained plant safety, and the NRC maintained oversight. The FY 2012 AO report discusses the full details of the event under EOI-04.

Updated Information— SONGS Units 2 and 3 remained shut down from January 2012 to June 7, 2013, when Southern California Edison (SCE), the licensee, announced its decision to permanently retire Units 2 and 3. On June 12, 2013, SCE submitted a Certification of Permanent Cessation of Power Operations letter to the NRC, certifying that Units 2 and 3 have permanently ceased power operations.

On June 28 (ADAMS Accession No. ML13204A304) and July 22, 2013 (ADAMS Accession No. ML13183A391), the licensee certified that all fuel had been permanently removed from the Units 3 and 2 reactors, respectively. On September 20, 2013, the NRC issued inspection report 05000361/2012009 and 05000362/2012009 (ADAMS Accession No. ML13263A271) documenting the results of the SONGS Confirmatory Action Letter Response Inspection. The

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 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.

EOI-02 Arkansas Nuclear One, Unit 1: Dropped Electrical Generator Stator Resulting in Unit 1 Loss of Offsite Power and Unit 2 Reactor Trip and Partial Loss of Offsite Power

The NRC included this event in this report because of the extensive interest by the public as well as the local and national media. The health and safety of members of the public was not impacted because the event took place in the non-radiological area of the plant. However, the event resulted in the death of a plant worker and injuries to several other workers.

On March 31, 2013, during movement of the 525-ton Arkansas Nuclear One (ANO) Unit 1 main generator stator, the stator fell approximately 30 feet into the train bay killing one worker who was in the path of the falling generator stator and rigging that collapsed and injuring eight others. ANO is a dual reactor site located near Russellville, Arkansas. It is operated by Entergy Operations, Incorporated (the licensee).

ANO Unit 1 was in a refueling outage when the dropped stator caused structural damage to the Unit 1 turbine building and damage to electrical switchgear cabinets resulting in a loss of offsite power. Both Unit 1 emergency diesel generators started and supplied power to the vital electrical busses. Cooling to the reactor core was quickly restored. The Unit 1 emergency diesel generators supplied power to the vital electrical busses for over five days until temporary power supply modifications were completed to restore power from offsite sources.

ANO Unit 2 experienced a reactor trip from 100 percent power after the falling stator and lifting rig components caused a loss of power to reactor coolant pump B. About 1½ hours later, water from damaged fire suppression system piping caused a breaker failure in ANO Unit 2, resulting in loss of power to one vital bus. The licensee declared a Notification of Unusual Event, the lowest of four NRC emergency classification levels in ascending order of severity. The associated emergency diesel generator for Unit 2 started and supplied vital loads. Power supply from off-site sources was restored to the affected electrical busses of Unit 2 after 2 days and the emergency diesel generator was shut down. Both units remained stable in a shutdown condition throughout the event.

The event met criteria in NRC procedures for conducting reactive inspection follow-up by an Augmented Inspection Team (AIT). On April 8, 2013, the NRC commenced an AIT assessment of the circumstances surrounding the March 31, 2013, loss of offsite power for ANO Unit 1, and the reactor trip and subsequent Notification of Unusual Event for ANO Unit 2. The basis for conducting an AIT was the failures of systems needed to mitigate an actual event and possible adverse generic implications of lifting heavy loads. The AIT was onsite April 8-12, 2013, and completed their inspection on May 9, 2013, with 10 unresolved items identified. The AIT report was issued on June 7, 2013 (ADAMS Accession No. ML13158A242).

The NRC resident inspectors monitored the licensee's actions during repair activities, reviewed corrective actions, and reviewed the licensee's root cause determination for both the Unit 1 stator drop and the Unit 2 reactor trip. On April 28, 2013, following repairs and retesting of electrical equipment, the licensee restarted ANO Unit 2.

An AIT follow-up inspection was conducted onsite during the week of July 22, 2013. On August 6, 2013, following structural repairs and replacement of the main generator stator, the licensee restarted ANO Unit 1.

The NRC and the Occupational Safety and Health Administration (OSHA) coordinated

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-03 Nuclear Facilities Response during Hurricane Sandy

The NRC included Hurricane Sandy in this report because the storm itself received significant media and congressional attention. However, as described below, the storm did not result in any damage to plant safety equipment, nor was there a threat to the public health or safety from any NRC-licensed facility. No problems at nuclear power plants associated with Hurricane Sandy occurred, and all plants responded appropriately.

On the evening of October 29, 2012, Hurricane Sandy made landfall in southern New Jersey, with impacts felt across more than a dozen states. Hurricane Sandy, also known as "Superstorm Sandy," was the deadliest and most destructive hurricane of the 2012 Atlantic hurricane season, as well as the second-costliest hurricane in United States history. The East Coast, particularly the New York and New Jersey coasts, experienced heavy rain, strong winds, and record storm surges.

All 34 nuclear power facilities in the path of Hurricane Sandy responded appropriately prior to and during the storm. Preparations were undertaken days in advance of the storm at the facilities as required by plant procedures to ready the plant to safely respond to high winds, flooding and grid disturbances. These actions included securing or moving equipment that could possibly become airborne due to high winds, and verifying that weather-tight doors and water intakes were prepared. Each plant site has multiple emergency diesel generators that are tested and provide electricity for critical operations if electric power from the grid is lost. Each plant also coordinated with local, state and federal emergency response officials. Plant operators and emergency response personnel were stationed at the plants throughout the storm to take whatever actions might be needed to ensure public health and safety.

Of the 34 nuclear facilities (from South Carolina to Vermont) in Hurricane Sandy's path, 24 continued to operate and generate electricity throughout the event. Seven were already shut down for refueling or inspection and were unaffected. The remaining three facilities were safely shut down, as designed, due to storm conditions or grid disturbances. The NRC inspectors were stationed at each nuclear power facility to oversee preparation for and recovery from the storm.

The Oyster Creek plant in New Jersey, declared a Notice of Unusual Event and subsequently an Alert due to elevated levels of water in its water-intake structure. The plant, about 33 miles north of Atlantic City and near the center of the storm's landfall, was already offline for a refueling outage. An Unusual Event is declared if the winds are sustained for greater than 15 minutes, or if the water level exceeds 4.5 feet above mean sea level (MSL). An Unusual Event is the lowest of four emergency action levels used by the NRC. The Alert (> 6 feet above MSL), the second lowest of four emergency action levels, was in response to actual high water levels (~7.4 feet above MSL) at the facility's intake structure. A loss of offsite power and high water levels in the intake structure were the main impacts to the station. No safety systems were adversely impacted by the storm. Afterwards, the NRC conducted a Special Inspection (SIT) at the Oyster Creek facility to review whether the Alert notification by the licensee was done in a timely manner. There were no findings resulting from the SIT.

As with Hurricane Sandy, U.S. nuclear power plants have a long history of successfully and safely responding to natural challenges as a result of their robust design, redundant and diverse safety systems, and well-trained plant staff.

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 reviewing these evaluations.

This event is closed for the purpose of this report.

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[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[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[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 of interest; the units of dose equivalent are the roentgen equivalent man (rem) and Sievert (Sv).

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

2 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).

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

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

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

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

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

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

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

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

Medical Event—as defined in 10 CFR 35.2, an event that meets the criteria in 10 CFR 35.3045(a) or (b). Regulations in 10 CFR 35.3045(a) state that a licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:

(1) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin and: (i) the total dose delivered differs from the prescribed dose by 20 percent or more; (ii) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or (iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more

(2) a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following: (i) an administration of a wrong radioactive drug containing byproduct material; (ii) an administration of a radioactive drug containing byproduct material by the wrong route of administration; (iii) an administration of a dose or dosage to the wrong individual or human research subject; (iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or (v) a leaking sealed source;

(3) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

Regulations in 10 CFR 35.3045(b) state that a licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Perineum[2]—the area between the base of the scrotum and the anus.

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

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

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

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

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

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

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

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

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

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

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

Source Material—as defined in 10 CFR 40.4; (1) uranium or thorium, or any combination thereof, in any physical or chemical form; or (2) ores that contain by weight one-twentieth of one percent (0.05 percent) or more of: (i) uranium; (ii) thorium; or (iii) any combination thereof. Source material does not include special nuclear material.

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

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

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

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

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

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

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

APPENDIX E
CONVERSION TABLE

Radioactivity and Ionizing Radiation

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

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10. SUPPLEMENTARY NOTES

NRC Project Manager Gladys Figueroa

11. ABSTRACT (200 words or less)

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Report Elimination and Sunset Act of 1995 requires that the AOs be reported to Congress on an annual basis. This report includes those events that the NRC has determined to be AOs during fiscal year 2013.

This report describes 10 events at Agreement State-licensed facilities that meet the criteria to be classified as AOs. During this reporting period, no events at NRC-licensed facilities including commercial nuclear power plants, were significant enough to be reported as AOs. In addition, this report provides an update to three events reported in fiscal year 2012 and three other events of interest.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

Exposure, Dose, Dosage, Medical Event, Fuel Facility, Nuclear Power Reactor

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