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United States Nuclear Regulatory Commission
Protecting People and the Environment

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Volume 37

Report to Congress on Abnormal Occurrences

Fiscal Year 2014

Office of Nuclear Regulatory Research

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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 one event involving an NRC licensee that the NRC identified as an AO during fiscal year (FY) 2014 based on the criteria defined in Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." This event occurred at an NRC-licensed medical institution and is a medical event, as defined in Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material."

In addition, this report describes twelve events that Agreement States identified as AOs during FY 2014 based on the criteria defined in this report's Appendix A. 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. One event involved radiation exposure to an embryo/fetus and the other eleven events were medical events, as defined in 10 CFR Part 35. It should be noted that the number of identified AOs is small in comparison to the millions of medical procedures performed annually.

Appendix A to this report presents the NRC's criteria for determining AOs, as well as the guidelines for selecting "other events of interest." Appendix B, "Updates of Previously Reported Abnormal Occurrences," provides updated information for two events previously updated in past years' "Report to Congress on Abnormal Occurrences." The update includes a medical event at Lovelace Medical Clinic in Albuquerque, New Mexico and a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama. During FY 2014, the NRC identified no events that met 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.

CONTENTS

EXECUTIVE SUMMARY

INTRODUCTION

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

This report describes those events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 2014, 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 here meet the criteria for being reported as AOs. For each AO, this report documents the date and place, nature and probable consequences, cause(s), and actions taken to prevent recurrence.

It should be noted that two of the thirteen AOs included in this report occurred in previous FYs. The NRC completed its evaluation for these AOs in FY 2014. The 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 FY 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 two events previously 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 are on a medical event at Lovelace Medical Clinic in Albuquerque, New Mexico and a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama. During FY 2014, the NRC identified no events that met 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* (10 CFR). The agency informs and involves stakeholders to ensure openness in the agency's regulatory process, consistent with the NRC's "Strategic Plan: Fiscal Years 2014–2018," (NUREG-1614, Volume 6, dated August 2014, Accession No. ML14246A439). 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 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 making the regulatory system more risk-informed and performance-based, where appropriate.

REPORTABLE EVENTS

The NRC initially issued the AO criteria in a Commission policy statement published in the *Federal Register* on February 24, 1977 (42 FR 10950), followed by several revisions in subsequent years. The most recent revision to the AO criteria was published in the *Federal Register* on October 12, 2006 (71 FR 60198), and became effective on that date. That revision established the criteria presented in Appendix A of this report, which the NRC used to define AOs for the 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 FY 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 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 2014, 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 involving 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 two 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 commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama and a medical event at Lovelace Medical Center in Albuquerque, New Mexico.

OTHER EVENTS OF INTEREST

The NRC provides information concerning other events of interest that are not reportable to Congress as AOs but are included in this report based on the Commission's guidelines, listed in Appendix A. During FY 2014, the NRC identified no events that met 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
AO	abnormal occurrence
AS	Agreement State
CAL	confirmatory action letter
CFR	*Code of Federal Regulations*
Ci	curie
cm	centimeter
CT	computed tomography
DOH	Department of Health
DSHS	Department of State Health Services
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel
Gy	gray
HCG	human chorionic gonadotropin
HDR	high dose rate
IIP	integrated improvement plan
LDR	low dose rate
LPCI	low pressure coolant injection
MBq	megabecquerel
µCi	microcurie
mCi	millicurie
mm	millimeter
mSv	millisievert
NOV	notice of violation
NRC	U.S. Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
rem	roentgen equivalent man
RHR	residual heat removal
RSO	radiation safety officer
Sv	sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
TVA	Tennessee Valley Authority

ABNORMAL OCCURRENCES IN FISCAL YEAR 2014

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, one event involving an Agreement State licensee was significant enough to be reported as an AO based on criteria in Appendix A, Criterion I, to this report. Although the event occurred at a medical facility, it involved unintended exposure of an individual who was not the patient. Therefore, this event belongs under the Criterion I.A, "All Licensees," category, as opposed to the Criterion III.C, "Medical Licensees," category.

AS14-01 Human Exposure to Radiation Event at Adventist Health Systems in Altamonte Springs, Florida

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides 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—June 26, 2014, Altamonte Springs, Florida

Nature and Probable Consequences— Adventist Health Systems (the licensee) reported that a pregnant patient received 3.7 gigabecquerels (GBq) [100 millicuries (mCi)] of iodine-131 for thyroid ablation therapy. On June 25, 2014, the patient tested negative for pregnancy. Subsequent to the procedure, her physician requested a re-test, which confirmed that she was pregnant. The estimated date of conception was June 23, 2014. The licensee calculated an estimated dose of 250 mSv (25 rem) to the fetus from the procedure.

The patient and referring physician were informed of this event. The dose was received during the first week of pregnancy, before the formation of any internal organs in the fetus. The administered iodine-131 was out of the patient's body before critical development of the fetus occurred; therefore, this exposure should not cause any developmental effects. The only effect noted in the licensee's report was the possibility the fetus might not have been viable, however, the patient was still pregnant as of August 3, 2014, and the licensee believes that the effect of the exposure to the fetus was minimal.

Cause(s)—The patient became pregnant immediately (a few days) prior to the procedure and the pregnancy was not detected via a standard HCG (human chorionic gonadotropin) pregnancy test until July 7, 2014.

Actions Taken To Prevent Recurrence

Licensee—Given that an HCG pregnancy test has a delayed response of approximately 10 days, patients will be advised to abstain from sexual intercourse for 2 weeks prior to the thyroid ablation procedure. The licensee also added this advisory to its patient interview worksheet that is used to screen patients.

State—The State of Florida did not cite any violations and the licensee's corrective actions were adequate. No further action will be taken for this event.

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 AOs 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, one event at an NRC licensee and 12 events involving Agreement State licensees were significant enough to be reported as AOs, based on Criterion III in Appendix A to this report.

AS14-02 Medical Event at an Unspecified Licensee in New York State

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—December 17, 2007 (reported on March 13, 2009), Unspecified City, New York

Nature and Probable Consequences—The unspecified licensee reported a medical event to the New York State Department of Health (DOH). The DOH reported the event to the NRC but has only recently provided the NRC with required information for this report. The DOH did not specify the name of the licensee for medical events in an effort to comply with New York state law designed to protect the privacy of the patient. This event occurred during a brachytherapy seed implant treatment for prostate cancer. The patient was prescribed to receive a total dose of 144 Gy (14,400 rad) to the prostate using 50 seeds of iodine-125. However, it was determined during post implant seed count that many of the seeds were implanted in the rectum and urethra (wrong treatment site). The calculated dose to the wrong treatment site is 144 Gy (14,400 rad), assuming the same volume of tissue was treated as was expected to be treated during treatment planning.

Ultrasound and fluoroscopy systems were used to aid with positioning the seeds; however, the radiation oncologist misidentified the prostate, resulting in the incorrect placement of many of the 50 seeds. On April 16, 2008, the Radiation Safety Officer performed a review of the patient's chart, including all films and images taken, and identified that many seeds had not been properly placed. It was determined that the tumor was under-dosed but additional radiation treatment of the prostate was not recommended. The patient and referring physician were informed of this event. The licensee concluded that the medical event would not have a significant adverse effect on the patient.

Cause(s)—The cause of the medical event was human error in that the medical staff did not follow the licensee's policies to properly image the patient's prostate.

Actions Taken To Prevent Recurrence

Licensee—The corrective action taken by the licensee includes developing and implementing written procedures for improved prostate imaging and requiring that the urologist document the verification and the identification of the prostate.

State—At the DOH's next routine inspection of the licensee, the DOH reviewed the licensee's response to this event, and noted no violations.

This event is closed for the purpose of this report.

NRC14-01 Medical Event at Camden-Clark Memorial Hospital in Parkersburg, West Virginia

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 gray (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—February 25, 2011 (reported on March 5, 2012), Parkersburg, West Virginia

Nature and Probable Consequences—Camden-Clark Memorial Hospital (the licensee), per the request of NRC Region I, performed a reassessment of the records associated with a prostate radioactive seed implantation procedure performed on February 25, 2011. The record review indicated that the patient treated with permanent implant palladium-103 seeds received roughly 53 percent of the prescribed dose. Additionally, the record review indicated that 50 percent of the tissue located adjacent to the prostate volume being treated (wrong treatment site) received a dose between 275 Gy (27,500 rad) and 375 Gy (37,500 rad). The attending physician did not notify the patient because he felt it would be of no benefit to the patient.

The licensee concluded that the medical event would not have a significant adverse effect on the patient.

Cause(s)—The cause of the medical event was that the licensee failed to develop and implement effective procedures to ensure that treatments were performed in accordance with written directives.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included developing a detailed procedure specific to the prostate brachytherapy program and providing additional training to personnel involved in the program.

NRC—An NRC inspection was conducted from January 18, 2012 through April 22, 2013, which identified several programmatic weaknesses associated with the prostate brachytherapy program. On August 8, 2013, the NRC issued a notice of violation (NOV) to the licensee for failure to implement procedures to provide high confidence that each administration was performed in accordance with the written directive.

This event is closed for the purpose of this report.

AS14-03 Medical Event at Baptist Health Madisonville in Madisonville, Kentucky

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—October 10, 2013, Madisonville, Kentucky

Nature and Probable Consequences—Baptist Health Madisonville (the licensee) reported that a medical event occurred associated with an intra-vaginal low dose rate (LDR) brachytherapy treatment for cervical cancer. Two sources contained approximately 1.95 GBq (52.7 millicuries (mCi)) of cesium-137 each and a third source contained approximately 1.08 GBq (29.1 mCi) of cesium-137. The patient was prescribed a total dose of 7,000 centigray (cGy) [rad] to the vaginal area. However, the patient received a dose of approximately 1,509 cGy (rad) to the surface of the patient's inner thighs (wrong treatment site). The patient and referring physician were informed of this event. Daily checks of the skin of the inner thighs in December 2013 have shown no adverse effects since the event occurred.

Cause(s)—The intra-vaginal applicator became dislodged as a result of the patient tossing and turning during the night. Due to the patient's partial paralysis below the waist, she was not aware that the applicator had become dislodged. The nursing procedures did not include instructions to check the position of the applicator; therefore, no check of the applicator position was made between the evening of October 9, 2013, when the applicator was last noted by nursing personnel to be in the correct position and the morning of October 10, 2013, when it was discovered to be dislodged by the prescribing physician and authorized medical physicist.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised the nursing instructions and post-operative orders to include a check of the implant position every shift, after bowel movements, and as necessary, and to document those checks in the patient's clinical record. Nursing staff received instruction in the use of these new procedures prior to the next brachytherapy procedure.

State—The Kentucky Radiation Health Branch conducted an inspection on January 13, 2014, to verify that the corrective measures had been developed and implemented by the licensee. Results of that inspection verified that revised nursing instructions and post-operative orders had been developed and were being implemented by the nursing staff.

This event is closed for the purpose of this report.

AS14-04 Medical Event at Radiotherapy Clinics of Georgia in Snellville, Georgia

Criteria III.C.1.b, III.C.2.b(iii), and III.C.2.b(vi), "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 or is delivered to the wrong individual.

Date and Place—December 16, 2013, Snellville, Georgia

Nature and Probable Consequences—Radiotherapy Clinics of Georgia (the licensee) reported that a medical event occurred associated with a 296 GBq (8 Ci) iridium-192 high dose rate (HDR) brachytherapy treatment for basal cell carcinoma on the patient's right temple. The patient was prescribed 4,000 cGy (rad) to be delivered in eight fractions of 99.61 seconds each to the skin on the temporal region of the patient's head. However, the physicist inadvertently selected a different patient's treatment plan and initiated the treatment. An area adjacent to the intended site (wrong treatment site) received a maximum dose of 2,300 cGy (rad) to a single point and 1,000 cGy (rad) to a 1 centimeter (cm) radius and 4.5 millimeter (mm) depth.

The physicist identified the error after 113.9 seconds and manually interrupted the procedure. The erroneous selection of the wrong treatment plan caused the iridum-192 source to stop short of the intended treatment area due to a shorter channel length. The physicist believes the source was in that position for nearly the entire treatment time. In addition to the dose to the wrong treatment site, this error resulted in the intended treatment site receiving less than half of the intended dose for the first fraction.

The referring physician and patient were notified of the error. The patient opted to proceed with a new treatment plan and the dose to the tumor volume was corrected on the subsequent treatments. The licensee concluded that the medical event would not have a significant adverse effect on the patient.

Cause(s)—The cause of the medical event was human error, which resulted in loading the wrong patient's treatment plan into the HDR control console.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included procedure modifications to require that a pretreatment checklist be physically signed by two independent qualified HDR operators/users. The licensee will now print the treatment parameters at the HDR control console after the treatment plan is loaded. The printout is then verified and signed by both the radiation oncologist and the physicist prior to initiating treatment.

State— The Georgia Department of Natural Resources performed a reactive investigation on December 18, 2013. The State has incorporated the licensee corrective action plan into the licensee licensing conditions/commitments and will review the implementation of this plan during future inspections.

This event is closed for the purpose of this report.

AS14-05 Medical Event at Central Arkansas Radiation Therapy Institute Inc. in Conway, Arkansas

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—December 31, 2013, Conway, Arkansas

Nature and Probable Consequences—Central Arkansas Radiation Therapy Institute (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure for prostate cancer treatment. The patient was prescribed a dose of 16,786 cGy (rad), but only received a dose of 2,531 cGy (rad) to the intended treatment site. The procedure was performed using 128 iodine-125 brachytherapy seeds, which contained a total activity of 1.592 GBq (43.036 mCi). Out of the 128 seeds, only 34 seeds were implanted into the patient's prostate gland (intended treatment site). The remaining seeds were implanted outside the prostate and resulted in estimated average doses of 1,399 cGy (rad) to the seminal vesicles, 4,580 cGy (rad) to the rectum, 389 cGy (rad) to the bladder, and 18,524 cGy (rad) to the penile bulb (wrong treatment sites).

The patient and referring physician were informed of this event. The patient received an additional seed implant on April 4, 2014, to complete the treatment for prostate cancer. No adverse health effects from this medical event have been reported to the State.

Cause(s)—The cause of the medical event was determined to be failure to accurately identify the treatment site.

Actions Taken To Prevent Recurrence

Licensee—The corrective actions taken by the licensee included centralizing prostate seed implant programs such that fewer facilities will be performing these implants, ensuring consistent adherence to the implant procedures and policies, evaluating implant procedures, requiring quality assurance on ultrasound equipment, and requiring training and proficiency records for operating room staff assisting with implants.

State—The Arkansas Department of Health performed an investigation on January 16, 2014. In addition, routine compliance inspections were performed on February 27, 2014, and July 24, 2014. The licensee's corrective actions were determined to be effective.

This event is closed for the purpose of this report.

AS14-06 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—January 24, 2014, 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 procedure to treat liver metastases from colorectal cancer. The licensee prescribed a patient dose of 0.53 GBq (14 mCi) of Y-90 microspheres to the left liver lobe for a planned dose of 989.8 Gy (98,980 rad) to the tumor and a resultant 11.99 Gy (1199 rad) to the liver. The licensee prescribed a patient dose of 0.92 GBq (25 mCi) of Y-90 microspheres to the right liver lobe for a planned dose of 446.7 Gy (44,670 rad) to the tumor and a resultant 12.97 Gy (1,297 rad) to the liver. The left liver lobe was treated as planned.

Due to unanticipated shunting while treating the right liver lobe, a dose of 11 Gy (1100 rad) from 21.57 MBq (0.58 mCi) Y-90 was delivered to the duodenum (wrong treatment site). The licensee uses contrast dye between vials to ensure the continued proper treatment and immediately discontinued the procedure when the shunting was identified. The final activity of Y-90 microsphere delivered to the right liver lobe was 0.55 GBq (15 mCi) for a dose of 265.9 Gy (26,590 rad) to the tumor and 7.7 Gy (770 rad) to the liver. The patient and referring physician were informed of this event.

The consequence of the event is the potential generation of a duodenal ulcer caused by the radiation. The licensee is treating the patient to minimize radiation damage to the duodenum and will continue to monitor the patient's condition. The prognosis of the patient will be determined by the underlying cancer and spread of the tumors. The licensee identified the event during the procedure and discontinued treatment.

Cause(s)—The cause of the medical event was 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 with its 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 February 20, 2014, to review the incident and initial reports. The Department concluded that the licensee had applied due diligence in performing the medical procedure. The Department did cite the licensee for failing to report the event within 1 day after determining this was a reportable event.

This event is closed for the purpose of this report.

AS14-07 Medical Event at Emory University in Atlanta, Georgia

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—February 27, 2014, Atlanta, Georgia

Nature and Probable Consequences—Emory University (the licensee) reported that a medical event occurred associated with an yttrium-90 (Y-90) microsphere procedure to treat liver cancer. The licensee prescribed a patient dose of 6,900 cGy (rad) with 2 GBq (54.05 mCi) of Y-90 to the left lobe of the liver. However, the medical team could not properly position the catheter due to anatomical issues not previously anticipated. A post-delivery scan revealed that approximately 0.81 GBq (21.8 mCi) went to the left lobe of the liver and 0.91 GBq (24.5 mCi) went to the right lobe of the liver, resulting in doses of 2,783 and 3,128 cGy (rad) to the left and right lobes, respectively. Since this was a bilateral disease that would eventually require the treatment of both lobes of the liver, the authorized user intended to treat the right lobe next. The team reported that the treatment plan would be adjusted to take into account the diseased areas that were already treated and no unintended adverse effects were expected due to this event. The patient and referring physician were notified of this event.

Cause(s)—Anatomy changes in arterial formation prevented navigation of the hepatic artery as intended by the initial shunt study on February 5, 2014. The patient's medical team decided to proceed with the catheter orifice at an earlier branching of the artery since they ultimately intended to treat both impacted regions of the liver. The resulting shunt fractions were different from the originally intended treatment for that day.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions included revising procedures to have written directives reflect the dose to the entire target organ as opposed to segmenting the written directives for each treatment region. The licensee also instructed the medical team to immediately report events with microspheres to extra-hepatic organs above the acceptable levels of anticipated shunting.

State—Telephone investigations were held with the medical team at the time of reporting and follow-up discussions were held during a routine inspection a couple months after the incident.

This event is closed for the purpose of this report.

AS14-08 Medical Event at Miami Neuroscience Center, Larkin Community Hospital in Miami, Florida

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—April 8, 2014, Miami, Florida

Nature and Probable Consequences—Miami Neuroscience Center, Larkin Community Hospital (the licensee) reported that a medical event occurred associated with cobalt-60 gamma knife stereotactic radiosurgery procedure for palliative treatment of trigeminal neuralgia. On April 8, 2014, the patient was prescribed a dose of 20,000 cGy (rad) to the left side of the brain, but the treatment was started on the right side of the brain. The treatment planner started the treatment on the right side because the planner knew that the patient had been previously treated on the right side of the brain in 2007 and 2008 and did not realize the new treatment site was now on the left side of the brain. The error was recognized by a nurse and she notified the doctors to stop the treatment. The treatment was stopped at 1.72 minutes into the planned 19.14 minute procedure. This resulted in a dose to the right side of the brain (wrong treatment site) of approximately 1,800 cGy (rad).

The patient and referring physician were informed of this event. After the error was identified, a new treatment plan was made and the patient received the prescribed treatment to the left side of the brain. The licensee determined the medical event would not have a significant adverse effect on the patient.

Cause(s)—The cause of the medical event was determined to be deficient Quality Management Program protocols.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions taken by the licensee included procedure modifications requiring the doctor to mark on the side of the patient's head to be treated the day before the treatment.

State—Corrective actions were found to be adequate and no fines were imposed.

This event is closed for the purpose of this report.

AS14-09 Medical Event at the Cedars Sinai Medical Center in Los Angeles, California

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

Date and Place—April 30, 2014, Los Angeles, California

Nature and Probable Consequences—Cedars Sinai Medical Center (the licensee) reported that a medical event occurred associated with an yttrium-90 (Y-90) microsphere procedure to treat liver cancer. The event took place during the second phase of a liver treatment when the patient was prescribed a maximum of 0.463 GBq (12.5 mCi) of Y-90 to deliver a maximum dose of 102 Gy (10,200 rad) to the liver, but instead was administered 1.59 Gbq (43 mCi) of Y-90 and received a dose of 363 Gy (36,300 rad) (256 percent greater than the maximum dose prescribed).

Local traffic congestion resulted in shipment delays and the Y-90 radiopharmaceutical arrived after the patient was anesthetized. An ambiguous written directive was misinterpreted by the radiopharmacist, who prepared an incorrect dosage. In its rush to get the Y-90 ready for administration, the licensee failed to have an authorized user present during dosage preparation to verify the correct dosage prior to administering it to the patient. The patient and referring physician were informed of the medical event. No unintended medical effects have been identified. The patient will continue to be medically monitored.

Cause(s)—A pre-anesthetized patient and a shipment delay of the Y-90 caused the licensee to rush and not follow written procedures requiring the authorized user to be present during the dosage preparation to verify that the correct dosage was prepared by the radiopharmacist. Additionally, inadequate training of the radiopharmacist and a recent treatment planning software revision resulted in the preparation of the incorrect dosage.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions included changes to the written directive format to reduce the potential for misinterpretation, changes to scheduling Y-90 microsphere procedures so that anesthetization of patients does not occur until the radiopharmaceutical is onsite, updates to treatment planning software, strengthening the verification process for written procedures, and training of radiopharmacists and authorized users concerning the lessons learned from this event.

State—Enforcement action was taken by the State of California to address the authorized user's failures to: 1) follow the treatment plan and written directive, 2) comply with procedures to be physically present when the radiopharmacist prepared the radiopharmaceutical, and 3) correctly confirm the radiopharmaceutical and dosage before administration to the patient.

This event is closed for the purpose of this report.

AS14-10 Medical Event at Watson Clinic in Lakeland, Florida

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 19, 2014, Lakeland, Florida

Nature and Probable Consequences—Watson Clinic (the licensee) reported that a medical event occurred that was associated with a patient receiving high dose rate (HDR) brachytherapy intra-vaginal cancer treatment. The patient was prescribed a dose of 700 cGy to the tumor site during three treatment fractions using a 342.25 GBq iridium-192 (I-192) source on March 31, April 7, and April 14, 2014. However, it was determined that the skin on the patient's thighs and labia (wrong treatment site) received an estimated dose of 4,200 cGy (rad).

During the follow-up visit on May 19, 2014, the patient had burns on the thighs and the labia. Investigation of the treatment planning revealed that an error occurred while entering the short source reference length into the treatment planning software, resulting in the source being positioned 10 cm short of the intended treatment site for all fractions of the treatment. The patient and prescribing physician were informed of the event.

Cause(s)—The cause of the medical event was an error in entering the reference source length into the treatment planning software and failure to identify the error during quality assurance checks.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions include modifying procedures to incorporate a second-person check of the source reference length, performing pre-treatment imaging checks using a dummy source, posting the expected reference length for applicators used, and adding a step to the HDR treatment check list to ensure review of the source reference length.

State—The State of Florida imposed an administrative fine of $1,000.

This event is closed for the purpose of this report.

AS14-11 Medical Event at Unspecified Licensee in Unspecified City, 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—June 5, 2014, Unspecified City, Texas

Nature and Probable Consequences—The unspecified licensee reported a medical event to the Texas Department of State Health Services (DSHS). The DSHS reported the event and provided the NRC with the required information for the report. The DSHS has redacted the name of the licensee in an effort to comply with Texas state law. This event occurred during a brachytherapy procedure for prostate cancer treatment. The patient was prescribed to receive a total dose of 14,400 cGy (rad) to the prostate using 58 iodine-125 (I-125) seeds. Instead, the seeds were implanted 3.5 centimeters inferior (below) to the target volume, resulting in 14,400 cGy to a small volume of the rectum and other normal tissue below the target volume (wrong treatment site). The patient and referring physicians were informed of the event.

During the treatment, the I-125 seeds were manually being implanted with ultrasound guidance. After the implantation began, the imaging deteriorated and it was difficult to determine the boundary between the prostate and bladder. After discussion, the radiologist and urologist decided to continue with the procedure as they thought they had identified the bladder base. After the procedure was completed, it was discovered that the Foley bulb used to visualize the bladder had been pierced and deflated. During the post-plan evaluation using a post-implant computed tomography (CT) acquired on August 7, 2014, it was discovered that the seeds were positioned 3.5 centimeters inferior to the target volume. Rectal and bladder doses were not significantly impacted by the seed misplacements and remained within typical doses for prostate impacts. The patient is receiving external beam radiation therapy to boost areas of the prostate that did not receive the prescribed dose. The licensee concluded that there were no acute medical effects to the patient and no long-term significant complications are expected.

Cause(s)—The application needle used to manually implant the seeds is believed to have punctured the Foley bulb, resulting in reduced visibility of the bladder and misplacement of the seeds. Additionally, the radiation oncologist had not performed a prostate seed implant in 5 years and was not an authorized user on the license.

Actions Taken To Prevent Recurrence

Licensee—The licensee has revised its procedures to ensure that physicians are authorized users on its license before radioactive material therapy use. Additionally, the licensee has instituted the practice that if at any time during the procedure adequate visualization is compromised, the procedure will be interrupted until visualization is reestablished. The radiation oncologist who performed this procedure has decided to discontinue performing the prostate seed implant procedure.

State—The State cited the licensee for failure to report a medical event within the required time and for the performing physician not being on the license as an authorized user.

This event is closed for the purpose of this report.

AS14-12 Medical Event at University of Virginia in Charlottesville, Virginia

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

Date and Place—September 4, 2014, Charlottesville, Virginia

Nature and Probable Consequences— University of Virginia (the licensee) reported that a medical event occurred associated with an yttrium-90 (Y-90) microsphere procedure to treat lesions in the liver. On September 4, 2014, the patient received the prescribed activity of 1,499.61 MBq (40.53 mCi). Based on evaluation of pre-treatment imaging, this activity was expected to deliver the prescribed dose of 11,700 cGy (rad) to the left lobe of the liver and 370 cGy (rad) to the lungs. However, following the treatment, the licensee determined the patient had higher than expected Y-90 activity shunt into the lungs due to patient specific complicated shunting pathways, resulting in a dose of 6,700 cGy (rad) to the liver and 3,450 cGy (rad) (832 percent greater than the prescribed) to the lungs. The patient and referring physician were informed of this event. During the week of February 2, 2015, the patient was admitted to a hospital with acute respiratory distress like symptoms with lung infiltrates consistent with radiation pneumonitis. The patient passed away over the following weekend. However, the cause of death and any potential association with the medical event are being evaluated.

Cause(s)—Complications in the patients' shunting pathways resulted in two different lung shunt pathways that were not identified during pre-treatment imaging because the licensee did not evaluate both the left and right arteries located in the liver for lung shunting. The complicated shunting pathway resulted in higher than expected Y-90 activity to move to the patient's lungs during the treatment.

Actions Taken To Prevent Recurrence

Licensee—Corrected procedures to measure shunting from both left and right arteries located in the liver when appropriate, measure lung volumes for lung mass calculations when appropriate, review lung shunting calculations, and clarify the locations of the arterial injections for the treatments.

State—A member of the Virginia Radioactive Materials Program observed a Y-90 microsphere procedure on September 23, 2014. The observation included viewing the dose being drawn and delivered to the operating room, patient injection, surveys performed and patient release. Licensee staff utilized the new procedures during this implantation. Licensee staff was observed verbally describing each step of the procedure and a discussion was held regarding the written directive and lung shunt calculations.

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.

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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.

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

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

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

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

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

occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

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

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

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

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.

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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.

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

B. For Fuel Cycle Facilities

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

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

C. For Medical Licensees

A medical event that:

1. Results in a dose that is

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 two 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 medical event at Lovelace Medical Clinic in Albuquerque, New Mexico and a commercial nuclear power plant event at Browns Ferry Nuclear Power Plant, Unit 1, in Athens, Alabama.

Medical Event at Lovelace Medical Clinic in Albuquerque, New Mexico (previously reported as AS11-09 in NUREG-0090, Volume 34, with updates in Appendix B of NUREG-0090, Volume 35)

Date and Place—May 4, 2010, Albuquerque, NM

Background—The Lovelace Medical Clinic (the licensee) reported that a medical event occurred with a high dose rate (HDR) brachytherapy treatment for endometrial carcinoma. The patient was prescribed a total radiation dose of 21 gray (Gy) (2,100 rad) in three fractions of 7 Gy (700 rad) each to a distance of 0.5 cm from the surface of an applicator of diameter 2.3 cm to the treatment site, but instead, the skin tissue on the patient's thigh received 30.6 Gy (3,060 rad) and received a dose to the thigh at 2.5 cm depth of 4.08 Gy (408 rad).

The licensee determined that the medical event was caused by either improper placement or by workers inadvertently moving the catheter while adjusting the patient for better alignment with the treatment device. The licensee's corrective actions included revising the procedures to ensure that the catheter is correctly positioned before the start of the treatment. In addition, the licensee required staff training to address the procedure updates. The licensee concluded that no long-term adverse effects are expected for the patient. The FY 2011 AO report discusses the full details of the event under AS11-09.

Update on Actions Taken To Prevent Recurrence

State—The New Mexico Environment Department's long-term enforcement action has been ongoing through calendar year 2014.

This event is closed for the purpose of this report.

Commercial Nuclear Power Plant Event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama (previously reported as NRC11-02 in NUREG-0090, Volume 34, with updates in Appendix B of NUREG-0090, Volume 35)

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

Background—The Tennessee Valley Authority (TVA) (the licensee) reported a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, a boiling-water reactor designed by General Electric. During a refueling outage, it was discovered that a residual heat removal (RHR) low pressure coolant injection (LPCI) flow control valve failed while the licensee was attempting to establish shutdown cooling. The NRC reviewed this event under its significance determination process and determined that the licensee's history with regard to this valve performance issue represented a finding of high safety significance (Red finding). The NRC determined that this event did not represent an immediate safety concern, because the licensee staff had, as part of its immediate corrective actions, implemented repairs and modifications that returned the flow control valve to an operational condition.

Update on Actions Taken To Prevent Recurrence

NRC—NRC staff initiated a supplemental inspection per Inspection Procedure 95003 (ADAMS Accession No. ML102020551), which was implemented in three parts beginning on September 12, 2011. The three parts of the inspection were completed and documented in inspection reports (Part 1 documented November 17, 2011 (ADAMS Accession No. ML113210602); Part 2 documented February 28, 2012 (ADAMS Accession No. ML12059A314); and Part 3 documented August 22, 2013 (ADAMS Accession No. ML13234A539)). The NRC used the results of these inspections to determine the breadth and depth of safety, organizational, and programmatic issues at Browns Ferry Nuclear Power Plant and to assess the adequacy of their Integrated Improvement Plan (IIP) submitted to the NRC on August 23, 2012 (available at ADAMS Accession No. ML12240A106). The NRC reviewed the TVA committed IIP actions and issued a Confirmatory Action Letter (CAL) (ADAMS Accession No. ML13232A105) on August 22, 2013. This letter confirmed TVA's actions, which when completed by TVA and verified to be adequate by the NRC, would reasonably serve to inform the NRC's decision regarding closure of the Red finding and the transition of Browns Ferry Nuclear Plant Unit 1 out of the Multiple/Repetitive Degraded Cornerstone Column (Column 4) consistent with the NRC's Reactor Oversight Process. The NRC verified and documented, in an inspection report issued January 27, 2014 (ADAMS Accession No. ML14027A742), the conclusion that TVA had taken sufficient actions to support closure of the Red finding. Browns Ferry Nuclear Plant, Unit 1, was moved to the Licensee Response Column (Column 1) of the NRC Action Matrix on October 1, 2014 (ADAMS Accession No. ML14289A458).

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 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.

There are no other events of interest that meet the above criteria to report in FY 2014.

APPENDIX D
GLOSSARY

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

Acute respiratory distress syndrome[1]—respiratory failure in adults or children that results from diffuse injury to the endothelium of the lung (as in sepsis, chest trauma, massive blood transfusion, aspiration of the gastric contents, or pneumonia) and is characterized by pulmonary edema with an abnormally high amount of protein in the edematous fluid and by difficult rapid breathing and hypoxemia.

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 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.

Basal cell carcinoma[1]—a skin cancer derived from and preserving the form of the basal cells of the skin.

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

Brachytherapy Seed Implantation for Prostate Cancer[2]—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, and each needle is inserted through the skin in the perineum and into the prostate using continuous ultrasound guidance. Once accurate needle placement is confirmed, the seeds in that needle are released. This process is continued until all of the radioactive seeds have been implanted.

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

Catheter[1]—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.

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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 (*see* http://www.nlm.nih.gov/medlineplus/mplusdictionary.html).

Cervical Cancer[1]—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).

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.

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.

Foley Catheter[2]—a flexible plastic tube (a catheter) inserted into the bladder to provide continuous urinary drainage.

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;

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

(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.

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 pneumonitis[2]—Inflammation of the lungs as a result of radiation.

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."

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.

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.

Trigeminal Neuralgia[2]—Inflammation of the trigeminal nerve (the fifth cranial nerve) that most commonly causes paroxysms of very intense lightning pain in the areas of the face the nerve supplies -- the lips, eye, nose, scalp, forehead, gums, cheek, and chin -- on the involved side of the face. A less common "atypical" form of the disease causes a more constant, dull, burning, or aching pain.

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.

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)	curie (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)	roentgen equivalent man (rem)	0.01
	centisievert (cSv)	rem	1.0
	millisievert (mSv)	rem	10
	mSv	millirem (mrem)	0.01
	microsievert (µSv)	mrem	10

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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 2014.

This report describes 1 event at NRC-licensed facility and 12 events at Agreement State-licensed facilities that meet the criteria to be classified as AOs. In addition, this report provides an update to two events reported in fiscal year 2011.

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