Report to Congress on Abnormal Occurrences

Fiscal Year 2016

United States Nuclear Regulatory Commission
Washington, DC 20555-0001

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 three events involving NRC licensees that the ~~NRC~~ agency identified as AOs during fiscal year (FY) 2016 based on the criteria defined in the report's Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." One AO occurred at an NRC-licensed fuel cycle facility. The other two AOs were medical events 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 eight other AOs: six medical events as defined in 10 CFR Part 35; one event involving radiation exposure to an embryo/fetus; and one radiography operations event that occurred in Agreement States and were identified as AOs during FY 2016 based on the criteria defined in 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, as amended (AEA) (Public Law 83 703), to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 37 Agreement States.

~~It should be noted that the eight medical event AOs represent a small fraction of the average number of nuclear medicine and radiation therapy procedures involving byproduct material conducted in the United States annually. In the United States in 2006, 5,048,231 diagnostic nuclear medicine procedures were performed, as reported in the National Council on Radiation Protection Report 160 "Ionizing Radiation Exposure of the Population of the United States," issued in 2009. The IMV "Benchmark Report for Radiation Therapy," issued in 2014 reports approximately 107,660 radiation therapy procedures involving byproduct material were performed in 2013.~~

Appendix A to this report presents the NRC's criteria for identifying AOs, as well as the guidelines for selecting "other events of interest." Appendix B, "Updates of Previously Reported Abnormal Occurrences," provides updated information for one event that was previously identified in the FY 2015 "Report to Congress on Abnormal Occurrences." The NRC ~~did not identify~~ identified one ~~any~~ event~~s~~ during FY 2016 that met the guidelines for inclusion in Appendix C, "Other Events of Interest." Appendix D, "Glossary," contains definitions of terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

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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) 2016, 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, as amended (AEA) (Public Law 83 703), to regulate certain quantities of AEA material at facilities 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 report meet the criteria for being reported as AOs. For each AO, this report documents the date and place, nature and probable consequences, cause, or causes, and actions taken to prevent recurrence.

It should be noted that ~~while~~ 3 of the 11 AOs ~~included in this report~~ occurred in the previous fiscal year, but are included in this report because the NRC did not complete its evaluation for these three AOs until FY 2016. Information concerning AOs must be complete in order to perform an adequate evaluation. Occasionally, all the required information is not available in time to evaluate and report on an AO in the fiscal year of its occurrence.

Appendix A to this report presents the NRC's criteria for identifying AOs, as well as the guidelines for selecting other "events of interest." Appendix B, "Updates of Previously Reported Abnormal Occurrences," provides updated information for one event previously identified in the FY 2015 "Report to Congress on Abnormal Occurrences."

The NRC ~~did not identify any~~ identified one event~~s~~ during FY 2016 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," contains 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 NRC regularly conducts licensing reviews, inspections, enforcement, investigations, operating experience evaluations, incident response, and confirmatory research. The agency informs and involves stakeholders and the public to ensure openness in its regulatory process, consistent with the NRC's "Strategic Plan: Fiscal Years 2014–2018," ~~(NUREG-1614, Volume 6, issued September 2014, Agencywide Documents Access and Management System (ADAMS) Accession No. ML14246A439)~~.

The NRC adheres to the philosophy that multiple levels of protection best ensure public health and safety. The agency achieves and maintains these levels of protection 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 offer 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* (FR) 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 to this report, which the NRC used to define AOs for the report.

Reviews 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 of events.

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 authorizes the Commission to enter into agreements with States whereby the Commission relinquishes, and the States assume, certain regulatory authority over byproduct material, source material, and certain quantities of special nuclear material. States that enter into such agreements with the NRC are known as Agreement States.~~ 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, as amended (AEA) (Pub. L. 83-703), to regulate certain quantities of AEA material at facilities located within their borders. 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. Currently, there are 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 3, 1997 (62 FR 46517). The NRC also has put procedures into place for evaluating materials events and to identify those that meet the AO criteria. The NRC uniformly applies the AO criteria (in Appendix A to this report) to events at licensee facilities or activities involving use of radioactive material 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 reports only domestic AOs.

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC includes updates on previously reported AOs if they remain open during the fiscal year addressed in the report or if significant new information becomes available. Appendix B to this report provides updated information for one AO that was previously identified in NUREG 0090, Volume 38, "Report to Congress on Abnormal Occurrences: Fiscal Year 2015," issued May 2016~~ (ADAMS Accession No. ML16145A026)~~. This AO involved a medical event at Legacy Good Samaritan Medical Center in Portland, OR.

OTHER EVENTS OF INTEREST

The NRC offers 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. The NRC ~~did not identifidentified oney any~~ event during FY 2016 that met the guidelines for inclusion in Appendix C~~, either as an update to previously reported information or~~ as a new event that received significant public interest.

ABBREVIATIONS

~~ADAMS~~	~~Agencywide Documents Access and Management System~~
AEA	Atomic Energy Act of 1954, as amended
ALI	annual limit on intake
AMP	authorized medical physicist
AO	abnormal occurrence
AS	Agreement State
AU	authorized user
CFR	*Code of Federal Regulations*
cGy	centigray(s)
Ci	curie(s)
Cs	cesium
DAC	derived air concentration
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
GDC	general design criterion/criteria
Gy	gray(s)
HDR	high dose rate
I	iodine
Ir	iridium
~~IROFS~~	~~items relied on for safety~~
LDR	low dose rate
MBq	megabecquerel(s)
mCi	millicurie(s)
MD	management directive
mrem	millirem
mSv	millisievert(s)
NRC	U.S. Nuclear Regulatory Commission
rad	radiation absorbed dose
rem	roentgen equivalent man
RSO	radiation safety officer
SAR	safety analysis report
SMHMC	Saint Mary's Hospital and Medical Center
Sv	sievert(s)
TBq	terabecquerel(s)
TEDE	total effective dose equivalent
TS	technical specification(s)
UCLA	University of California, Los Angeles
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2016

Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest," to this report supplies the specific criteria for determining whether an event is an abnormal occurrence (AO). It also offers the guidelines for reporting other events of interest that may not meet the AO criteria but that the U.S. Nuclear Regulatory Commission (NRC) has determined should be in this report. Appendix A contains criteria for 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

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 fiscal year (FY) 2016, two events involving Agreement State licensees were significant enough to be reported as AOs based on the criteria in Appendix A, Criterion I, "For All Licensees," to this report. Although one of the events occurred at a medical facility, it involved unintended exposure of an embryo/fetus, not the patient. Therefore, this event belongs under Criterion I.A.2, "All Licensees," rather than Criterion III.C, "Medical Licensees."

AS16-01 Human Exposure Event at Mistras Group, Deer Park, Texas

Criterion I.A.1, "For All Licensees," of Appendix A to this report provides, in part, that a human exposure event shall be considered for reporting as an AO if it results in a shallow dose equal to or greater than 2,500 mSv (250 rem) to the skin or extremities.

Date and Place — May 11, 2016, Deer Park, Texas

Nature and Probable Consequences — Mistras Group reported a radiation overexposure to a radiographer during operations on May 11, 2016. The source guide tube and collimator fell from a jig it had been taped to while the 1,237.6-gigabecquerel (GBq) (33.4-curie (Ci)) iridium (Ir) -192 source was extended. The radiographer's dosimetry was sent for immediate processing. Mistras Group re-enacted the incident using video and an empty exposure device with attachments to represent what the radiographer had done. The reenactment demonstrated that the radiographer had placed his left hand on the collimator and inserted his middle finger into its port hole. The radiation safety officer (RSO) calculated a dose of 467 centisievert (cSv) (roentgen equivalent man (rem)) to the finger. Dosimetry badge results revealed a whole-body dose of 9.37 mSv (937 millirem (mrem)); that badge was worn for 8 days during the month. The radiographer's finger appeared to show slight reddening; otherwise, no visible effects have been observed. Bloodwork ~~was also done and~~ showed no unusual results.

Cause(s) — The radiographer failed to retract the source into the exposure device before he walked to the end of the guide tube, picked it up, and taped it back onto the jig.

Actions Taken To Prevent Recurrence

Licensee — The corporate RSO sent out an alert to remind personnel to be safety-conscious. The radiographer involved was disciplined.

State — The Texas Department of State Health Services investigated the incident and concurred with the exposure results for the radiographer.

This event is closed for the purpose of this report.

AS16-02 Human Exposure to Radiation Event at Saint Mary's Hospital and Medical Center, Grand Junction, Colorado

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 — July 13, 2016, Grand Junction, Colorado

Nature and Probable Consequences — Saint Mary's Hospital and Medical Center (SMHMC) reported that a pregnant patient received 2.78 GBq (75 mCi) of iodine (I)-131 for a thyroid ablation treatment on July 13, 2016. The patient became aware that she was pregnant shortly after treatment and informed SMHMC on August 16, 2016. Gestational age at the time of treatment was estimated to be 9 days after conception. The RSO estimated an exposure to the embryo of approximately 20 cGy (rad). No adverse health effects are expected because of this event.

Cause(s) — The patient did not follow medical instructions to have no sexual contact before the administration of I-131. The limitations in the sensitivity of pregnancy tests in the early stages of pregnancy were another contributing cause; ~~the patient was administered~~ a pregnancy test was administered before treatment and the results were negative.

Actions Taken To Prevent Recurrence

Licensee — The licensee will review the processes and timing of dosing women of child-bearing age with respect to the timing of their menstrual cycles, with the understanding that irregular menstrual cycles are common in patients with thyroid disease.

State — The Colorado Department of Health will continue to conduct inspections to ensure that the licensee follows procedures.

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, three events at ~~an~~ NRC licensee facilities and six events at Agreement State licensee facilities were significant enough to be reported as AOs based on Criterion III, "Events at Facilities Other Than Nuclear Power Plants and All Transportation Events," in Appendix A to this report.

AS16-03 Medical Event at Mount Carmel Saint Ann's Hospital in Westerville, Ohio

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

Date and Place – August 21, 2015, Westerville, Ohio

Nature and Probable Consequences – Mount Carmel Saint Ann's Hospital reported a medical event involving brachytherapy seed implant treatment for prostate cancer. The patient was prescribed a dose of 145 Gy (14,500 rad) to the prostate using iodine-125 seeds with a total activity of 644.8 MBq (17.43 mCi). Instead, the iodine-125 seeds were implanted into a nearby tissue mass (wrong treatment site) that was mistakenly identified as the prostate gland with ultrasound imaging, resulting in no dose to the prostate. The patient and referring physician were informed of this event.

The patient ~~denied~~ did not report ~~experiencing~~ any side effects or adverse reactions. The patient has been in consultation with colorectal surgeons and urologists, to determine a plan of care. The patient is under hormone treatment for his prostate cancer and remains under the care of the colorectal surgeon.

Cause(s) – The cause of the event was human error by the licensee staff. ~~This event occurred because a~~A mass was mistakenly identified by the radiation oncologist as the prostate on a transrectal ultrasound volume study, and these images were used for treatment planning of the iodine-125 seed implant.

Actions Taken to Prevent Recurrence

Licensee – A root cause analysis meeting was held among many of the licensee's departments on October 9, 2015. The hospital policies had been followed. This incident occurred due to the patient's abnormal anatomy as viewed on a transrectal ultrasound.

State – The Ohio Department of Health conducted an investigation on October 9, 2015. The State inspector reviewed the pre-treatment scans that showed the patient's abnormal anatomy, which was mistaken for the prostate. No violations were issued to the licensee due to this event.

This event is closed for the purpose of this report.

AS16-04 Medical Event at Hardin Memorial Hospital, Elizabethtown, Kentucky

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

Date and Place — Feb 12, 2015, Elizabethtown, Kentucky

Nature and Probable Consequences — Hardin Memorial Hospital reported a medical event involving a patient that received an I-125 prostate brachytherapy seed implant involving a total activity of 680.8 megabecquerels (MBq) (18.4 mCi). A computerized tomography scan performed March 25, 2015, approximately 5 weeks after the implant, revealed that 30 percent of the seeds were implanted outside the brachytherapy planning target volume. As a result, the rectum received 61 percent higher dose than intended as it received 18,500 cGy (rad) instead of the expected approximate 11,500 cGy (rad), or a 61 percent higher dose than intended if the seeds had been implanted as prescribed.

The authorized user (AU) reviewed the post-plan metrics with the patient and referring physician within 24 hours of discovery of the event. The Kentucky Department for Public Health determined that the prostate gland (treatment site) received the prescribed dose, but the rectum received more dose than intended. No adverse health effects are expected because of the medical event.

Cause(s) — The placement of radioactive seeds inferior to the prostate was primarily because the patient's prostate had decreased in size significantly as a result of external beam radiation therapy, which was performed prior to seed implantation.

Actions Taken To Prevent Recurrence

Licensee — Corrective actions included modifying procedures and providing additional training to personnel responsible for performing brachytherapy procedures.

State — The Kentucky Department for Public Health, Radiation Health Branch, continued to follow up with the licensee until all required information was obtained.

This event is closed for the purpose of this report.

AS16-05 Medical Events at RadAmerica, Baltimore, Maryland

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, 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 11, 2015, through December 21, 2015, Baltimore, Maryland

Nature and Probable Consequences — RadAmerica reported that a patient received two fractions of high-dose-rate (HDR) brachytherapy on December 15 and December 21, 2015, in which the Ir-192 source was approximately 4 centimeters away from the prescribed treatment location. The incident involved an Elekta Flexitron HDR afterloader unit and was discovered before performing the third fraction on January 12, 2016. The patient was being treated for exuberant granulation tissue of the right lung lower lobe bronchus. The patient was prescribed ~~to receive~~ 4 fractions of 500 cGy (rad) each. The patient received 500 cGy (rad) to the wrong site and 0 cGy to the intended treatment site during the first two fractions. The patient's third and fourth fractions were performed correctly.

Following evaluation of this event, RadAmerica did a retrospective review of its casework and determined that medical events occurred during two ~~other~~ additional patients' treatments using the Flexitron unit. ~~One~~ A second patient received 500 cGy (rad) to the wrong site during each of two fractions performed on May 11 and May 18, 2015. The patient received the prescribed dose of 500 cGy (rad) to 45 percent of the intended site on May 11 and 500 cGy (rad) to 20 percent of the intended site on May 18. The ~~other~~ third patient received 500 cGy (rad) to the wrong site during each of three fractions performed on September 3, September 9, and September 17, 2015. The third patient received no dose to the intended treatment site during these fractions. The patients and physicians were informed of the medical events. No adverse health effects are expected because of these medical events.

Cause(s) — The licensee determined that an adapter piece had been used with the dummy source for marking the dwell position of the Ir-192 source. This adapter was not supposed to be used with the Flexitron HDR afterloader unit. The Flexitron unit replaced the former Nucletron MicroSelectron unit in August 2014.

Actions Taken To Prevent Recurrence

Licensee — Corrective actions taken included revising the Flexitron applicator/transfer tube/channel chart to reflect the appropriate use of the bronchial adaptor, revising the HDR afterloader bronchoscopy treatment procedure, and revising the universal protocol form.

State — The Maryland Department of the Environment performed an inspection on January 18, 2016.

This event is closed for the purpose of this report.

AS16-06 Medical Event at Saint Joseph's Hospital, Atlanta, Georgia

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 — February 15, 2016, Atlanta, Georgia

Nature and Probable Consequences — Saint Joseph's Hospital reported that a medical event occurred on February 15, 2016, involving gamma knife stereotactic radiosurgery. The patient was prescribed 1,200 and 2,100 cGy (rad) to 14 subcentimeter brain metastases using a gamma knife stereotactic radiosurgery unit. Following treatment to 6 of the 14 sites, the patient was given a break. The AU and authorized medical physicist (AMP) entered the room to release the patient from the restraining device and saw that the restraining device was locked, but not in the correct position. The displaced distance was measured at a maximum of 2 centimeters in the direction of one plane, resulting in the patient receiving unintended radiation dose to normal brain tissue. The licensee determined that a total volume of 0.16 cubic centimeters of healthy brain tissue had been irradiated. The possibility of necrosis to normal brain tissue is approximately 15 percent and may take approximately 8 months to develop. The patient and referring physician were informed of the event.

Cause(s) — The primary cause of this incident was the staff's use of the new frame adapter without receiving training on the device from the manufacturer. This cause was attributed to a combination of three failures: a non-keyed design of the frame adapter that resulted in the possibility of placing the head frame incorrectly; a discrepancy in the clamping force between the old and new frame adapters, making it possible to lock the new frame adapter onto the stereotactic head frame in an incorrect position while still being able to lock the frame firmly; and a misunderstanding of the instructions for connecting the frame and frame adaptor, resulting in a large deviation between the two frames from the intended placement of the patient's head.

Actions Taken To Prevent Recurrence

Licensee — The licensee took the following five actions:

(1) The AMP, nurse, and AU will position and secure the frame adapter and confirm proper positioning for all patients. This will allow a triple check of alignment before any treatment delivery has begun.

(2) The frame adapter will be placed with the patient sitting in a wheelchair to allow better visibility of the frame placement.

(3) A pretreatment checklist, including the frame alignment parameters, to be executed by gamma knife nursing staff, medical physics staff, and the AU will be required to be completed. This checklist has been developed and will be used for all future gamma knife cases.

(4) Additional training has been developed and was delivered to all staff involved in the care of gamma knife patients before participation in gamma knife procedures so that all are aware of the potential of a misalignment of the frame adapter. This has also been

incorporated into the initial and annual training for all applicable staff, and all staff ~~has~~ have completed the updated training to date.

(5) The vendor has been notified of the event and the feasibility of misalignment and has committed to notify all customers using the new frame adapter of the risks of misalignment when docking.

State — The State of Georgia conducted a reactive inspection on February 16, 2016. The State verified that the licensee had implemented the plan to ensure that several staff members who are involved with the procedure will verify that the adaptors are properly aligned ~~with each other~~. The State also verified that the licensee notified the vendor of the situation.

On February 17, 2016, the vendor submitted to the State a copy of the field change order and instructions for use for the adaptor. On April 8, 2016, the State received the vendor's follow-up report, which included the vendor's investigation, root cause investigation, and corrective action/preventive actions.

This event is closed for the purpose of this report.

NRC16-01 Medical Event at Spectrum Health, Grand Rapids, Michigan

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 — April 27, 2016, Grand Rapids, Michigan

Nature and Probable Consequences — Spectrum Health reported that a patient received 3.3 GBq (89.19 mCi) of yttrium (Y)-90 microspheres to an incorrect segment of the liver. The patient had liver cancer and was prescribed ~~to receive~~ treatment to segments in the right lobe of the liver. However, during treatment on April 27, 2016, the catheter moved and the microspheres were administered to a segment in the left lobe. The prescribed dose was 12,000 cGy (rad) to the segments in the right lobe, but the patient received approximately 11,850 cGy (rad) to the incorrect segment in the left lobe. Spectrum Health stated that the segment in the left lobe was previously treated and there was some residual cancer remaining. It is anticipated that the patient's right lobe will be treated at some future time. The patient and prescribing physician have been notified. The licensee and an expert medical consultant contracted by the NRC to independently review this event concluded that the event would not result in significant physiological consequence to the patient.

Cause(s) — Contrary to the licensee's written procedures, the AU did not verify the position of the catheter's tip within the vasculature of the patient's liver immediately before administering the dose of microspheres. As a result, the AU did not notice that, between the time he finished placing the catheter and the time he performed the administration (approximately 10 minutes), the tip of the catheter had moved out of the intended artery to another. Although the exact cause for this movement is not known, the small distances involved suggest that patient movement could have caused the catheter to slip from its intended position.

Actions Taken To Prevent Recurrence

Licensee — The licensee revised its operating room checklist for this particular treatment to explicitly require the attending interventional radiology technologist to verify with the AU that a final check of catheter position has been performed *immediately* before administration. In the standard practice of medicine, the AU would verify the placement of the catheter before administering material; however, the previous version of this checklist was not explicitly clear that the verification must take place immediately before administration and not earlier.

NRC — The NRC conducted a reactive inspection on May 2, 2016, to review the circumstances of the medical event. The inspection did not identify any discrepancies in the licensee's assessment of the event. In May 2016 the expert medical consultant contracted by the NRC conducted an independent assessment of the probable deterministic effects of the radiation exposure to the patient as a result of this medical event. In August 2016 the consultant provided the results of his independent assessment. The consultant concluded that while some radionecrosis was evident from follow-up evaluation of the patient's liver via computerized tomography scans and enzyme testing, no significant consequences to the patient were to be expected as a result of the medical event.

This event is closed for the purpose of this report.

NRC16-02 Medical Event at Medstar Georgetown Medical Center, Washington, D.C.

Criteriaon 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, 2016, Washington, D.C.

Nature and Probable Consequences — Medstar Georgetown Medical Center reported that physicians planned to treat tumors located in the right lobe and the left lobe of a patient's liver with Y-90 microspheres (Sirtex Medical Model SIRSpheres). On May 19, 2016, a written directive was prepared and called for 943 MBq (25.49mCi) of Y-90 SIRSpheres to be administered to the right lobe of the patient's liver for a prescribed dose of 3,213 cGy (rad). The licensee reported that on May 19, 2016, the patient's written directive was not followed as the Y-90 microspheres were administered to the left lobe of the patient's liver. The licensee also reported that the physician was only able to safely administer 868.8 MBq (23.48 mCi) of Y-90 microspheres during the May 19, 2016, administration because stasis occurred. On June 16, 2016, while preparing to treat the left lobe of the liver, the physicians noted that they had mistakenly treated the left lobe on May 19, 2016. Using the actual activity delivered and the volume of the left lobe of the liver, the physicians determined the administered dose to the left lobe was 5,177 cGy, or 119 percent of the 4,337 cGy dose that the physician intended to prescribe to the left lobe. On June 16, 2016, a written directive was prepared to treat the right lobe of the patient's liver. As before, the written directive called for 943 MBq (25.49 mCi) of Y-90 microspheres to be administered to the right lobe of the patient's liver for a prescribed dose of 3,213 cGy (rad). The licensee reported that the administration on June 16, 2016, was uneventful and 92 percent of the 3,213 cGy was administered.

Cause(s) — The event was caused by the failure of the interventional radiologist to follow the licensee's procedure for verification of the written directive.

Actions Taken To Prevent Recurrence

Licensee — The licensee modified its SIRSphere Policy to require: (1) a "time out" prior to the administration of the SIRSphere dose ~~when~~ during which the participants in the dose administration all communicate the specifics of the treatment plan by asking open-ended questions; (2) signatures from each of the participants in the dose administration confirming that the "time out" occurred; and (3) the Interventional Radiologist will document clearly in her/his notes the preferred treatment site(s) so that the AU is clear on how the Interventional Radiologist would like to proceed with the treatment. Furthermore, the licensee provided instruction to each member of the SIRSphere team regarding the policy changes and the licensee ~~input~~ placed the ~~specifics~~ details of the medical event into their Internal Risk Management System for further review and potential improvements to the program. These actions were completed prior to conducting the next SIRSphere brachytherapy procedure.

NRC — During the NRC's reactive inspection, conducted between July 13, 2016, and September 13, 2016, the licensee's proposed corrective actions were reviewed, accepted, and will be followed up on during the next inspection.

This event is closed for the purpose of this report.

AS16-07 Medical Event at Loma Linda University Medical Center, Loma Linda, California

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

Date and Place — May 27, 2016, Loma Linda, California

Nature and Probable Consequences — Loma Linda University Medical Center reported that a patient undergoing cesium (Cs)-137 low-dose-rate (LDR) brachytherapy for cervical cancer received an unintended dose of 3,492 cGy to the lower rectum and vaginal areas. The treatment plan for this patient involved insertion of a tandem and ovoid, which was inserted into the patient without complication. However, the tandem insert catheter containing the tandem source was not completely inserted into the tandem applicator. This resulted in an inferior shift of the prescribed dose delivery by approximately 8 centimeters (wrong treatment site) causing the lower rectum and vaginal walls to receive more dose than expected. The patient and referring physicians were notified of the medical event. No adverse health effects are expected because of the medical event.

Cause(s) — The cause was determined to be inadequate training and inadequate written procedures that contributed to avoidable human errors. The catheter used to place the source into the tandem applicator was inexplicably placed in the incorrect well during transport from the storage location to the patient's room for insertion. This caused the catheter to stick out of the transport shielding. As a result, the catheter was crimped when the cover was placed on the transport shield. The medical physicist was unable to insert the entire length of the catheter into the tandem applicator because of the crimping. Instead of determining whether the tandem insert catheter was correctly positioned, the medical physicist and the radiation oncology resident decided to clip the protruding catheter at the crimp and continue with the treatment.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions include the following:

- Existing procedures were reviewed and revised to address issues from this event, as well asand to ensure that other potential contingencies are addressed.
- Training of all parties involved in these LDR brachytherapy treatments (medical physicists, dosimetrists, and radiation oncology residents) was formalized on using a demonstration methodology to include a detailed written program of lectures, hands-on demonstration, procedures, radiological and patient safety aspects, and regulatory criteria. Staff will need to document completion of the training in order to work unsupervised.
- Pending completion of the training and certification, the chief physicist will directly supervise the medical physics staff, and an AU will directly supervise the loading of sources for all LDR brachytherapy cases.

State — The State of California met with involved licensee personnel to ensure that all errors that contributed to this event were identified and that proposed licensee corrective actions were adequate. The licensee was cited for “serious” non-compliance in terms of inadequate training, procedures, and supervision.

This event is closed for the purpose of this report.

NRC16-03 Westinghouse Columbia Fuel Fabrication Facility (CFFF), Columbia, SC

~~Criteria~~ CriterionIII.A.2 of Appendix A to this report provides that an event at a facility other than a nuclear power plant or a transportation event shall be considered for reporting as an AO report if it results in a major deficiency in design, construction, control or operation having significant safety implications that require immediate remedial action.

Date and Place — July 14, 2016, Columbia, SC

Nature and Probable Consequences — On July 14, 2016, the Westinghouse Electric Corporation (licensee) reported that during annual cleaning of the S-1030 scrubber at the Westinghouse Columbia Fuel Fabrication Facility, an excessive amount of low enriched uranium was found in the inlet ducting to the scrubber, potentially exceeding the uranium mass limit established for nuclear criticality safety. The facility fabricates low enriched uranium fuel assemblies for commercial nuclear power plants. The S-1030 scrubber removes gases and particulates from various exhaust streams associated with the uranium conversion process. The licensee conducted multiple inspections and cleanouts and quantified the amount of uranium that had built up in different sections of the scrubber. Approximately 87 kilograms of uranium was initially found in the inlet ducting, exceeding the nuclear criticality safety mass limit of 29 kilograms. An additional 172 kilograms was cleaned from the scrubber internals, exceeding its mass limit of 21 kilograms. No nuclear criticality safety controls, such as moderator limits or favorable geometry restrictions, were present. As a result, the safety margin available to preclude an inadvertent criticality was substantially degraded. This represented a major deficiency in control having significant safety implications requiring immediate remedial action. Specifically, the event called into question the licensee's controls for nuclear criticality safety associated with wet scrubbers and non-favorable geometry components and justified the immediate shut down of the conversion process. An actual nuclear criticality did not occur and there were no health consequences to the public, workers, or impact to the environment.

Cause(s) — Configuration management controls were not effective in managing increased uranium accumulation in the scrubber over an extended period of time when design and operational changes to the system were made. Operating experience and the corrective action processes were not effectively used to pursue the actions needed to detect, estimate, and mitigate deposited uranium in the scrubber. Organizational safety culture weaknesses contributed to invalid assumptions in criticality safety evaluations and the failure to scrutinize the content of the evaluations and as-found conditions in the scrubber with a questioning attitude. Management did not ensure the organization had sufficient procedures and training to recognize and respond to deviations from the safety basis described in the criticality safety evaluation. Furthermore, the scope of licensee audits did not provide a comprehensive review of the Nuclear Criticality Safety Program ~~with an appropriate level of intrusiveness~~.

Actions Taken to Prevent Recurrence

Licensee — The conversion process was shut down and the licensee performed extent of condition and root cause evaluations. On August 9, 2016 ~~(Agencywide Documents Access and Management System (ADAMS) Accession No. ML16223A003)~~, Westinghouse submitted a letter committing to take actions to ensure that the causes of the uranium buildup were adequately identified and evaluated and that appropriate corrective actions were implemented to improve the performance of the nuclear criticality safety program.

NRC — On July 28, 2016, the NRC initiated an Augmented Inspection Team to inspect and assess the facts and circumstances of the event. The team's report was issued on October 26, 2016 ~~(ADAMS Accession No. ML16301A001)~~. On August 11, 2016, the NRC issued a Confirmatory Action Letter documenting the commitments made by Westinghouse ~~(ADAMS Accession No. ML16224B082)~~. The NRC verified through inspection the licensee's corrective actions required to be completed prior to restart and provided written consent to restart in a letter dated October 20, 2016 ~~(ADAMS Accession No. ML16294A296)~~. On December 20, 2016, the NRC issued a letter ~~(ADAMS Accession No. ML16355A078)~~ notifying Westinghouse that increased inspection oversight will be performed until longer term corrective actions have been completed.

This event is closed for the purpose of this report.

AS16-08 Medical Event at University of California, Los Angeles, California

~~Criterion~~ 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, or 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 — June 16, 2016, Los Angeles, California

Nature and Probable Consequences — The University of California, Los Angeles (UCLA), reported that on June 16, 2016, a patient received 4.02 GBq (108.6 mCi) Y-90 microsphere brachytherapy dosage (Nordion model TheraSpheres) that was intended for another patient's treatment scheduled for June 17, 2016. In addition to incorrect dosage, the Y-90 microspheres were delivered to the wrong lobe of the liver. The patient was prescribed ~~to receive~~ 12,000 cGy(rad) to the left lobe ~~of the liver~~. However, as a result of the medical event, the patient received 32,800 cGy (rad) to the right lobe (wrong treatment site). The patient's physicians and the patient were notified, and UCLA investigated the event to determine the cause. A two-month follow-up liver function test showed acceptable liver function in spite of the event.

Cause(s) — The root causes of the event were inadequate procedures and insufficient training. These led to improper identification of the vial containing the correct dosage, improper verification of the calculated dosage by the preparing technician, and inadequate involvement by the AU to verify the radiopharmaceutical dosage before treatment. Treatment of the wrong lobe was attributed to displacement of the catheter after its insertion in the patient. The displacement was not detected because of a failure to verify catheter position during injection of the Y-90 to ensure that the catheter location remained constant.

Actions Taken To Prevent Recurrence

Licensee — The UCLA Radiation Safety Division ~~will~~ developed and implemented a formal standard operating procedure for Y-90 microsphere brachytherapy. The Radiation Safety Division and Nuclear Medicine staff conducted additional training. Multiple forms of visual and written verifications will be implemented so that the multiple parties involved ~~can~~ agree on the patient information and dose calculations and to ensure that the written directive is followed. Additional imaging techniques will also be incorporated to verify that catheter placement does not change significantly post-catheter insertion.

State — The State of California met on site with involved licensee personnel to ensure that all errors that contributed to this event were identified and that proposed licensee corrective actions were adequate. The State also took enforcement actions ~~to address the licensee failings~~ and will follow up to ensure proper implementation of licensee corrective actions.

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

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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.”

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.

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.

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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 Accident Sequence Precursor program to have a conditional core damage probability or change in core damage probability of greater than 1×10^{-3}.

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

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 one abnormal occurrence event that the U.S. Nuclear Regulatory Commission reported in NUREG-0090, Volume 38, "Report to Congress on Abnormal Occurrences: Fiscal Year 2015," issued May 2016 (~~Agencywide Documents Access and Management System Accession No. ML16145A026)~~. This AO involved a medical event at Legacy Good Samaritan Medical Center in Portland, OR.

Medical Events at Legacy Good Samaritan Medical Center in Portland, OR (previously reported as AS15-08 in NUREG-0090, Volume 38) (May 2016)

Date and Place — January 7, 2015, to February 12, 2015, in Portland, OR

Background — Legacy Good Samaritan Medical Center reported eight medical events associated with a gamma knife stereotactic radiosurgery (Elekta's Perfexion unit) that occurred between January 7, 2015, and February 12, 2015. Five of these events exceeded the 10-Gy (1,000-rad) dose threshold in the AO criterion. All eight patients received the prescribed dose, ranging from 7 to 24.9 Gy (700 to 2,490 rad), to the wrong location because of the manufacturer's misalignment of the patient positioning system during maintenance that was performed on the unit between December 13, 2014, and January 1, 2015. As a result of the maintenance, the positioning system was off target by 1.87 millimeters, which resulted in the medical events. Following the event, the licensee established a new set of quality assurance tests, with the cooperation of Elekta, to verify positioning.

Update on Consequences — As of fiscal year 2016, no patient effects have been observed.

Cause(s) — The medical events were caused by human error. According to Elekta, this adjustment was made without following the correct service procedures, which would have detected the error.

Update on Actions Taken to Prevent Recurrence

State — The Oregon Health Authority, Radiation Protection Services, continues its investigation relating to these events. Upon completion of the initial investigation in May 2015 the State identified, and during fiscal year 2016, continued to do further analysis in the following four focus areas:

(1) Further examine Elekta's license as it relates to the supervision of repair, operation, and testing of the Leksell Gamma Systems; specifically, reviewing Elekta's service technician employment qualification programs, including education history, training, and certifications.

(2) Determine whether adequate communications are in place between Elekta and licensees about the repair and maintenance of Elekta's devices.

(3) Determine the qualifications of the field service technician(s) who caused the misalignment of the patient positioning system during repair and the cause of the misalignment.

(4) Determine whether State regulations should be changed with regard to the qualifications and training of field service technicians, and, if a licensee is authorized to use a gamma knife, whether it should be required to perform routine quality checks by “pin prick” films.

The State has completed the review of these focus areas and is validating information by conducting interviews with personnel directly or indirectly involved with this event.

This event is open 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 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 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 fiscal year 2016.~~

OEI 16-01 Creusot Forge Documentation Anomalies and Carbon Segregation

The NRC included this event in this report because of the significant media coverage and congressional attention the event received.

In June 2016, the NRC became aware that the French Nuclear Safety Authority (ASN) was reviewing information related to anomalies with quality assurance documents and potential carbon segregation issues associated with components manufactured at Creusot Forge, which is located in central France. Creusot Forge, a 100% subsidiary of the AREVA group, was purchased by AREVA in 2006 and manufactures forgings and castings used throughout the world-wide energy market. There are 17 US operating plants with components supplied from Creusot Forge.

Quality Assurance Records:
NRC staff participated in a multinational inspection at AREVA's Creusot Forge (ACF) focused on quality assurance documentation in late 2016 and the report was issued on February 27, 2017 (http://www.french-nuclear-safety.fr/Inspections/Supervision-of-the-epr-reactor/Anomaly-affecting-the-Flamanville-EPR-reactor-vessel/Multinational-inspection-of-AREVA-NP-in-its-Creusot-Forge-plant-in-Le-Creusot-France). As a result of the inspection, AREVA is conducting a number of internal corrective actions to address the quality assurance document issue. In addition, AREVA stated that files associated with ~~United States (~~U.S.~~)~~ licensees were reviewed and four of its U.S. purchasers were notified of the documentation issue and the conclusion of no safety significance. The NRC inspectors reviewed a sample of AREVA discrepancy notices and concluded that AREVA's evaluations were reasonable based on the test results and compliance with applicable ASME Code requirements. NRC inspectors confirmed that ACF is not currently producing components for U.S. nuclear facilities.

On December 7, 2016, AREVA issued an interim report for the identification of an issue related to fabrication record anomalies at Creusot Forge. AREVA issued the interim report because its evaluation will not be completed within 60 days as required by NRC regulations. AREVA stated its evaluation of documents is scheduled to be completed in June 2017. They also stated that, at this time, it does not appear that the documentation anomalies being evaluated could create a substantial safety hazard. NRC staff has requested additional information from AREVA to independently verify the extent of condition, and assess potential impacts, for U.S. facilities.

Carbon Segregation:

It was reported in 2015 that reactor components manufactured at Creusot Forge for use in France exhibited carbon segregation that was not expected under the applicable French standards. Carbon segregation is a ~~naturally occurring~~ phenomena that arises during the casting of large ingots which are used to form large pressure vessel components. Concentrations of carbon will not be present, on a scale of engineering significance, in components properly manufactured following NRC regulations and ASME Code for use at U.S. facilities. The NRC staff has not identified a safety concern ~~concluded that there is no safety significance~~ regarding carbon segregation based on knowledge of the U.S. material qualification process and preliminary structural evaluations for hypothesized concentrations of carbon in pressure vessels. Furthermore, the NRC has extensively evaluated the potential for reactor pressure vessel failure using state-of-the-art probabilistic fracture mechanics methodologies and concluded that the carbon segregation issue would be expected to have an insignificant impact on the probability of reactor pressure vessel failure in U.S. facilities. The NRC staff continues to follow the international response and perform inspection activities as needed to ensure there is no safety impact~~validate the minimal safety impact~~.

APPENDIX D
GLOSSARY

Ablation[1] — removal or excision. Ablation is usually carried out surgically. For example, surgical removal of the thyroid gland (a total thyroidectomy) is ablation of the thyroid.

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

Authorized User — as defined in Section 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.

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, 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.

Bronchoscopy[1] — procedure during in which an examiner uses a viewing tube to evaluate a patient's lung and airways including the voice box and vocal cord, trachea, and many branches of bronchi.

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 Title 10 of the *Code of Federal Regulations* (10 CFR), a management directive (MD), an inspection procedure, or a U.S. Nuclear Regulatory Commission (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).

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).

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.

Gamma knife — a type of radiosurgery (radiation therapy) machine that acts by focusing low-dosage gamma radiation from many sources on a precise target. Areas adjacent to the target receive only slight doses of radiation, while the target gets the full intensity.

Granulation tissue[3] — the part of the healing process in which lumpy, pink tissue containing new connective tissue and capillaries forms around the edges of a wound. ~~Granulation of a wound is normal and desirable.~~

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 per kilogram (100 rad).

High dose-rate remote afterloader — as defined in 10 CFR 35.2, a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1,200 rads) per hour at the point or surface where the dose is prescribed.

Interstitial[3] — situated within, but not restricted to or characteristic of, a particular organ or tissue; used especially of fibrous tissue.

Low dose-rate remote afterloader - as defined in 10 CFR 35.2, a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rad) per hour at the point or surface where the dose is prescribed.

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[2] These terms are not defined in 10 CFR, an MD, 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).

[3] These terms are not defined in 10 CFR, an MD, 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).

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 one of the following:

(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 rems) effective dose equivalent, 0.5 Sv (50 rems) to an organ or tissue, or 0.5 Sv (50 rems) 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 rems) effective dose equivalent, 0.5 Sv (50 rems) to an organ or tissue, or 0.5 Sv (50 rems) 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 rems) 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 nonionizing radiation, such as radio waves or microwaves, or visible, infrared, or ultraviolet light.

Radiation oncologist [4]— a specialist in using radiation therapy as a treatment for cancer.

Radiation therapy (radiotherapy)[4] — 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."~~

Radioembolizations[4] — a cancer treatment in which radioactive particles are delivered to a tumor through the bloodstream.

Radionecrosis[5] — ulceration or destruction of tissue resulting from irradiation

Reactive inspection — as defined in NRC Inspection Procedure 43003, "Reactive Inspections of Nuclear Vendors," an inspection performed for the purpose of obtaining additional information 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 grays multiplied by the quality factor (1 Sv = 100 rem).

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[4] These terms are not defined in 10 CFR, an MD, 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).

[5] These terms are not defined in 10 CFR, an MD, 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).

Source material — as defined in 10 CFR 40.4, "Definitions"; (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 of 1954, as amended,, 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.

Stasis[6] — A stoppage or slowdown in the flow of blood or other body fluid, such as lymph.

Stereotactic radiosurgery — as defined in 10 CFT 35.2, the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

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.

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."

[6] These terms are not defined in 10 CFR, an MD, 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).

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