Report to Congress on Abnormal Occurrences

Fiscal Year 2017

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) changed the AO reporting requirement from a quarterly basis to an annual one.

This report describes five events involving NRC licensees that the agency identified as AOs during fiscal year (FY) 2017 based on the criteria defined in the report's Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." All five AOs were medical events as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material."

In addition, this report describes six other medical events, as defined in 10 CFR Part 35 that occurred in Agreement States and were identified as AOs during FY 2017 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 within their borders. Currently, there are 37 Agreement States.

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 identified in the FY 2016 "Report to Congress on Abnormal Occurrences." The NRC identified one event during FY 2017 that met the guidelines for inclusion in Appendix C, "Other Events of Interest." Appendix D, "Glossary," defines 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, 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) changed the AO reporting requirement from a quarterly basis to an annual one. .

This report describes events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 2017, 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.

Of the 11 AOs discussed, 2 occurred in previous fiscal years but are included in this report because the NRC did not complete its evaluation of them until FY 2017. Information concerning AOs must be complete to permit 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. One of the two events occurred in 2011, but it was not discovered until late in FY 2016.

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 2016 "Report to Congress on Abnormal Occurrences."

The NRC identified one event during FY 2017 that met the guidelines for inclusion in Appendix C, "Other Events of Interest," as new events that received significant public interest. Appendix D, "Glossary," defines 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 used by the NRC 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)," published August 2014.

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. Agreement States conduct regulatory programs that are adequate and compatible with NRC's program.

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 agency published the most recent revision to the AO criteria in the *Federal Register* on October 2, 2017 (82 FR 45907); the revised criteria became effective on that date. This revision establishes the criteria that will be used to define AOs for the FY 2018 report and forward. This FY 2017 report uses the revision to the AO criteria published in the *Federal Register* on October 12, 2006 (71 FR 60198), which 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 this report.

Reviews of, and responses to, operating experience are essential to ensure that licensees conduct their activities safely. Toward that end, NRC 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

Agreement States are those States that have entered into formal agreements with the NRC, pursuant to Section 274 of the AEA, to regulate certain quantities of AEA material at facilities 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; Wyoming and Vermont have submitted applications to become 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 procedures in place for evaluating materials events and

identifying 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 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. The agency reviews and considers this foreign information in its 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 identified in NUREG-0090, Volume 39, "Report to Congress on Abnormal Occurrences: Fiscal Year 2016," issued May 2017. 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 identified one event during FY 2017 that met the guidelines for inclusion in Appendix C as a new event that received significant public interest.

ABBREVIATIONS

AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
AS	Agreement State
AU	authorized user
CFR	*Code of Federal Regulations*
cGy	centigray(s)
Ci	Curie(s)
CT	computerized tomography
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
Gy	gray(s)
I	iodine
MBq	megabecquerel(s)
mCi	millicurie(s)
MD	management directive
mrem	millirem
mSv	millisievert(s)
NIST	National Institute of Standards and Technology
NRC	U.S. Nuclear Regulatory Commission
Pd	palladium
PPS	patient positioning system
rad	radiation absorbed dose
rem	roentgen equivalent man
RHB	Radiation Health Branch (KY)
RPS	Radiation Protection Services (OR)
Sv	Sievert(s)
TRH	Taylor Regional Hospital
TBq	terabecquerel(s)
TEDE	total effective dose equivalent
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2017

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.

This section discusses events in Categories I, II, and III. Appendix C to this report addresses Category IV events.

I. ALL LICENSEES

During fiscal year (FY) 2017, no events were significant enough to be reported as AOs based on Criterion I, “All Licensees” in Appendix A to 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, five events at 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.

AS17-01 Medical Event at Taylor Regional Hospital in Campbellsville, Kentucky

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, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place — September 26, 2011, Campbellsville, KY

Nature and Probable Consequences — On May 9, 2016, Taylor Regional Hospital (TRH) reported that during a 2016 examination of prostate brachytherapy procedures, the hospital discovered that a prostate brachytherapy seed implant procedure that met the medical event criteria had occurred on September 26, 2011. The patient was prescribed to receive an activity of 4.16 gigabecquerels (GBq) (112.5 millicuries (mCi)) of palladium (Pd)-103 brachytherapy seeds for a total dose of 9,500 centigrays (cGy) (rad). Post-implant dosimetry for the patient revealed that the total dose delivered to the prostate was 16,480 cGy (rad), which was approximately 73 percent greater than prescribed.

The referring physician was notified. The licensee reported that no adverse health effects are expected as a result of the additional dose.

Cause(s) — The investigation of the cause of the event is ongoing at this time.

Actions Taken To Prevent Recurrence

Licensee — As of October 2016, TRH discontinued its manual brachytherapy program after discovering that multiple prostate brachytherapy medical events had occurred between 2011 and 2016 (including the one event that met the AO criteria as described above).

State — The Commonwealth of Kentucky, Radiation Health Branch (RHB), conducted routine health and safety and followup inspections at TRH as a result of the discovery of multiple medical events involving prostate brachytherapy. RHB issued several notices of violation to TRH including one for failure to report medical events in accordance with Kentucky's regulations. On October 26, 2016, TRH sent RHB a letter requesting the removal of manual brachytherapy authorization from the facility's license, and RHB removed such authorization on December 5, 2016, for failure to achieve compliance.

This event is closed for the purpose of this report.

NRC17- 01 Medical Event at Washington University in St. Louis, St. Louis, Missouri

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

Date and Place — April 8, 2016, St. Louis, MO

Nature and Probable Consequences — On April 8, 2016, Washington University in St. Louis treated a patient with yttrium (Y)-90 (Nordion Model TheraSphere®) microsphere brachytherapy for liver cancer. The authorized user (AU) prescribed 117 Gy (11,700 rad) by administering 4.15 GBq (112.16 mCi) to the left lobe of the liver. During the treatment, the interventional radiologist used an angiogram to confirm the catheter placement, which controls where the microspheres will be delivered. The delivered activity was 4.07 GBq (110 mCi). Images from post-treatment positron emission tomography/magnetic resonance imaging (PET/MRI) indicated that approximately 95 percent of the microspheres were deposited in the right (unintended) lobe of the liver, resulting in a dose of 93.8 Gy (9,380 rad). The patient and the prescribing physician were notified of this event. The patient remained under the care of the licensee after the Y-90 procedure. The AU chose not to administer microspheres to the left lobe of the patient's liver to make up for the underdose. Instead, the patient was treated with chemotherapy. Following the procedure, the patient had no significant changes to liver function that were inconsistent with liver cancer and had no abdominal pain.

Cause(s) — The licensee speculated that the cause of the medical event was unintentional "patient intervention" (defined in 10 CFR 35.2, "Definitions") that shifted the catheter tip because of breathing, coughing, or other movement; however, there was no indication that patient intervention occurred. The NRC inspector could not determine the cause of the medical event because there was no indication of patient intervention, shunting, or other potential causes. Nonetheless, the inspector identified the amount of time between the angiogram and the administration of the microspheres to the patient as a contributing factor to the medical event. Specifically, the 32-minute gap between the angiogram and the microsphere administration increased the potential for catheter tip movement away from the intended position.

Actions Taken To Prevent Recurrence

Licensee — Although the licensee could not determine the cause of the medical event, soon after identifying the medical event, the licensee implemented generic, immediate corrective actions to prevent a similar medical event. The focus was on communications between the team members of any concerns about catheter placement, including establishing standard language to voice a concern, reminding the team about safety culture to include stopping the process and speaking up if there is any concern, and requiring that all participating team members confirm that the administration should proceed.

NRC — The NRC performed a reactive inspection to review the circumstances and root and contributing causes, and proposed corrective actions for a medical event identified by the inspector. The NRC's medical consultant stated that the patient's right liver lobe will atrophy with focal fibrosis, and the left lobe may somewhat hypertrophy.

This event is closed for the purpose of this report.

AS17-02 Medical Event in the State of New York

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, or the lens of the eye, or the gonads) and a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place — December 29, 2016, NY

Nature and Probable Consequences — New York reported a medical event involving Y-90 (Sirtex Medical model SIR-Spheres®) microsphere brachytherapy for a patient with a history of neuroendocrine tumor of uncertain origin with metastatic disease to the liver and lung. The AU prescribed Y-90 treatment activity of 90.76 megabecquerels (MBq) (2.453 mCi) to a small lesion of the liver and 816.85 MBq (22.077 mCi) to a large lesion of the liver. A technologist prepared the two dosages in two vials in accordance with the written directive and placed the vials into shields bearing labels of the activity on each lid. In preparation for treatment of the small lesion, the technologist inadvertently delivered the wrong vial to the procedure room and left. Before administering the Y-90, the AU questioned if the dosage was correct because there was more volume of material in the vial than expected. When contacted, the technologist who prepared the dosage confirmed that it was the correct dosage, and the AU proceeded with treatment of the small lesion. Following the administration, the vial was returned to the shield. In preparation for treatment of the large lesion, the technologist delivered the shielded vial that was labeled as 816.85 MBq (22.077 mCi). Upon opening the lid, the technologist observed that the vial containing the 816.85 MBq (22.077 mCi) dosage had been used to treat the small lesion. The AU directed the staff to prepare a dose to treat the large lesion and was able to treat the large lesion as prescribed. The patient and referring physician were notified of the incident. The licensee reported that no adverse health effects are expected as a result of the additional dose.

Cause(s) — The event was initiated because the technologist inadvertently brought the wrong dosage to the procedure room and apparently failed to read the label or misread the label. There was a failure in communication in that the significance of the AU's concern about the dosage was not conveyed to the technologist. Rather than performing a physical check of the activity, the technologist simply provided a verbal confirmation.

Actions Taken To Prevent Recurrence

Licensee — The licensee implemented a requirement for a "timeout" before all treatments. As used in this procedure, a "timeout" is a brief pause that allows the medical staff to confirm that the treatment conforms to the written directive from the AU. The labeling requirements were revised so that both the vial and vial shield must be labeled and the label must be read three times before administration. All staff involved in Y-90 microsphere brachytherapy received training on the revised protocols in January 2017.

State — The State of New York's Bureau of Environmental Radiation Protection Program required and received a root cause analysis and corrective action from the licensee. A reactive inspection was conducted on March 29–30, 2017, in conjunction with a full routine inspection.

This event is closed for the purpose of this report.

NRC17-02 Medical Event at Henry Ford Hospital, Detroit, Michigan

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

Date and Place — January 31, 2017, Detroit, MI

Nature and Probable Consequences — On January 31, 2017, Henry Ford Hospital reported that a patient undergoing Y-90 (Nordion Model TheraSphere®) microsphere brachytherapy for liver cancer received an unintended dose to the right lobe of the liver. The AU prescribed 60 Gy (6,000 rad) by administering 1665 MBq (45 mCi) of Y-90 to only the left lobe of the patient's liver. However, post-treatment imaging identified that an unintended dose of 36.5 Gy (3650 rad) was administered to the right lobe of the patient's liver during the procedure.

The patient had previously had a Y-90 microsphere brachytherapy on December 7, 2016, with an intended dose of 141.6 Gy (14,160 rad) to the right lobe of the liver. The unintended dose received by the right lobe during the January 31 administration brings the cumulative dose to the right lobe to 178.2 Gy (17,820 rad). The licensee reported that no adverse health effects are expected as a result of the additional dose. The referring physician and patient were notified of the incident.

Cause(s) — The NRC and the licensee could not determine the cause because there was no indication of patient movement, shunting, or other possible explanations. The patient had complex vascular anatomy, so the unintended administration is believed to have resulted from either a potential movement of the catheter caused by an unnoticed patient movement or undetected reflux.

Actions Taken To Prevent Recurrence

Licensee — After review, the licensee believes that the challenging vascular anatomy of the patient led to this unintended administration, and a corrective action to prevent recurrence of a similar event would be to exclude patients with similar anatomy. However, given the rarity of this type of incident and the potential benefits of the treatment, the licensee believes that this action is not viable. After the evaluation, the licensee determined that no action is warranted.

NRC — The NRC has performed a reactive inspection and had a medical consultant review any possible medical effects from this medical event. The medical consultant reviewed the circumstances of this event and agreed with the licensee's evaluation of (1) why the event occurred, (2) the effects on the individual who received the unintended dose, (3) the licensee's immediate actions on discovery, and (4) the licensee's determination that no further action was warranted. The medical consultant added that patient movements as subtle as breathing may have affected the position of the catheter enough to influence the path of the microspheres within the liver once injected. Therefore, the NRC is in agreement with the licensee's determination of no warranted action.

This event is closed for the purpose of this report.

AS17-03 Medical Event at Duke University Medical Center, Durham, North Carolina

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, 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 — February 24, 2017, Durham, NC

Nature and Probable Consequences — On February 24, 2017, a patient with colon cancer that had metastasized to the liver underwent Y-90 (Nordion Model TheraSphere®) microsphere brachytherapy. The AU prescribed the treatment to be delivered in two rounds during the same procedure. Two segments of the liver were treated per round, with four segments total being treated. All segments were located in the left lobe of the liver. The first round of treatment administered 0.87 GBq (23.51 mCi) to segments IVa and IVb. The second round administered 2.05 GBq (59.50 mCi) to segments II and III. After completion of the procedure, while dictating a record of the treatment, the AU who performed the procedure noted that the dosage for the second vial seemed high. After reviewing the written directive, the AU noted that the dosage for the first round was administered correctly; however, the dosage for the second round to segments II and III was originally prescribed on the written directive to be 1.05 GBq. Upon review of the written directive and discussion with the radiopharmacist who ordered the dosage, it was determined that the radiopharmacist misread the prescribed dosage for the second round and entered 2.05 GBq into the dosage conversion system instead of 1.05 GBq. This resulted in a calculation of 55.35 mCi instead of 28.3 mCi. After performing the conversion, the radiopharmacist wrote the incorrectly converted amount in mCi on the written directive, so that when the dosages were received, the error was not noticed (because the dosage label was in mCi and not GBq, and there was no procedural requirement to do a confirmatory dosage conversion check when receiving the material). Subsequently, segments II and III of the liver received a dose of about 245 Gy (24,500 rad) instead of the prescribed 120 Gy (12,000 rad).

The referring physician and patient were notified of the incident. The licensee reported that no adverse health effects are expected as a result of the additional dose.

Cause(s) — The event was caused by human error. Specifically, the radiopharmacist misread the written directive and therefore incorrectly converted the dosage from GBq to mCi.

Actions Taken To Prevent Recurrence

Licensee — The licensee added a layer of verification to ensure that the accuracy of the conversion has been checked in both the nuclear medicine and the radiopharmacy departments and developed a new written directive form to increase the clarity of the prescribed dose. Additionally, the licensee has committed to using a new computational tool that includes automatic conversion of GBq to mCi. The licensee has started using a new radiopharmacy form that ensures accountability for activity calculations. At the request of the licensee, the manufacturer is now providing the activity of each dosage in GBq and mCi on the paperwork associated with each dose.

State — The North Carolina Radiation Protection Section performed a reactive inspection on March 2, 2017, and March 17, 2017. As a result of the inspection, the agency issued two violations for failure to follow state requirements.

This event is closed for the purpose of this report.

AS17-04 Medical Event at The Urology Center, Cincinnati, 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, 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 — March 2, 2017, Cincinnati, OH

Nature and Probable Consequences — On March 3, 2017, The Urology Center reported a medical event involving brachytherapy seed implant treatment for prostate cancer. The written directive prescribed a dose of 110 Gy (11,000 rad) to the treatment region (prostate gland) utilizing 90 iodine (I)-125 seeds (999 MBq (27 mCi) total/ (11.1 MBq (0.3 mCi) per seed — Theragenics® model AgX100). During the procedure, the AU placed the first three needles, and the urologist placed the last 21 needles under ultrasound guidance, which revealed that needle placement was correct.

However, the post-implant dosimetric evaluation using a computerized tomography (CT) scan performed on March 3, 2017, demonstrated that the dose delivered to the prostate was 27.6 Gy (2,760 rad), which was 25 percent of the prescribed dose. The CT images revealed that seeds from the last 21 needles were "dropped" approximately 1 centimeter inferiorly. The seeds did not end up in the rectum or the bladder, but in the most inferior aspect of the prostate extending down to the penile bulb (wrong treatment site). It is noted that the seeds "dropped" from the first three needles were placed adequately.

A medical physicist calculated the following D90 doses (dose that 90 percent of the volume received) to these structures: urethra = 26.02 Gy (2,602 rad); rectum = 8.61 Gy (861 rad); penile bulb = 86.89 Gy (8,689 rad). The licensee reports that there are no acute effects to the patient or side effects to the rectum, urethra, or the penile bulb. The licensee notified the patient on March 3, 2017, about the inadequate implant and that he needed a subsequent implant.

Cause(s) — The cause of the event was human error by the licensee staff. The placement of the needles by the urologist under ultrasound guidance was appropriate. However, the technique used to "drop" the seeds from the needles may have caused a 1-centimeter shift inferiorly in the placement of the seeds in the prostate gland.

Actions Taken To Prevent Recurrence

Licensee — Corrective actions included restricting the urologist participation in brachytherapy cases until he receives additional mentoring and training to verify the effectiveness of his needle placement and seed "dropping" technique.

State — The Ohio Department of Health investigated on March 22, 2017. The department issued no violations to the licensee because of this medical event.

This event is closed for the purpose of this report.

NRC17-03 Medical Event at Siouxland Urology Center, Dakota Dunes, South Dakota

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, 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 — March 16, 2017, Dakota Dunes, SD

Nature and Probable Consequences — On March 16, 2017, a patient at Siouxland Urology Center was administered 6.838 GBq (184.8 mCi) of Pd-103 in 110 brachytherapy seeds to the prostate. The written directive prescribed 5 GBq (135 mCi) in 80 seeds for a dose of 12,500 cGy (rad). However, the administered dose was 157.81 percent of the prescribed dose. The medical physicist identified the error immediately following the procedure, and the referring physician and patient were notified of the event. The licensee reported that no adverse health effects are expected as a result of the additional dose.

Cause(s) — This event was caused by the failure of the licensee's medical physicist to enter the correct activity per seed into the spreadsheet used for the physics calculations. The spreadsheet contained a value from a previous calculation that was incorrect for this patient and was carried over during the calculations. Additionally, an independent verification of the treatment data was not performed.

Actions Taken To Prevent Recurrence

Licensee — Corrective actions included requiring a new secondary hand calculation and revising procedures to require that a blank spreadsheet template be used. Additionally, new procedures call for all staff members to agree that all input parameters for treatment are correct before beginning the implantation of radioactive seeds. Current employees have been trained, and new employees will be trained, on these new procedures. The licensee will maintain records of this training in each employee's file.

NRC — The NRC conducted a reactive inspection and issued a notice of violation to the licensee on July 25, 2017, for a failure to develop, implement, and maintain written procedures to provide high confidence that each administration is performed in accordance with the written directive, to include checking both manual and computer-generated dose calculations. The licensee replied to the notice of violation on August 16, 2017.

This event is closed for the purpose of this report.

AS17-05 Medical Event at Ochsner Clinic Foundation, Baton Rouge, Louisiana

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, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place — April 20, 2017, Baton Rouge, LA

Nature and Probable Consequences — On April 20, 2017, Ochsner Clinic Foundation reported a medical event involving a patient who was administered 74 MBq (2 mCi) of I-131 when the patient was prescribed to receive 0.37 MBq (10 microcuries) of I-131 for a whole-body scan to image for possible metastatic progression of the patient's thyroid cancer. As a result, the patient's thyroid was estimated to have received a radiation dose of approximately 16.3 Gy (1,630 rad). The administration of the wrong dosage was discovered when a followup scan showed significantly higher uptake of I-131 in the thyroid than expected. The licensee determined that a nurse practitioner working under the supervision of an AU selected the wrong diagnostic test on the licensee's electronic ordering software. Additionally, the AU did not complete a written directive for the administered activity as required by the license.

The patient and referring physician were notified of this event. As a result of this event, the licensee determined that the patient could experience an increased risk of hypothyroidism; however, this outcome is not expected because of the patient's thyroid cancer. The licensee will perform blood tests to monitor the patient's thyroid function as medically necessary.

Cause(s) — This event was caused by human error by the licensee's staff. The nurse practitioner selected the wrong diagnostic test on the licensee's electronic software system, and the nuclear medicine technologist failed to verify that the activity ordered and received was that prescribed.

Actions Taken To Prevent Recurrence

Licensee — The licensee revised its procedures to require medical personnel to verify that the activity of ordered radiopharmaceuticals is equal to the activity prescribed and that the AU has completed a written directive when administering greater than 30 microcuries of I-131. The licensee also required training on its new procedures for all its technologists, ordering physicians, physician's assistants, nurse practitioners, and AUs. The licensee suspended use of I-131 for diagnostic purposes until the training is completed.

State — Louisiana investigated this medical event and verified that the licensee's corrective actions appear appropriate to prevent recurrence.

This event is closed for the purpose of this report.

NRC17-04 Medical Event at Providence Alaska Medical Center, Anchorage, Alaska

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, 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 — June 14, 2017, Anchorage, AK

Nature and Probable Consequences — On June 15, 2017, Providence Alaska Medical Center reported a medical event involving a patient who underwent Y-90 (TheraSphere® Model) microsphere brachytherapy treatment in the liver. Using a treatment plan worksheet, the Authorized User (AU) intended to prescribe a dose of 11,000 cGy (rad) to the right lobe of the liver based on the treatment plan. After the administration of Y-90 to the patient, the AU prepared, signed, and dated the written directive. Following the administration, the licensee determined that the patient had received a total of 54,000 cGy (rad) to the right lobe of the liver. As a result, the radiation dose to the right lobe of the liver was approximately 491 percent of the intended radiation dose from the treatment plan. The referring physician and patient were notified of the medical event. On December 8, 2017, the licensee reported that the patient is doing well without significant symptomatic complications as a result of the medical event.

Causes — The nuclear medicine technologist ordered the activity of Y-90 based on the AU's circled values on the treatment plan worksheet. The AU's circled values lacked clarity and as a result, the nuclear medicine technologist ordered an incorrect activity of Y-90. The activity of Y-90 required to administer the AU's planned radiation dose to the right lobe of the liver on the scheduled treatment date and time was 1.691 GBq (45.7 mCi); however, the nuclear medicine technologist ordered and received a vial of Y-90 that contained approximately 8.604 GBq (232.5 mCi) on the scheduled treatment date and time. The vial of Y-90 was measured by the nuclear medicine technologist prior to the administration and was documented to contain 8.550 GBq (231.1 mCi) of Y-90. The nuclear medicine technologist failed to compare the measured activity of Y-90 from the dose calibrator with the activity of Y-90 that was required to administer the planned dose to the right lobe of the liver, and therefore did not identify the discrepancy in activity. The vial of Y-90 was provided to the AU for administration to the patient. Before administering the Y-90 to the patient, the AU did not verify that the activity of the Y-90 prepared for administration by the nuclear medicine technologist was consistent with the activity required to administer the planned radiation dose. Following the administration of the incorrect activity of Y-90 to the patient, the written directive was prepared and the error was identified.

Actions Taken To Prevent Recurrence

Licensee — Corrective actions included (1) temporarily suspending all Y-90 procedures until the licensee reviewed the event, (2) reinforcing the regulatory requirements for having properly prepared, dated, and signed written directives before the administration of Y-90, (3) providing additional specific training from the Y-90 Therasphere® manufacturer/vendor to appropriate staff (nuclear medicine technicians, authorized users and auxiliary staff), (4) developing a standard operating procedure for the ordering of Y-90 doses and the preparation of Y-90 for administration, including revising procedures and forms used to order Y-90 doses, (5) using timeouts for verification purposes during the Y-90 administration process, and (6) performing a

simulation/dry run before the resumption of Y-90 procedures. The licensee reported that they resumed Y-90 TheraSphere® procedures on August 9, 2017, without incident.

NRC — The NRC conducted a reactive inspection of the reported event and an independent review of the causal factors that led to the medical event. Additionally, the NRC contracted with a physician and a medical physicist consultant to perform an independent determination of potential adverse effects on the patient. The NRC is currently reviewing the supplemental information provided by the licensee and the information from the NRC's medical consultants. The inspection effort is ongoing.

This event is open for the purpose of this report.

AS17-06 Medical Event at Mayo Clinic, Jacksonville, Florida

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, 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 — July 28, 2017, Jacksonville, FL

Nature and Probable Consequences — On July 28, 2017, a patient underwent Y-90 (TheraSphere®) microsphere brachytherapy for liver volume ablation. The AU prescribed 630 MBq (17 mCi) to the left lobe of the patient's liver for a total dose of 33,810 cGy (rad).

To achieve the prescribed dose, the volume of Y-90 needed for administration was calculated based on the decay difference between the vial calibration date and the treatment date listed on the final treatment plan. The scheduling nurse scheduled the patient for Friday, July 28, 2017 instead of Monday, July 31, 2017, when the final treatment plan listed for the procedure to take place.

On the day of the procedure, neither the pretreatment calculations performed by the physicist nor the timeout required by the licensee's procedures caught the change in treatment date. The half-life of Y-90 is 2.6 days, so the administered radioactivity on July 28 was twice as high as it would have been if administered on July 31.

The error was discovered when the residual waste container was surveyed immediately following treatment. The completed survey showed that the dose variation was high, and calculations performed by the licensee after the survey indicated that the patient received a total dosage of 1,500 MBq (40.56 mCi), which resulted in a dose of 80,780 cGy (rad) to the liver instead of the prescribed dosage of 630 MBq (17 mCi) or 33,810 cGy (rad).

The patient and referring physician were notified of the incident. The licensee reported that no adverse health effects are expected as a result of the additional dose. At the time of the treatment, the activity being administered, although high, was within practice standards for an ablative treatment. Because of the range for this type of treatment, the dosage did not register as an outlying variation.

Cause — The cause of the event was (1) error of the scheduling nurse in scheduling the patient for the procedure based on the pretreatment plan instead of the final treatment plan, and (2) the failure of the physicist's pretreatment calculations and the preadministration timeout (to confirm the ordered vial calibration activity and calibration date) to notice the change in treatment date.

Actions Taken To Prevent Recurrence

Licensee — The AUs use an electronic spreadsheet to calculate the patient radiation dose. This spreadsheet was modified to include a check to compare the number of days between the Y-90 calibration date and the treatment administration date to the Y-90 decay days used for treatment planning. If the values do not agree, the spreadsheet displays an error message. Additionally, the licensee added a step to its preadministration timeout procedure to include confirmation of the dose vial calibration activity, calibration date, and the administration date

according to the written directive. All licensee staff members who handle Y-90 treatments received training on the revised spreadsheet and procedure.

State — The Florida Bureau of Radiation Control inspected the licensee September 18–20, 2017, and issued no violations.

This event is closed for the purpose of this report.

NRC17-05 Medical Event at Washington University in St. Louis, St. Louis, Missouri

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, 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 18, 2017, St. Louis, MO

Nature and Probable Consequences — On August 18, 2017, Washington University in St. Louis treated a patient with Y-90 (Nordion Model TheraSphere®) microsphere brachytherapy for liver cancer. The AU prescribed 124 Gy (12,400 rad) by administering 1.74 GBq (47.03 mCi) to the left lobe of the liver. During the treatment, the interventional radiologist incorrectly placed the catheter in the right hepatic artery. The licensee inadvertently administered 1.71 GBq (46.2 mCi) to the right lobe of the patient's liver via the right hepatic artery. The catheter placement resulted in a dose to the right (unintended) lobe of the liver of 61 Gy (6,100 rad). The patient and prescribing physician were notified of this event. Because the right lobe was scheduled to receive treatment, the licensee does not expect any adverse health effects from this event.

Cause(s) — The NRC inspectors determined that the cause of the medical event was human error. The interventional radiologist mistakenly thought that the treatment site was the right lobe of the patient's liver, and he did not verify this assumption against the patient's treatment plan.

Actions Taken To Prevent Recurrence

Licensee — The licensee implemented the generic corrective actions as listed in the NRC17-01 abnormal occurrence event as reported on page 4 of this report. Corrective actions included increased communications between therapy staff and verification of the written directive.~~.~~" Specifically, the licensee revised its written directive procedure to include a review of the patient treatment plan immediately prior to a procedure.

NRC — The NRC performed a reactive inspection to review the circumstances, root and contributing causes, and proposed 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 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.

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 39, "Report to Congress on Abnormal Occurrences: Fiscal Year 2016," issued May 2017. This AO involved a medical event at Legacy Good Samaritan Medical Center in Portland, Oregon.

Medical Events at Legacy Good Samaritan Medical Center, Portland, Oregon (previously reported as AS15-08 in NUREG-0090, Volume 38, issued May 2016, and in Appendix B to NUREG-0090, Volume 39, issued May 2017)

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

Background — Legacy Good Samaritan Medical Center reported eight medical events associated with a gamma knife stereotactic radiosurgery unit (Leksell Gamma Knife® Perfexion™) that occurred between January 7, 2015, and February 12, 2015. Five of these events exceeded the 10-gray (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 (PPS) during maintenance that was performed on the unit between December 13, 2014, and January 1, 2015. The cause of the misalignment was human error resulting from an Elekta field service engineer's failure to follow correct procedures. As a result of the maintenance, the PPS was off target by 1.87 millimeters, causing the medical events. Following the event, the licensee established a new set of quality assurance tests, with the cooperation of Elekta (the manufacturer), to verify positioning.

Update on Actions Taken To Prevent Recurrence

State — The State of Oregon, Oregon Health Authority, Radiation Protection Services (RPS) completed a comprehensive investigation of the eight medical events. RPS revised its inspection focus to evaluate the following three areas:

(1) a reconstruction of the sequence of events leading to the misalignment of the PPS
(2) adequacy of Elekta's onboarding and training processes for the field service engineer who performed the misalignment
(3) adequacy of the applicable regulatory authority's regulations and license conditions

RPS identified the following as contributing factors:

- manufacturer service technician qualification, evaluation, and training
- communication and expectation issues among Elekta's field service technician, technical advisory group, and management

Legacy Good Samaritan has implemented corrective actions to ensure proper therapy alignment and address patient health and safety. RPS is evaluating both Federal regulations and Oregon Administrative Rules to determine if violations occurred.

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 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.

OEI 17-01 Human Exposure Event at the Department of Commerce, National Institute of Standards and Technology, Gaithersburg, Maryland

Date and Place — August 18, 2017, Gaithersburg, MD

The NRC included this event as a result of moderate media interest and increased NRC attention on the licensee including the initiation of a special inspection. This event involved a positive bioassay result on an individual who was exposed to a broken ampule containing 1.27 mCi of americium-241. On August 18, 2017, the U.S. Department of Commerce, National Institute of Standards and Technology (NIST), discovered that a flame-sealed glass ampoule that contained a well-characterized solution of amercium-241 with an activity of 47 MBq (1.27 mCi) had been broken. The activity was in a solution. The broken ampoule resulted in radioactive contamination of the countertop and other surfaces of a lead-shielded storage area within a room of the Gaithersburg campus. The contamination was discovered after wipe test results identified alpha contamination on a beta/gamma source located in the same storage area. NIST performed extensive surveys of the area and air monitoring and confirmed that the contamination was isolated to portions of that one room. NIST issued a stop work order for all other laboratories storing similar ampoules until the extent of the condition was evaluated or mitigated. NIST performed and received three bioassay results from personnel who were determined to be the most likely to be exposed to the contamination. One of the bioassays indicated that the individual was exposed. NIST consulted with the Oak Ridge Associated Universities Radiation Emergency Assistance Center/Training Site (REAC/TS) program to perform additional analysis of the individual. The NRC's Region I Office initiated a special inspection at the facility on September 26, 2017. The inspection is ongoing.

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.

Angiogram[1] — a radiograph made by the radiographic visualization of the blood vessels after injection of a radiopaque substance.

Authorized user — as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.2, "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.

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.

Dose equivalent (H_T) — as defined in 10 CFR 20.1003, "Definitions," the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest; the units of dose equivalent are the roentgen equivalent man (rem) and Sievert (Sv).

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[1] These terms are not defined in 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. These definitions are based on those 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 https://medlineplus.gov/mplusdictionary.html).

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.

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).

Hypothyrodism[1] — deficient activity of the thyroid gland; also a resultant bodily condition characterized by lowered metabolic rate and general loss of vigor.

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

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

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

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

Metastasis[1] — the spread of a disease-producing agent (such as cancer cells or bacteria) or disease from the initial or primary site of disease to another part of the body.

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."

Neuroendrocrine[1] — of, relating to, or being a hormonal substance that influences the activity of nerves and of, relating to, or functioning in neurosecretion.

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[1] — a specialist in using radiation therapy as a treatment for cancer.

Radiation therapy (radiotherapy)[1]— treatment in which high-energy rays are used to damage cancer cells and stop them from growing and dividing.

Radioembolization[1] — a cancer treatment in which radioactive particles are delivered to a tumor through the bloodstream.

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).

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 1/20th of 1 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.

Stereotactic radiosurgery — as defined in 10 CFR 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."

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