# Report to Congress on Abnormal Occurrences

Fiscal Year 2015

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 two medical events involving NRC licensees that the NRC identified as AOs during the fiscal year (FY) 2015 based on the criteria in Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." One event involved radiation exposure to an embryo/fetus during treatment of the patient, and the other event was a medical event as defined in Part 35 of Title 10 of the *Code of Federal Regulations*, "Medical Use of Byproduct Material."

In addition, this report describes fifteen medical events involving Agreement State licensees that have been identified as AOs during FY 2015 based on the criteria defined in this report's Appendix A. Agreement States are those States that have entered into formal agreements with the NRC, pursuant to Section 274 of the Atomic Energy Act of 1954, 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 seventeen AOs represent a small fraction of the average number of nuclear medicine and radiation therapy procedures conducted annually. In the United States in 2006, the number of diagnostic nuclear medicine procedures performed was 5,048,231, as reported in the National Council on Radiation Protection Report 160 – Ionizing Radiation Exposure of the Population of the United States (2009). The number of radiation therapy treatment procedures performed in 2013 was 1,016,565, as reported by the IMV Benchmark Report for Radiation Therapy (2014).

Appendix A to this report provides the NRC's criteria for identifying AOs, as well as the guidelines for identifying "other events of interest" (OEI). During FY 2015, the NRC identified no events that met the guidelines for inclusion in Appendix B, "Updates of Previously Reported Abnormal Occurrences." During FY 2015, the NRC identified three events that met the guidelines for inclusion in Appendix C, "Other Events of Interest," because these events attracted significant public interest. These events were a release of hydrogen fluoride at the Honeywell Metropolis Works Facility, a conversion facility located in Metropolis, Illinois; an event involving human exposure at International Isotopes Incorporated, Idaho Falls, Idaho; and a dual state (Oklahoma-Texas) contamination event from a generator operated by Tracerco at the University of Tulsa, Oklahoma. Appendix D, "Glossary," presents definitions of terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

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# 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) 2015, based on the criteria defined in this report's Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." Agreement States are those States that have entered into formal agreements with the NRC, pursuant to Section 274 of the Atomic Energy Act of 1954 (AEA) (Public Law 83-703), to regulate certain quantities of AEA material at facilities within their borders. The NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described here meet the criteria for being reported as AOs. For each AO, this report documents the date and place, nature and probable consequences, cause(s), and actions taken to prevent recurrence.

Four of the seventeen AOs included in this report occurred in previous fiscal years. The NRC completed its evaluation for these AOs in FY 2015. The NRC requires that information about AOs be complete to allow for adequate evaluation. Occasionally, all of the required information is not available in time to report an AO in the fiscal year of its occurrence.

It should be noted that the seventeen AOs represent a small fraction of the average number of nuclear medicine and radiation therapy procedures conducted annually. In the United States in 2006, the number of diagnostic nuclear medicine procedures performed was 5,048,231, as reported in the National Council on Radiation Protection Report 160 – Ionizing Radiation Exposure of the Population of the United States (2009). The number of radiation therapy treatment procedures performed in 2013 was 1,016,565, as reported by the IMV Benchmark Report for Radiation Therapy (2014).

Appendix A to this report provides the NRC's criteria for determining which events are identified as AOs, as well as the guidelines for identifying "other events of interest." Appendix B to this report is provided to supply updates of previously reported AOs; however, no events met the criteria to be included. During FY 2015, the NRC identified three events that met the guidelines for inclusion in Appendix C, "Other Events of Interest," because they attracted significant public interest. Appendix D, "Glossary," presents definitions of terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

## THE LICENSING AND REGULATORY SYSTEM

The system of licensing and regulation that the NRC uses to carry out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations*. The agency informs and involves stakeholders to ensure openness in the agency's regulatory process, consistent with the NRC's "Strategic Plan: Fiscal Years 2014–2018," (NUREG-1614, Volume 6, dated September 2014, Agencywide Documents Access and Management System

(ADAMS) Accession No. ML14246A439). The NRC regularly conducts licensing reviews, inspections, enforcement, investigations, operating experience evaluations, incident response, and confirmatory research. In addition, the agency involves the public in the regulatory process.

The NRC adheres to the philosophy that multiple levels of protection best ensure the health and safety of the public. 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 strives to make the regulatory system more risk-informed and performance-based, where appropriate.

## REPORTABLE EVENTS

The NRC initially issued the AO criteria in a Commission policy statement published in the *Federal Register* on February 24, 1977 (42 FR 10950), followed by several revisions in subsequent years. The most recent revision to the AO criteria was published in the *Federal Register* on October 12, 2006 (71 FR 60198), and became effective on that date. That revision established the criteria presented in Appendix A to this report, which the NRC used to determine which events are AOs.

Review of, and responses to, operating experience is 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 and security 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 effective collection, storage, retrieval, and evaluation.

The NRC routinely makes information and records on reportable events at licensed facilities available to the public. The NRC 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. The NRC routinely informs Congress of significant events, including AOs that occur at licensed facilities or involving licensed activities.

## AGREEMENT STATES

Section 274 of the AEA authorizes the Commission to enter into agreements with States whereby the Commission relinquishes and the States assume certain regulatory authority over byproduct, source, and certain quantities of special nuclear materials. States that enter into such agreements with the NRC are known as Agreement States. Under these agreements, Agreement States must maintain programs that are adequate to protect public health and safety, and are compatible with the Commission's program for such materials. At the end of FY 2015, there were 37 Agreement States.

Agreement States report event information to the NRC in accordance with compatibility criteria established by the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," which the agency published in the *Federal Register* on September 2, 1997 (62 FR 46517). The NRC also has put procedures into place for evaluating materials events 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.

## INTERNATIONAL INFORMATION

The NRC exchanges information with various foreign governments that regulate nuclear facilities and materials. This international 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 international information in its AO reports to Congress, the agency generally reports only domestic AOs.

## UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC supplies updates of previously reported AOs if significant new information becomes available. During this fiscal year reporting period, there were no updates to previously reported events.

## OTHER EVENTS OF INTEREST

The NRC provides information concerning other events of interest that are not reportable to Congress as AOs but are included in this report based on the Commission's guidelines, listed in Appendix A. During FY 2015, the NRC identified three events that met the guidelines for inclusion in Appendix C, "Other Events of Interest," because they attracted significant public interest.

# ABBREVIATIONS

| | |
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| ADAMS | the NRC's Agencywide Documents Access and Management System |
| AEA | Atomic Energy Act of 1954, as amended |
| AMP | authorized medical physicist |
| AO | abnormal occurrence |
| AS | Agreement State |
| CFR | *Code of Federal Regulations* |
| cGy | centigray(s) |
| Ci | curie(s) |
| cm | centimeter(s) |
| CT | computed tomography |
| DNR | Department of Natural Resources |
| EPIP | emergency plan implementing procedure |
| ERT | emergency response team |
| FMB | feed materials building |
| FR | *Federal Register* |
| FY | fiscal year |
| GBq | gigabecquerel(s) |
| GDC | general design criterion/criteria |
| Gy | gray(s) |
| HDR | high dose rate |
| IEP | Interim Enforcement Policy |
| MBq | megabecquerel(s) |
| mCi | millicurie(s) |
| MD | management directive |
| mm | millimeter(s) |
| mSv | millisievert(s) |
| NRC | U.S. Nuclear Regulatory Commission |
| OEI | other events of interest |
| rad | radiation absorbed dose |
| rem | roentgen equivalent man |
| ROP | Reactor Oversight Process |
| RSO | radiation safety officer |
| Sv | sievert(s) |
| TBq | terabecquerel(s) |
| TEDE | total effective dose equivalent |
| TS | technical specification |

# ABNORMAL OCCURRENCES IN FISCAL YEAR 2015

Appendix A supplies the specific criteria for determining whether an event is an abnormal occurrence (AO) and offers the guidelines for reporting other events of interest that may not meet the AO criteria, but which the U.S. Nuclear Regulatory Commission (NRC) has determined should be in this report. Appendix A contains four major categories:

I. All Licensees

II. Commercial Nuclear Power Plant Licensees

III. Events at Facilities other than Nuclear Power Plants and All Transportation Events

IV. Other Events of Interest.

Categories I, II, and III are discussed in this section, and Category IV events are discussed in Appendix C to this report.

## I. ALL LICENSEES

During this reporting period, one event involving an NRC licensee was significant enough to be reported as an AO based on Criterion I, "All Licensees," in Appendix A to this report.[1] Although the event occurred at a medical facility, it involved unintended exposure of an embryo, not the patient. Therefore, this event belongs under the Criterion I.A "Human Exposure to Radiation from Licensed Material," category, as opposed to the Criterion III.C, "Medical Licensees," category.

### NRC15-02 Human Exposure to Radiation Event at Department of the Army, Womack Army Medical Center in Fort Bragg, North Carolina

Criterion I.A.2, of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 millisieverts (mSv) (5 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—December 11, 2014, Fort Bragg, North Carolina

Nature and Probable Consequences—Department of the Army, Womack Army Medical Center (the licensee), reported that a pregnant patient received approximately 3.6 gigabecquerels (GBq), which equates to 97 millicuries (mCi) of iodine-131 (I-131) for thyroid ablation treatment.

[1] In the NRC's Fiscal Year 2015 Performance and Accountability Report (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1542/v21/) and 2017 Congressional Budget Justification (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1100/v32/), the agency reported two Abnormal Occurrences (AOs) involving NRC licensees that met or exceeded "AO Criteria 1.A.1, I.A.2, or I.A.3." in its performance indicators. However, upon further review the staff determined that there was only one event that met this AO criteria for 2015. The agency will review its processes to verify the accuracy of the performance indicator results reported in all future documents.

On December 31, 2014, the patient reported to the medical center that it had been determined that she was pregnant on the day of the treatment and the gestational age of the embryo was determined to be 2 to 4 weeks at the time of the thyroid ablation treatment. The Womack Army Medical Center's radiation safety officer (RSO) was notified of this event on January 5, 2015, by the authorizing physician. The licensee calculated an estimated dose of 204.3 milligrays, which is the equivalent to 20.43 rad, to the embryo from the procedure.

The patient and referring physician were informed of this event. The expected effect to the embryo was determined to be either miscarriage or no effect. The fetus developed normally and was born with no abnormalities noted.

Cause(s)—The cause of this event was a false negative pregnancy test that the licensee performed approximately 1.5 hours before the dosage administration and the patient's lack of awareness that she was pregnant.

Actions Taken To Prevent Recurrence

Licensee—The licensee modified its "I-131 Patient Questionnaire" to include a question about the status of the patient with regard to pregnancy to help increase the patient's awareness of possible pregnancy. The licensee revised its "Radiation Safety Precautions for the Home After Release" to include instructions for the patient to follow if she learns she was pregnant at the time of the treatment, which included a specific phone number to call during working hours and after working hours. A refresher session was held with all applicable authorized users (AUs) about the reporting requirements.

NRC—The NRC conducted an inspection from January 21, 2015, through March 4, 2015. The NRC identified one Severity Level IV violation of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3047(c) for failure to notify the NRC by the next calendar day following the discovery of an unintended dose to an embryo/fetus.

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 Criterion II in Appendix A to this report.

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

During this reporting period, one event at an NRC licensee and fifteen events at Agreement State licensee facilities were significant enough to be reported as AOs, based on Criterion III in Appendix A to this report.

### NRC15-01 Medical Events at University of Michigan in Ann Arbor, Michigan

Criteria III.C.1.b and III.C.2.a of Appendix A to this report provide that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 gray (Gy), or 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 at least 50 percent greater than that prescribed.

Date and Place—November 17, 2006, through January 6, 2010, Ann Arbor, Michigan

Nature and Probable Consequences—The NRC identified four medical events at the University of Michigan (the licensee), which occurred between November 2006 and January 2010 involving four patients. The events were associated with brachytherapy procedures using iodine-125 (I-125) seed mesh implants for lung cancer treatments. Each patient was prescribed approximately 100 Gy (10,000 rad) to his or her lung tissue at 5 millimeters (mm) from the center of the mesh, but instead the patients were administered doses that were 40 percent, 74 percent, 99 percent, and 114 percent greater than prescribed. The referring physicians were informed of these events. In accordance with 10 CFR 35.3045(e), the licensee did not inform the patients of these events because, based on medical judgment, the referring physicians determined that telling the patients would be harmful.

On October 1, 2014, the NRC informed the licensee that all four events met the criteria to be reported as medical events. However, in accordance with the Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting (IEP), dated July 9, 2013 (78 FR 41125), the NRC did not take enforcement action against the licensee for failure to report the events. In the IEP, the Commission authorized the staff to exercise enforcement discretion for existing and future violations of the current section 35.3045(a)(1)(i) medical event reporting requirement when a treatment site total dose equals or exceeds 120 percent of the prescribed dose, provided that the treatment would not have to be reported based on other criteria such as the dose exceeding regulatory limits to adjacent, normal tissue. In all four cases, all conditions were met to exercise the enforcement discretion granted in the IEP. The licensee determined that none of the procedures resulted in harm to the patient or caused excessive dose to an unintended treatment site. Further the licensee determined that the doses to tissues other than the treatment site did not exceed reportable limits.

Cause(s)—The licensee determined, and the NRC confirmed, that the cause of the events was that the prescribed doses of approximately 100 Gy (10,000 rad) were determined assuming the seed mesh lies flat after implantation. However, due to re-inflation of the lung after surgery, the mesh curved such that the concave surface of the mesh faced the lung tissue. Because of the curved mesh, the I-125 sources contained in the mesh were located closer to the treatment site, which resulted in the treatment sites receiving higher doses than prescribed.

Actions Taken To Prevent Recurrence

Licensee—The licensee has suspended conduct of this treatment protocol and has no plans in the foreseeable future to resume its use.

NRC—The NRC exercised enforcement discretion via the IEP dated July 9, 2013. The NRC is undertaking a rulemaking that will amend 10 CFR Part 35. One element of this rulemaking is an amendment to the medical event reporting criteria that will establish criteria for permanent implant brachytherapy medical event reporting that are activity-based, because activity-based criteria are more appropriate for this treatment method than dose-based criteria. If approved by the Commission, these criteria would be effective in 2017 and would supersede the IEP at that time.

This event is closed for the purpose of this report.

**AS15-01 Medical Event at an Unspecified City, New York**[2]

Criterion III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 25, 2013, Unspecified Licensee, New York

Nature and Probable Consequences—The New York State Department of Health reported that a medical event occurred associated with an I-125 radioactive seed implantation. During the radioactive seed localization procedure, the surgeon successfully removed the tumor and lymph node; however, the seed had migrated deeper into tissue (wrong treatment site) and was not removed. The surgeon determined that the migrated seed location prevented safe extraction due to scarring from previous node removal, mastectomy, and reconstructive surgery. The licensee calculated a localized dose at 0.5 cm from the seed of 2,290 centigray (cGy or rad) and negligible dose at 6 cm. The patient, referring physician, medical oncologist, and radiologist were notified. The State withheld the licensee name and location in accordance with N.Y. Pub. Health Law § 2805-m.

Cause(s) — The New York State Department of Health did not provide the cause of the medical event.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions included discontinuation of radioactive seed localization procedure for axillary node lesions.

State — The New York State Department of Health did not provide the actions taken to prevent reoccurrence.

This event is closed for the purpose of this report.

[2] The State of New York Department of Health did not provide the facility name or location for the two AOs that it reported and informed the NRC that withholding this information is consistent with New York State Public Health Law § 2805-l.

**AS15-02 Medical Event at Abington Memorial Hospital in Abington, Pennsylvania**

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

Date and Place — August 15, 2013, Abington, Pennsylvania

Nature and Probable Consequences—Abington Memorial Hospital (the licensee) discovered and subsequently reported a medical event on March 10, 2014, that occurred on August 15, 2013, that was associated with an yttrium-90 microspheres infusion procedure for treatment of cancer in the liver. On August 15, 2013, the patient was treated with 1,339.77 megabecquerels (MBq), the equivalent of 36.21 mCi, with a prescribed dose of 107 Gy through the right hepatic artery. On September 6, 2013, the physician noted that the patient was experiencing intermittent abdominal pain. On October 10, 2013, the patient was administered 188.33 MBq (5.09 mCi) through the proximal left hepatic artery and 179.45 MBq (4.85 mCi) through the distal left hepatic artery. On February 24, 2014, the patient was admitted because of severe anemia and suspected gastrointestinal bleeding. On February 27, 2014, endoscopy revealed a duodenum lesion and an ulcer that had developed seemingly because of microspheres migrating to the stomach (wrong treatment site) yielding an unknown dose. The licensee determined that the delivered dose was 160 Gy to the liver; however, the licensee stated they could not determine the dose to the stomach. A dose greater than 10 Gy is required in order for pain and gastrointestinal bleeding, as experienced by this patient, to occur. The patient and referring physician were informed of this event.

Cause(s) — The cause of the medical event was determined to be the migration of microspheres through an aberrant hepatic arterial vasculature supplying the stomach.

Actions Taken To Prevent Recurrence

Licensee — The licensee reevaluated its procedure with the manufacturer's guidance.

State — Pennsylvania performed a full reactive inspection to investigate this event.

This event is closed for the purpose of this report.

**AS15-03 Medical Event at Affiliated Oncologists in Mokena, Illinois**

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 10 through March 14, 2014, Mokena, IL

Nature and Probable Consequences – Affiliated Oncologists of Southland Oncology (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) brachytherapy treatment for breast cancer using 314.5 GBq (8.5 Ci) of iridium-192. The patient was prescribed a total dose of 34 Gy (3,400 rad) in 10 fractionated doses to a treatment volume of the left upper quadrant of the breast (treatment site). However, it was determined that the skin at the incision site for the catheter (wrong treatment site) received a dose of 100 Gy (10,000 rad). The patient and referring physician were informed of this event upon its discovery on March 25, 2015.

On June 24, 2014, the patient returned to the licensee to discuss a non-healing breast wound that occurred following the treatment. The patient was referred to her surgeon who excised some additional tissue associated with the injury at that time. However, no connection was made between a potential medical event and the observed injury at the site until an investigation was conducted at another facility that utilized the same HDR equipment and support services. From a review of the results of that investigation, it was determined that the same error resulted in the dose to the wrong treatment site. This error was a default entry in the treatment planning system that was not correctly changed during treatment planning, which led the source placement to be rotated 180 degrees along the applicator's long axis.

Cause(s) – The medical event was caused by human error. The medical physicist failed to change a default entry in the treatment planning system as required by the licensee's procedure. Further, the licensee did not have a procedure in place to independently review the prepared plan to ensure with high confidence that the plan would be implemented appropriately.

Actions Taken to Prevent Recurrence

Licensee – The licensee has suspended future treatments pending completion of remedial actions including establishment of a review plan for all treatment plans by an independent authorized medical physicist and the use of a documented pre-treatment checklist.

State – The Illinois Emergency Management Agency conducted an on-site investigation into the circumstances surrounding the event and program management. The Agency issued citations regarding the failure to ensure adequate testing of the treatment planning system with the applicator system and the failure to establish adequate written procedures to ensure administrations were in accordance with written directives.

This event is closed for the purpose of this report.

**AS15-04 Medical Event at Presence Resurrection Medical Center in Chicago, Illinois**

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 — October 3 through 9, 2014, Chicago, IL

Nature and Probable Consequences – Presence Resurrection Medical Center (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for breast cancer using 257 GBq (6.95 Ci) of iridium-192. The patient was prescribed a total dose of 34 Gy (3,400 rad) in 10 fractionated doses to a treatment volume of the left breast (treatment site). However, it was determined that the skin at the incision site for the catheter (wrong treatment site) received a dose of 130 Gy (13,000 rad). The patient and referring physician were informed of this event.

On November 21, 2014, the patient returned to the licensee to discuss a non-healing breast wound that occurred following the treatment. The referring physician requested a review of the treatment plan. Following an investigation, it was determined that a default entry in the treatment planning system was not correctly changed during treatment planning. This led to the source reference location being misplaced by 4 cm along the applicator's long axis. This resulted in the dose to the wrong treatment site. A retrospective review of eight other cases at the facility revealed similar errors but none meeting the criteria of an AO. The licensee recommended that the best course of action was to perform a mastectomy, which was completed at another facility after receiving the patient's consent.

Cause(s) — The medical event was caused by human error. The medical physicist failed to change a default entry in the treatment planning system as required by the licensee's procedure. Further, the licensee did not have a procedure in place to independently review the prepared plan to ensure with high confidence that the plan would be implemented appropriately.

Actions Taken to Prevent Recurrence

Licensee — The licensee has modified the treatment and planning checklists to include verification of catheter orientation by two independent personnel before each fraction, and different planning software and hardware systems are now being used. Additionally, services have been converted from a third party provider to in-house resources.

State — The Illinois Emergency Management Agency conducted an on-site investigation into the circumstances surrounding the event and the program management. The Agency issued citations regarding the failure to ensure adequate testing of the treatment planning system with the applicator system and the failure to establish adequate written procedures to ensure administrations were in accordance with written directive.

This event is closed for the purpose of this report.

**AS15-05 Medical Event at MedStar Montgomery Medical Center (formerly University of Maryland), Helen P. Denit Cancer Center in Olney, Maryland**

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

Date and Place — December 10, 2014, Olney, Maryland

Nature and Probable Consequences — MedStar Montgomery Medical Center (formerly University of Maryland), Helen P. Denit Cancer Center (the licensee) reported that a medical event occurred during a brachytherapy procedure for prostate cancer treatment. The patient was prescribed a total dose of 10,800 cGy (rad) to the prostate using 53 iodine-125 (I-125) seeds on December 10, 2014. However, on December 10, 2014, the post implant computed tomography (CT) revealed that all seeds missed the prostate and were deposited in an unintended area of soft tissue at the base of the patient's penis, not in the prostate, resulting in a dose of 10,800 cGy to normal tissue at the base of the penis (wrong treatment site). The patient and referring physician were informed of the event. The licensee concluded that there were no noted medical effects based on this abnormal occurrence.

Cause(s) — Before patient treatment, the vendor serviced the licensee's ultrasound unit, which was used to guide the insertion of the prostate seeds. After service and prior to the patient treatment, some of the calibration settings were changed. The licensee failed to identify those changes and used the improperly calibrated ultrasound unit.

Actions Taken To Prevent Recurrence

Licensee — The licensee put procedures into place to ensure efficacy of the ultrasound unit after servicing and before use. Additionally, in the future, the licensee will ensure that the urologist and oncologist have demonstrated competency in using the ultrasound equipment by clearly identifying the prostate gland and the surrounding anatomy before implantation of seeds. During the procedure, the ultrasound technologist will also be available to troubleshoot any ultrasound equipment issues.

State — The State conducted an onsite reactive inspection on December 19, 2014. The inspection results indicated that several violations occurred that contributed to the event. The RSO failed to put adequate procedures into place that would offer a high confidence that the prescribed radioactive material (53 I-125 seeds) were implanted as prescribed by the written directive. As a result, the licensee failed to establish appropriate procedures, through compliance with the written directive, necessary to prevent the occurrence of a medical event. The licensee failed to follow appropriate procedures that would offer a high degree of confidence that the prescribed radioactive material (53 I-125 seeds) was implanted in the intended organ.

This event is closed for the purpose of this report.

**AS15-06 Medical Event at Christus St. Vincent Hospital, in Santa Fe, New Mexico**

Criteria III.C.1.b and III.C.2.b of Appendix A to this report provide that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) and represents a dose delivered to the wrong individual or human research subject.

Date and Place — December 17, 2014, Santa Fe, New Mexico

Nature and Probable Consequences — Christus St. Vincent Hospital (the licensee) reported that a medical event occurred during a radioiodine thyroid ablation procedure on December 17, 2014. The patient was prescribed 1.1 GBq (30 mCi) of I-131 resulting in a dose of 80 Gy (8,000 rad) to the thyroid. The wrong dose vial was selected from the cart and the patient received 5.3 GBq (143.2 mCi) of I-131 resulting in a dose of 379 Gy (37,900 rad) to the thyroid. This delivered dosage was approximately 400 percent greater than the prescribed dosage to the patient. The administering individual identified the medical event immediately and notified the patient and referring physician of this event. The licensee concluded there were no adverse health effects expected because of the medical event.

Cause(s) — The cause of the medical event was the selection of a dose vial prescribed for another patient and the failure to review the written directive as required by the licensee's quality management program before administering the dosage.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions included revision of the policy used for patient ID and written directive for radiopharmaceutical administration to ensure that a patient's identity is verified before administering the dose. Additionally, the licensee informed its staff of the event and put corrective actions put into place.

State — The State is currently reviewing all information. Once all information is compiled and reviewed, the State's Radiation Control Bureau will meet with its Office of General Counsel for disposition.

This event is closed for the purpose of this report.

**AS15-07 Medical Event at an Unspecified City, New York**

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 7, 14, and 19, 2015, Unspecified City, NY

Nature and Probable Consequences—The New York State Department of Health reported that a medical event occurred associated with a high dose rate brachytherapy treatment using an iridium-192 source for endometrial cancer. The patient was prescribed three fractional doses of 700 cGy (rad) each to a vaginal treatment volume. Following the completion of treatment, the patient reported bilateral labial itch, dryness, and tingling around the treatment area. The patient was referred to a dermatologist who identified a radiation reaction. A review of the films that had been taken to confirm the placement of the Ir-192 source revealed that the source was placed inferior to the treatment site and exterior to the opening of the vagina for all three fractions, resulting in a total dose of 2,100 cGy to the outer vaginal mucosa and upper thigh (wrong treatment site) and minimal dose to the intended treatment site. The patient and referring physician were notified.

Physical examination showed signs of radiation exposure in the vulvar area and on the skin of the upper inner thigh. Potential short term effects include progression of these skin reactions and possible urinary and rectal irritation. Long term effects may include thickening of the skin and the mucosa, development of scar tissue and urinary track and rectal issues. This patient continues care under a gynecological oncologist, a dermatologist, and a radiation oncologist as needed. The State withheld the licensee name and location in accordance with N.Y. Pub. Health Law § 2805-m.

Cause(s) — The causes of the medical event were determined to be the incorrect assembly of the applicator by nursing staff who were not trained for the task and the Authorized User's (AU) lack of experience with this type of applicator. The AU failed to verify the positioning of the applicator by visual inspection and to detect the incorrect positioning of the applicator in the patient on the verification image, attributing the poor image quality to the patient's obesity.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions included providing training to AUs on the correct assembly and insertion of the applicator; adding a bead dummy source to the end of the tandem and obtaining orthogonal images for verification for every treatment session; ensuring that the full length of the vaginal cylinder is visible on every image; having the verification images reviewed and approved by both the AU and a New York State licensed/registered Radiation Therapy Technologist or an authorized medical physicist (AMP) prior to treatment; and having the AU sign and date a written statement that the cylinder and tandem positioning was verified and found to be in accordance with the approved treatment plan that will go into the patient's medical record.

State — The New York State Department of Health required a root cause analysis, held a conference call with the licensee, and conducted a site visit that included interviews of staff, review of the quality assurance program, and training. The State determined that the licensee's root cause analysis, corrective action and preventive measures were acceptable. The Department of Health will continue to monitor the licensee's implementation of the corrective actions during subsequent inspections.

This event is closed for the purpose of this report.

**AS15-08 Medical Events at Legacy Good Samaritan Medical Center in Portland, Oregon**

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 7, 2015, to February 12, 2015, in Portland, OR

Nature and Probable Consequences — Legacy Good Samaritan Medical Center (the licensee) reported eight medical events associated with a gamma knife (Elekta's Perfexion unit), which contained 244,200 GBq (6,600 Ci) of cobalt-60 at the time of treatments. Five of these events exceeded the 10 Gy (1,000 rad) dose threshold in the abnormal occurrence criterion listed above. The medical events involved gamma knife therapy treatment for acoustic neuromas and metastatic brain tumors for the eight patients. All eight patients received the prescribed dose, ranging from 7 to 24.9 Gy (700 – 2490 rad), to the wrong location due to manufacture misalignment of the patient positioning system. The misalignment of the patient positioning system occurred during an Elekta's (maintenance provider) maintenance that was performed on the gamma knife unit between December 13, 2014 and January 1, 2015. As a result, the positioning system was off-target by 1.87 mm, which resulted in delivering the following doses to the patients to the wrong treatment site (normal tissue) (January 7 to February 12, 2015): patient 1 – 5 fields, maximum 24.9 Gy (2490 rad); patient 2 – 6 fields, maximum 24.6 Gy (2460 rad); patient 3 – 2 fields, maximum 16.8 Gy (1680 rad); patient 4 – 3 fields, maximum 19.1 Gy (1910 rad); patient 5 – 3 fields, maximum 23.1 Gy, (2310 rad); patient 6 – right acoustic neuroma, maximum 7 Gy,(700 rad); patient 7 – right acoustic neuroma, maximum 9.1 Gy (910 rad); and patient 8 – left acoustic neuroma, maximum 9.3 Gy, (930 rad). All patients and referring physicians were notified of the events. Patients were informed of the results associated with their individual cases. Effects from the resulting doses to the patients are still to be determined.

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.

Actions Taken to Prevent Recurrence

Licensee — The licensee is in the process of establishing a new set of tests, with the cooperation of Elekta. After any form of service, the absolute output of the unit will be checked and "pin prick" films will be taken to verify positioning. The licensee has permanently instituted a weekly "pin prick" film and focus precision check at the end of the day prior to the first gamma knife procedure of each week. In addition, the licensee also has added a consistency check as part of its monthly quality assurance routine.

State — The Oregon Health Authority is requesting information from Elekta (maintenance provider) to complete their investigation of the events.

This event is open for the purpose of this report.

**AS15-09 Medical Event at Abbott Northwestern Hospital in Minneapolis, Minnesota**

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 29, 2015, Minneapolis, Minnesota

Nature and Probable Consequences—Abbott Northwestern Hospital (the licensee) reported that a medical event occurred associated with a yttrium-90 (Y-90) microsphere procedure to treat liver cancer. The licensee prescribed a dose of 130 Gy (13,000 rad) from 1 GBq (27 mCi) of Y-90 TheraSpheres to a portion of the left lobe of the liver (the treatment site). A post-delivery scan revealed that the microspheres were delivered to the right lobe of the liver (wrong treatment site) rather than the left lobe, resulting in a dose of 43.7 Gy (4,370 rad) to the right lobe from 0.87 GBq (23.5 mCi) of Y-90. The patient and referring physician's partner were informed of this event; the referring physician was not available the day of the event. The licensee indicated that treatment of the right lobe of the liver was planned for an unspecified time in the future. Because of this event, the patient received a dose to the right lobe of the liver, but less than would have been given during the planned future treatment. The licensee will monitor the patient and offer additional therapy to the right lobe if necessary. Treatment will be given to the left lobe as originally planned. The licensee expects that the clinical outcome for the patient will not change because of this incident.

Cause(s) — The catheter delivering the microspheres was placed in the wrong artery because of a lack of clarity due to the fact that the patient's vessels were small and similar in appearance.

Actions Taken To Prevent Recurrence

Licensee — For future procedures, the licensee will have an image available from the planning angiogram with the vessels clearly labeled to refer to during placement of the catheter during microsphere delivery.

State — An onsite investigation was performed on June 11, 2015. The Minnesota Department of Health accepted the licensee's corrective actions.

This event is closed for the purpose of this report.

**AS15-10 Medical Event at Riverside Medical Center in Kankakee, Illinois**

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

Date and Place — June 2, 2015, Kankakee, IL

Nature and Probable Consequences — Riverside Medical Center (the licensee) reported that a medical event occurred associated with a yttrium-90 microsphere procedure treatment for metastatic cancer lesions in the liver; the treatment consisted of 1,302 MBq (35.2 mCi) of yttrium-90. On June 2, 2015, the patient was administered 1,302 MBq (35.2 mCi) of yttrium-90 microspheres through the wrong infusion site (the renal artery). Due to the error, the patient received an unintentional dose of 1,345 Gy (134,500 rad) to the right kidney (wrong treatment site).

The patient was informed of the error and consented to receive a second administration of 1,300 MBq (35 mCi) of yttrium-90 microspheres through the correct infusion site (the hepatic artery) to deliver the prescribed dose to the liver (the correct treatment site) that same day. The referring physician was also informed of this event. The patient was subsequently hospitalized for observation with no adverse complications noted. The patient has received regular monitoring since the event and no renal dysfunction or clinically significant radiation nephritis has been observed. The patient has received a second treatment to the liver for cancer.

Cause(s) — The cause of the medical event was determined to be human error. Due to the patient's unusual anatomy and poor imaging, the accessory right renal artery was mistaken for the hepatic artery.

Actions Taken To Prevent Recurrence

Licensee — The licensee has amended administration procedures to require that mapping images as well as CT images are available to the physician in the treatment room and these images will be compared with contrast images taken pre-dose administration to ensure treatment of the correct target site. Additionally, the licensee has amended procedures to require a review and verification of correct catheter placement by a second physician, and will develop a formal written checklist to be completed prior to each patient administration.

State — The Illinois Emergency Management Agency conducted an on-site investigation into the circumstances surrounding the event, patient follow-up, and the program management. The Agency's investigation revealed that the matter was sufficiently addressed by the licensee's corrective actions and the event warranted no citations.

This event is closed for the purpose of this report.

**AS15-11 Medical Event at Radiotherapy Clinics of Georgia, Conyers, Georgia**

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 — June 8, 2015, Conyers, Georgia

Nature and Probable Consequences—Radiotherapy Clinics of Georgia/Vantage Oncology (the licensee) reported that a medical event occurred during a patient treatment for endometrium cancer using a vaginal cylinder applicator. The treatment was delivered in three fractions from June 8 to June 17, 2015. The licensee used two different HDR Varian GammaMed Plus brachytherapy units, each containing a separate iridium-192 (Ir-192) source of 370 GBq (10 Ci) during the course of treatment. The three fractions were delivered with the first two fractions being performed using the same HDR unit and the third fraction being performed using a different HDR unit. Each fraction was prescribed to deliver 600 cGy (rad), for a total of 1,800 cGy (rad) to the treatment site. However, on a follow up exam the patient revealed two small sores on the skin of both her upper thighs. The radiation oncologist believed the marks were consistent with radiation dermatitis. The licensee discovered the incident on July 20, 2015, and determined that the third fraction was not administered as prescribed. Computer reconstruction of the event revealed that the dose delivered to the patient's skin was 4,000 cGy (rad) at a depth of 0.2 cm. The patient also received 33 percent less dose to the intended site than prescribed by the written directive.

Cause(s) — The cause of the medical event was determined to be incorrect assembly of the vaginal cylinder applicator. The physicist failed to inspect the applicator before administration.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions included putting procedures into place with specific requirements for the HDR simulation process to ensure that applicators are inspected for integrity before and after HDR procedures, requiring physicists to inspect all applicators before insertion, and requiring application of position verification marks on patient and inspection of marks before and after treatment. The licensee also expanded annual HDR training to include applicator handling, patient safety considerations, and review of current policies and procedures.

State — The Georgia Department of Natural Resources (DNR) conducted a reactive inspection on July 24, 2015. After interviewing personnel and reviewing documentation supplied by the licensee, the department determined that a reportable medical event occurred. The DNR issued violations in accordance with Rule 391-3-17-.05(20)(a) and (b)(2) and -.05(31)(d).

This event is closed for the purpose of this report.

## AS15-12 Medical Event at Radiotherapy Clinics of Georgia, Snellville, Georgia

Criteria III.C.1.b and III.C.2.a of Appendix A to this report provide 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 — June 9, 2015, Snellville, Georgia

Nature and Probable Consequences — Radiotherapy Clinics of Georgia (the licensee) reported that the dose administered to a patient treated for skin cancer on the nose exceeded the prescribed dose by more than 50 percent. The patient was treated using an HDR GammaMed Plus Varian brachytherapy unit with a 370-GBq (10-Ci) Ir-192 source. The physician's written directive specified a dose to the tumor volume and a maximum tumor dose of 130 percent of that prescribed. The total dose was delivered in eight fractions using a skin applicator from June 9 to July 2, 2015. The prescribed dose was 500 cGy/fraction (rad/fraction) for a total dose of 4,000 cGy (rad), with a maximum dose of 650 cGy/fraction (rad/fraction) for a total maximum dose of 5,200 cGy (rad). On a follow-up exam, the patient's skin reaction was more drastic than anticipated. The estimated dose received by the patient's target was 950 cGy (rad) for five fractions and 700 cGy (rad) for three fractions, for a total of 6,850 cGy (rad). The incident resulted in the patient receiving a dose 71.25 percent greater than prescribed.

Cause(s) — The cause of the medical event was determined to be a deficient treatment plan developed by a junior medical physicist. The licensee did not have documented procedures for the treatment plan in accordance with the written directive.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions included developing, documenting, and training personnel on specific procedures for verification of the physician's written directive and for the review of treatment plans before patient treatment. The licensee also put into place an HDR physics peer review to include review of prescription and treatment plans, evidence of appropriate quality assurance checks at each step, and appropriate documentation of HDR procedures.

State — The Georgia DNR conducted a reactive inspection on July 20, 2015, and, upon interviews with personnel involved and reviews of documentation pertaining to this report provided by the licensee, it was determined that a reportable medical event occurred. The State issued the violations in accordance with GA Rules 391-3-17-.05(20(a) & (b)(2) and 391-3-17-.05(31)(d).

This event is closed for the purpose of this report.

**AS15-13 Medical Event at University Hospitals of Cleveland in Cleveland, Ohio**

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 — July 14, 2015, Cleveland, Ohio

Nature and Probable Consequences — University Hospitals of Cleveland (the licensee) reported that a medical event occurred associated with a yttrium-90 (Y-90) microsphere procedure to treat liver cancer. The licensee prescribed a dose of 78 Gy (7,800 rad) from 758.5 MBq (20.5 mCi) of Y-90 SIR-Spheres® to the right lobe of the liver (the treatment site).

During the microsphere treatment, the procedure was discontinued because the administering physician, who was also the referring physician, determined that the dose was not being delivered to the liver. A post-delivery CT scan revealed that the microspheres were delivered to an area of 20 to 30 cm of the small bowel (wrong treatment site), resulting in a dose of 36 Gy (3,600 rad) from 288.2 MBq (7.79 mCi).

The patient was informed of this event on July 14, 2015. The patient experienced some abdominal pain approximately 3 weeks after the procedure. The patient was examined and admitted to a local hospital. A CT scan of the patient's abdomen and pelvis identified abnormal inflammation to a short segment of the small bowel, but no acute perforation or ulcers. The patient was discharged, and the licensee spoke to the patient on August 10, 2015. At that time, the patient presented with some abdominal discomfort or pain, which was relieved by prescribed pain medications.

Cause(s) — The cause of the medical event was determined to be that the fluoroscopy table may have been moved during the procedure, causing the microcatheter used to administer the Y-90 to change positions from the hepatic artery to the superior mesenteric artery. After the table and consequently the microcatheter were moved, a fluoroscopy of the patient was not performed, resulting in the licensee not identifying the relocated microcatheter in the patient's arteries before Y-90 SIR-Sphere administration.

Actions Taken To Prevent Recurrence

Licensee — Licensee staff members reviewed this event to emphasize the critical steps of radioembolization, "hard stop" times, and verification of microcatheter location for future Y-90 administrations. The licensee communicated to staff the importance of using intermittent fluoroscopy throughout Y-90 microsphere administrations.

State — The State investigated on July 30, 2015, to gather the facts surrounding the incident and to confirm the licensee followed required regulations, guidance, and procedures. A notice of violation was issued on August 26, 2015. An adjudication order and administrative penalty order were issued on September 16, 2015.

This event is closed for the purpose of this report.

## AS15-14 Medical Event at Wellstar Kennestone Hospital, Marietta, Georgia

Criteria III.C.1.b and III.C.2.a of Appendix A to this report provide 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 — August 5, 2015, Marietta, Georgia

Nature and Probable Consequences — Wellstar Kennestone Hospital (the licensee) reported that a patient received 900 cGy (rad) instead of the prescribed 300 cGy (rad) during one fraction of the treatment. Equipment used during the patient's cervical cancer treatment used a 185-GBq (5-Ci) Ir-192 source in a cervical applicator. The patient received 300 cGy (rad) during the first and second fractions. The source dwell time during the third fraction was 1,128 seconds instead of the correct time of 350 seconds. The patient received a total dose of 1,500 cGy (rad) during the three fractions instead of the intended 900 cGy (rad), which is a 66-percent increase over the prescribed dose. The patient was informed of the event on August 8, 2015.

Cause(s) — The cause of the medical event was determined to be software discrepancies, miscommunication between staff members, and failure to verify the treatment plan. The physicist used the wrong treatment plan (one that had been developed earlier for the patient) during the third fraction.

Actions Taken To Prevent Recurrence

Licensee — Licensee has implemented the following: Standardized language to include dose per fraction and total dose for radiation prescription; added "Verification of treatment plan" to the existing checklist; investigated Flexitron's missing safety feature and possible recall with vendor; evaluated adding MOSAIQ interface module to Flexitron; and started daily meetings within Radiation Oncology. All disciplines within the department will attend the meeting, which includes an assessment of staffing.

State —The State conducted an inspection on August 7, 2015. After interviewing personnel and reviewing documentation supplied by the licensee, the State determined that a reportable medical event did occur. The State did not issue any violations for this event.

This event is closed for the purpose of this report.

## AS15-15 Medical Event at Wake Forest Baptist Health, Winston-Salem, North Carolina

Criteria III.C.1.b and III.C.2.b(iii) of Appendix A to this report provide 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 — October 1, 2015, Winston-Salem, North Carolina

Nature and Probable Consequences — Wake Forest Baptist Health (the licensee) reported that a patient with trigeminal neuralgia received a gamma knife treatment to the wrong site on October 1, 2015. The patient was prescribed 8,500 cGy (rad) to a site in the right side of the brain at the 100-percent isodose line, but instead received the treatment to the left side of the brain. The 80-percent isodose line was approximately 33.5 cubic mm and was prescribed 6,800 cGy (rad). The incident was identified as patient treatment was completed. Medical personnel involved in the treatment reviewed, discussed, and confirmed the incident. The licensee determined that the isocenter was positioned incorrectly because of human error. The RSO was contacted and he notified the North Carolina Department of Health and Human Services. The patient was notified of the event by the attending neurosurgeon and then received the correct treatment that same day. The attending radiation oncologist notified the referring physician later the same day.

Cause(s) — The cause of the medical event was determined to be that the isocenter was positioned incorrectly because of human error. The incorrect side was targeted during treatment planning.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions included modifying the target identification procedure followed for identifying major anatomical features. This target designation process will be signed by the AMP performing treatment and the AU who prescribed the treatment. This will be followed by an independent timeout and target verification before treatment is performed. The AMP will perform a visual examination of the patient's position immediately before irradiation. The AMP's visual observation of patient's positioning will be recorded in writing.

State — The State conducted an onsite investigation of this event on October 5, 2015. The licensee agreed to conduct an internal root cause analysis of this event and to report the basic findings of the analysis to North Carolina upon completion. Furthermore, the licensee agreed to immediately put into place three changes to its procedures for gamma knife treatment of trigeminal neuralgia.

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; or

(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 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.

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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."

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

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

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)].

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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.

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

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

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

B. For Fuel Cycle Facilities

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, no events met the guidelines for inclusion in Appendix B, “Updates of Previously Reported Abnormal Occurrences,” as an update to previous years’ “Report to Congress on Abnormal Occurrences.”

# APPENDIX C
# OTHER EVENTS OF INTEREST

This appendix discusses other events of interest that do not meet the abnormal occurrence (AO) criteria in Appendix A but have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the U.S. Nuclear Regulatory Commission (NRC) to increase its attention to or oversight of a program area. This appendix includes updates to other events of interest (OEI) reported in previous AO reports to Congress.

There are three other events of interest that meet the above criteria to report for FY 2015.

**OEI 15-01 Cesium-137 contamination associated with University of Tulsa, Oklahoma**

The NRC included this event in this report as an Other Event of Interest because it involved radioactive material contamination in an area accessible by members of the public. It received a moderate amount of local media coverage.

Radioactive contamination occurred in a process building at the University of Tulsa (TU) from about October 14 through October 17, 2014, when technicians breached the containment of a Cesium-137/Barium-137(m) isotope generator used to elute radioactive material for injection into a closed pipeline research apparatus. Technicians for Tracerco, a Texas licensee working in Oklahoma under a reciprocity filing, modified a malfunctioning generator they were using. Their modifications caused the release of an estimated 3.7MBq (0.1mCi) of cesium-137 (Cs-137) that contaminated the process building area during their four day test.

Tracerco technicians returned to TU on two other occasions in November and December 2014 and used the same generator to elute radioactive material for flow studies. The breach of the generator's containment was undetected until May 2015, when Tracerco detected radioactive contamination at its Texas facility. The modified generator was identified as the contamination source. A Tracerco technician returned to TU on June 10, 2015, to survey for possible contamination; however, he did not survey the process building where the contamination existed due to the presence of workers there who were performing a system upgrade.

On August 24, 2015, after Tracerco's investigation revealed the breach had occurred in the process building, Tracerco personnel returned to TU, surveyed the process building and discovered the radioactive contamination. They also identified small levels of radioactive contamination in some other locations near the process building. Tracerco performed a partial decontamination of the process building area and reported the contamination event to the Oklahoma Department of Environmental Quality (OKDEQ), the Agreement State regulatory authority.

OKDEQ conducted a reactive inspection on August 27, 2015, and verified elevated radiation readings at some locations in and near the process building. OKDEQ calculated that one member of the public may have exceeded the regulatory limit of 100 mrem/year. OKDEQ's inspection activity for this event was ongoing as of the compilation of this report.

TU identified 51 individuals who were potentially exposed to the Cs-137 contamination. Urinalysis testing was performed on a majority of these individuals. None of the urinalysis tests identified any detectable uptakes of Cs-137. Eleven University employees underwent additional whole body radiation scanning. Whole body scans for all eleven individuals did not identify any detectable Cs-137.

Tracerco contracted with an environmental remediation service to characterize and remediate the site. The contractor arrived on-site on August 31, 2015, and located several other areas of contamination both at TU and off-site at a private residence. As of the compilation of this report, site remediation was nearly complete.

**OEI 15-02 Honeywell Metropolis Works: Uranium Hexafluoride Release**

The NRC included this event in this report because of the media attention the event received and increased attention by the NRC. Specifically, the visible leak of hydrogen fluoride outside[1] the Honeywell Metropolis Works process buildings (which resulted from a leak of uranium hexafluoride ($UF_6$) within the plant) and the migration of the plume toward the site boundary fence. Furthermore, the event received a significant level of media attention because videos of the release were recorded by bystanders and posted on social media. The event was of further interest because members of the public notified the NRC of the event before Honeywell supplied such notification. The event did not pose a public safety hazard and did not require any protective actions for members of the public.

On October 26, 2014, at approximately 7:20 p.m. CST, in Metropolis, Illinois, Honeywell identified a leak of $UF_6$ from a heated cold trap inside the feed materials building (FMB). The leak occurred during a routine sublimation and draining of a cold trap. A cold trap is a large tank where $UF_6$ accumulates, is cooled and solidified, and can be later heated and drained during normal plant operations. Operators noticed a haze in the FMB, and an operator confirmed the leak by donning a respirator and observing the conditions on the fourth floor of the FMB.

Honeywell emergency responders followed established emergency procedures, which included sounding the plant emergency alarm, shutting down all processes, declaring a plant emergency, and accounting for all personnel. Honeywell identified the cause of the leak as a crack in a weld between the body and head of the cold trap. Honeywell declared an "all clear" at 2:16 a.m. CST on October 27, 2014, and reported no significant injuries.

NRC inspectors followed up on the event and determined that Honeywell's emergency response team (ERT) members performed their roles and responsibilities to mitigate the leak. However, the ERT did not properly classify the event as an "Alert."[2] NRC inspectors determined that any $UF_6$ that may have traveled beyond the Honeywell fence line would have been of such low concentration that it would not pose a public safety hazard and would not require any protective actions.

Because the event was not properly classified, Honeywell failed to notify the NRC Operations Center within 1 hour. The NRC Operations Center was initially made aware of the $UF_6$ release by calls from the public. The Operations Center received cellphone videos from local residents on social media and phone calls from local government agencies the following morning.

On November 7, 2014, the NRC issued a Confirmatory Action Letter EA-14-183 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14311A670). Honeywell determined the cause of the misclassification of the $UF_6$ release to be inadequate visual observation and deficiencies in the emergency plan implementing procedures (EPIPs) regarding event classification. Honeywell agreed to review and revise its emergency preparedness procedures and conduct appropriate training to ensure that events will be

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1 When $UF_6$ is released, the $UF_6$ reacts with water vapor in the air to form hydrogen fluoride and uranyl fluoride.

2 Section 3.2.2 of the Honeywell Emergency Response Plan defines an "Alert," in part, as "an event that deviated from normal operating conditions creating a hazardous environment requiring an emergency response to mitigate a hazardous situation that either initiates or migrates outside of plant buildings and stays within the restricted area or inner fence line."

classified correctly and that appropriate emergency response actions are put into place. NRC inspectors reviewed Honeywell's revised EPIPs and observed the conduct of its emergency exercise on November 12, 2014. NRC inspectors concluded that Honeywell effectively put into place corrective actions, and Honeywell resumed licensed operations on November 13, 2014.

On January 30, 2015, the NRC issued an Inspection Report 40-3392/2014-005 (ADAMS Accession No. ML15030A166) with an apparent violation for the failure to declare an Alert during the release. The NRC subsequently issued a Severity Level III violation on April 20, 2015 (ADAMS Accession No. ML15110A228).

**OEI 15-03 Human Exposure Event at International Isotopes Incorporated, Idaho Falls, Idaho**

The NRC included this event in this report because of the unusual human exposure and the media attention the event received.

International Isotopes Incorporated (the licensee), located in Idaho Falls, Idaho, reported to NRC Region IV on August 20, 2015, that an occupational whole body overexposure and an occupational extremity overexposure occurred earlier that morning during a routine cobalt-60 (Co-60) source drawer transfer procedure. A technician was transferring a Co-60 source drawer from a shielded cask to a medical therapy head. The technician attempted to withdraw the Co-60 source drawer from the cask slightly to remove a handling tool that was attached to the drawer. The technician inadvertently withdrew the drawer fully from the shielded cask, exposing the Co-60 source. He caught the falling source by its extension and quickly re-inserted it into the cask. It has been determined that human error, due to poor coordination and control of the task, caused the event.

The technician was briefly exposed (for approximately 4 seconds) to a very high activity Co-60 source containing 135.57 terabecquerel (3,664 Ci). The technician was exposed to a peak exposure rate of 37.39 Gy/hr (3,739 rad/hour) from the Co-60 source. The calculated occupational whole body dose to the technician was 56.2 mSv (5.62 rem) and the calculated occupational extremity maximum dose was 384 mSv (38.4 rem). The event was not considered to be a clinically significant exposure.

The incident was reported as an International Nuclear and Radiological Event Scale level 3 event.[3]

The technician has not exhibited and is not expected to have any observable medical effects from either the whole body or the extremity dose.

The licensee corrective actions included personnel training and procedure modification. NRC Region IV dispatched inspectors to the facility on August 21, 2015, and again on September 14, 2015.

[3] According to the International Nuclear and Radiological Event Scale (INES) User's Manual 2008 Edition, an INES level 3 incident is the minimum level for events that result in: (1) "The occurrence or likely occurrence of a non-lethal deterministic effect or (2) Exposure leading to an effective dose greater than ten times the statutory annual whole body dose limit for workers."

# APPENDIX D
# GLOSSARY

**Acoustic Neuroma**[1]—a benign tumor that may develop on the hearing and balance nerves near the inner ear.

**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.

**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.

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

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

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1. 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).

**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.

**Endometrial Cancer**—cancer of the womb (uterus).

**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.

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

**Interstitial** [2]—situated within, but not restricted to or characteristic of, a particular organ or tissue; used especially of fibrous tissue.

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

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

(1) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 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;

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2. This term is not defined in 10 CFR, an MD, an inspection procedure, or an NRC policy statement. Rather, it is 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).

(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** [3]—a specialist in using radiation therapy as a treatment for cancer.

**Radiation Therapy (Radiotherapy)**[3]—treatment in which high-energy rays are used to damage cancer cells and stop them from growing and dividing. A specialist in radiation therapy is called a "radiation oncologist."

**Reactive Inspection**—as defined in U.S. Nuclear Regulatory Commission (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.

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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 MedicineNet's "Online MedTerms Medical Dictionary." MedicineNet is an online service part of WebMD (*see* http://www.medterms.com).

**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 rems).

**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, determines to be special nuclear material, but not including source material; or (2) any material artificially enriched by any of the foregoing but not including source material.

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

**Thyroid Ablation Treatment**—deactivate thyroid tissue using radioactive iodine.

**Trigeminal Neuralgia** [4]—inflammation of the trigeminal nerve (the fifth cranial nerve) that most commonly causes paroxysms of very intense lightning pain in the areas of the face the nerve supplies—the lips, eye, nose, scalp, forehead, gums, cheek, and chin—on the involved side of the face. A less common "atypical" form of the disease causes a more constant, dull, burning, or aching pain.

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

**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."

[4] This term is not defined in 10 CFR, an MD, an inspection procedure, or an NRC policy statement. Rather, it is 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 |