Report to Congress on Abnormal Occurrences

Fiscal Year 2012

Revision 1

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 four events involving NRC licensees that the NRC identified as AOs during fiscal year (FY) 2012 based on the criteria defined in Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest." The first event at an NRC-licensed facility was an occurrence at a commercial nuclear power plant. The other three events occurred at NRC-licensed medical institutions and are medical events, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material."

In addition, this report describes 18 events that Agreement States identified as AOs during FY 2012, based on the criteria in Appendix A to this report. 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 radioactive material within their borders. Currently, there are 37 Agreement States. The first Agreement State licensee event involved radiation exposure to an embryo/fetus and the second event involved an exposure to a radiographer. The other 16 Agreement State licensee events were medical events, as defined in 10 CFR Part 35. Two of the 16 Agreement State licensee medical events involve multiple medical events at the same treatment facility; however, one event report is provided for each of these two events.

Appendix A to this report presents the NRC's criteria for selecting AOs, as well as the guidelines for selecting "other events of interest." Appendix B, "Updates of Previously Reported Abnormal Occurrences," provides updated information for three events reported in the FY 2011 "Report to Congress on Abnormal Occurrences." The update involves a radiation exposure event at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas; a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama; and a medical event at Lovelace Medical Clinic in Albuquerque, New Mexico. During FY 2012, the NRC identified eight additional items as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest." Five of these events occurred at nuclear power plants, one event involved a medical treatment device, one event involved a lost well logging source, and the last event involved a fuel cycle facility. Appendix D, "Glossary," presents definitions of terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

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INTRODUCTION

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

This report describes those events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 2012, based on the criteria defined in 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 radioactive material 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. Two of the Agreement State licensee AOs involved permanent prostate brachytherapy implants, which involved multiple medical events at two treatment facilities. Because each of these two event descriptions address the licensee's permanent prostate brachytherapy implant program as a whole, one event report is provided for each of these two events.

Appendix A to this report presents the NRC's criteria for selecting AOs, as well as the guidelines for selecting other events of interest. Appendix B, "Updates of Previously Reported Abnormal Occurrences," provides updated information for three events reported in NUREG-0090 Volume 34, "Report to Congress on Abnormal Occurrences Occurrences—FY 2011," dated May 2012 (see Agencywide Documents Access and Management System (ADAMS) Accession No. ML12142A194). The update involves a radiation exposure event at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas; a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama; and a medical event at Lovelace Medical Clinic in Albuquerque, New Mexico. During FY 2012, the NRC identified eight additional events as meeting the guidelines for inclusion in Appendix C, "Other Events of Interest." Five of these events occurred at nuclear power plants, one event involved a medical treatment device, one event involved a lost well logging source, and the last event involved a fuel cycle facility. 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 the NRC uses to carry out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations* (10 CFR). The agency informs and involves stakeholders to ensure openness in the agency's regulatory process, consistent with the NRC's "Strategic Plan for FY 2008–2013 (Updated)," (NUREG-1614, Volume 5, dated February 2012). The NRC regularly conducts licensing reviews, inspections, enforcement, investigations, operating experience evaluations, incident response, and confirmatory research. The NRC also conducts other technical reviews and studies to support its regulatory and oversight responsibilities. In addition, the agency involves the public as an essential element in the regulatory process.

The NRC adheres to the philosophy that the health and safety of the public are best ensured by establishing multiple levels of protection. The agency normally achieves and maintains these levels through regulations specifying requirements that ensure the safe and secure use of radioactive materials. Those regulations contain design, operation, and quality assurance criteria appropriate for the various activities regulated by the NRC. Licensing, inspections, investigations, and enforcement programs provide a regulatory framework to ensure compliance with the regulations. In addition, the NRC is striving to make the regulatory system more risk-informed and performance-based, where appropriate.

REPORTABLE EVENTS

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

Review of and responses to operating experience are essential to ensure that licensees conduct their activities safely. Toward that end, the regulations require that licensees report certain incidents or events to the NRC. Such reporting helps to identify deficiencies and ensure that corrective actions are taken to prevent recurrence.

The NRC and its regulated industries review and evaluate operating experience to identify safety concerns. The NRC responds to risk-significant issues through licensing reviews, inspections, and enhancements to regulations. In addition, the agency maintains operational data in computer-based data files for more effective collection, storage, retrieval, and evaluation.

The NRC also routinely disseminates (to the public, industry, and other interested stakeholders) publicly available information and records on reportable events at licensed or regulated facilities. The agency achieves this dissemination through public announcements and special notifications to licensees and other stakeholders. To widely disseminate information to the public, the NRC also issues a *Federal Register* notice describing AOs that occurred in the previous fiscal year at facilities licensed or otherwise regulated by the NRC or Agreement States. In addition, the NRC routinely informs Congress of reportable events, including AOs.

AGREEMENT STATES

Section 274 of the AEA, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes and the States assume certain regulatory authority over byproduct, source, and certain quantities of special nuclear materials. States that enter into such agreements with the NRC are known as Agreement States. Agreement States must maintain programs that are adequate to protect public health and safety and are compatible with the Commission's program for such materials. At the end of FY 2012, 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 developed and carried out procedures for evaluating materials events to identify those that should be reported as AOs. Toward that end, the NRC uniformly applies the AO criteria (in Appendix A to this report) to events at licensees regulated by either the NRC or the Agreement States. In addition, in early 1977, the Commission determined that the annual report to Congress should include events that meet the criteria for AOs at licensees regulated by Agreement States. The *Federal Register* notice that the NRC issues to disseminate AO-related information to the public includes AOs involving Agreement State licensees.

FOREIGN INFORMATION

The NRC exchanges information with various foreign governments that regulate nuclear facilities and materials. This foreign information is reviewed and considered in the NRC's research and regulatory activities, as well as in its assessment of operating experience. Although the NRC may occasionally refer to such foreign information in its AO reports to Congress, the agency generally reports only domestic AOs.

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC provides updates of previously reported AOs if significant new information becomes available. Appendix B provides updated information for three events reported in NUREG-0090, Volume 34, "Report to Congress on Abnormal Occurrences—FY 2011," dated May 2012 (see ADAMS Accession No. ML12142A194). The update involves a radiation exposure event at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas; a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama; and a medical event at Lovelace Medical Clinic in Albuquerque, New Mexico.

OTHER EVENTS OF INTEREST

The NRC provides information concerning events that are not reportable to Congress as AOs but are included in this report based on the Commission's guidelines, as listed in Appendix A. During FY 2012, the NRC identified eight other events of interest as meeting the guidelines for inclusion in Appendix C. Five of these events occurred at nuclear power plants, one event involved a medical treatment device, one event involved a lost well logging source, and the last event involved a fuel cycle facility.

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AMP	authorized medical physicist
AO	abnormal occurrence
AS	Agreement State
ASR	alkali-silica reaction
AU	authorized user
BD	Bracco Diagnostics, Inc.
CAL	confirmatory action letter
CFR	*Code of Federal Regulations*
Ci	curie
cm	centimeter
cm^3	cubic centimeter
CT	computed tomography
DBNPS	Davis-Besse Nuclear Power Station
DSHS	Texas Department of State Health Services
ERP	emergency response plan
FCS	Fort Calhoun Station
FDA	U.S. Food and Drug Administration
FMB	feed material building
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel
gpd	gallons per day
Gy	gray
HDR	high dose rate
INES	International Nuclear and Radiological Event Scale
IMC	Inspection Manual Chapter
KDPH	Kentucky Department of Public Health
LPCI	low-pressure coolant injection
MBq	megabecquerel
MRI	magnetic resonance imaging
µCi	microcurie
mCi	millicurie
MDH	Minnesota Department of Health
mm	millimeter
mrem	millirem
mSv	millisievert
NG	nasogastric
NOUE	notice of unusual event
NOV	Notice of Violation
NRC	U.S. Nuclear Regulatory Commission
ODH	Ohio Department of Health
OPPD	Omaha Public Power District
ORNL	Oak Ridge National Laboratory
PA DEP	Pennsylvania Department of Environmental Protection
RCP	reactor coolant pump

rem	roentgen equivalent man
RHR	residual heat removal
SAR	safety analysis report
SAT	station auxiliary transformer
SIT	special inspection team
SIRWT	safety injection refueling water tank
SONGS	San Onofre Nuclear Generating Station
Sv	sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
TS	technical specifications
TVA	Tennessee Valley Authority
UF_6	uranium hexafluoride
WDHS	Wisconsin Department of Health Services

ABNORMAL OCCURRENCES IN FISCAL YEAR 2012

The following briefly explains the numbering system used in this section of the report. Appendix A provides the specific criteria for determining when an event is an abnormal occurrence (AO) and provides the guidelines for reporting other events of interest that may not meet the AO criteria, but which the Commission has determined should be in this report. Appendix A contains four major categories: I. All Licensees, II. Commercial Nuclear Power Plant Licensees, III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events, and IV. Other Events of Interest. Categories I, II, and III are discussed in this section and Category IV events are discussed in Appendix C to this report. The identification number for all Agreement State licensee AO reports starts with "AS." Similarly, the identification number for all U.S. Nuclear Regulatory Commission (NRC) AO reports starts with "NRC."

I. ALL LICENSEES

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

AS12-01 Embryo/Fetus Exposure to Radiation at Lankenau Hospital in Wynnewood, Pennsylvania

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 millisieverts (mSv) [5 roentgen equivalent man (rem)] or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

Date and Place—October 6, 2011, Wynnewood, PA

Nature and Probable Consequences—Lankenau Hospital (the licensee) reported that a patient received 2.7 gigabecquerel (GBq) (73.7 millicuries (mCi)) of iodine-131 for thyroid ablation therapy. Before the treatment, the patient informed the licensee that she was not pregnant, and was administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Therefore, the licensee administered iodine-131 to the patient.

On October 26, 2011, the patient became aware that she was pregnant. The licensee contacted the patient's obstetrician/gynecologist and was informed that an ultrasound confirmed that she was approximately 10 days pregnant at the time of the iodine-131 treatment. The NRC contracted a medical consultant, who estimated a fetal or embryo dose of 174 mSv (17.4 rem) and stated that embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, this tissue had not yet formed at the time of the treatment. The medical consultant concluded that there was a low possibility of carcinogenesis or malformations.

Cause(s)—The cause of this event was the inability of the pregnancy test to provide a positive determination of pregnancy in close proximity to conception.

Actions Taken To Prevent Recurrence

Licensee—The licensee assessed the event and determined that it is following best practices by ordering a pregnancy test and relying on its results.

State—The Pennsylvania Department of Environmental Protection (PA DEP) conducted a followup inspection to review this incident and collect information from the medical consultant and the licensee to complete this review. PA DEP has no further action planned for this event.

This event is closed for the purpose of this report.

AS12-02 Human Exposure to Radiation at Non-Destructive Inspection Corporation, in Pasadena, Texas

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, exposure to an adult (any individual 18 years of age or older) resulting in an annual TEDE of 250 mSv (25 rem) or more, shall be considered for reporting as an AO.

Date and Place—March 24, 2012, Pasadena, TX

Nature and Probable Consequences—The Non-Destructive Inspection Corporation (the licensee) reported that a radiographer received a TEDE of 293.2 mSv (29.3 rem). The licensee reported that the drive cable of a radiography camera containing 2.41 terabecquerels (TBq) (65.1 curies (Ci) of iridium-192 broke, and the source pigtail disconnected from the drive cable inside the source guide tube. The radiographer trainer disconnected the source guide tube from the exposure device and placed it around his neck while he climbed down the ladder of a scaffold. The source was in the guide tube at that time, but its location within the guide tube is uncertain. When the radiographer trainer reached the platform he removed the guide tube from his neck. He then noted that the other radiographer was having problems disconnecting the crank assembly from the exposure device and that the exposure device locking mechanism was still unlocked.

Radiation surveys were performed of the exposure device and source guide tube. Radiation levels revealed that the source was within the guide tube. The radiographer trainer picked up the guide tube with long tongs and the source fell out of the guide tube onto the floor. An authorized individual responded to the site and performed source retrieval. The radiographer trainer's film badge was processed and read 0.812 mSv (81.2 mrem). During event reenactment, it was determined that the source guide tube was around the radiographer trainer's neck for approximately 35 seconds. The licensee calculated and assigned an estimated TEDE dose of 293.2 mSv (29.3 rem). The event was reported as a Level 2 (incident) on the International Atomic Energy Agency's International Nuclear and Radiological Event Scale (INES).

Cause(s)—The cause of this event was corrosion of the drive cable and improper maintenance coupled with the failure of the operators to perform the proper radiation surveys.

Actions Taken To Prevent Recurrence

Licensee—The corrective action taken by the licensee included a complete cessation of operations and review of the incident with every radiographer in the company; and an inspection of all of the licensee's equipment, with replacement as needed. The radiographer trainer was retrained and re-tested. The licensee stated it will incorporate routine equipment maintenance and inspections performed by the manufacturer.

State—The Texas Department of State Health Services (DSHS) collected information from the licensee, including medical surveillance information, and completed its review of the event and the licensee's corrective actions. DSHS cited both the licensee and radiographer trainer with several violations associated with this event.

This event is closed for the purpose of this report.

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, one event at a commercial nuclear power plant in the United States was significant enough to be reported as an AO based on the criteria in Appendix A to this report.

NRC12-01 Commercial Nuclear Power Plant Event at Fort Calhoun Station, Unit 1, in Fort Calhoun, Nebraska

Criteria II.C and II.D, "For Commercial Nuclear Power Plant Licensees," of Appendix A to this report provide, in part, that a commercial nuclear power plant event shall be considered for reporting as an AO if it results in any reactor conditions or performance indicators that are determined to be of high safety significance (red findings) or are in a shutdown condition as a result of significant performance problems or operational events.

Date and Place—June 7, 2011, Fort Calhoun, NE

Nature and Probable Consequences—The Omaha Public Power District (OPPD) (the licensee) reported a commercial nuclear power plant event at Fort Calhoun Station (FCS), Unit 1, a single pressurized-water reactor designed by Combustion Engineering. On June 7, 2011, a fire started in a recently replaced safety-related electrical breaker in an electrical switchgear room at the plant. The fire resulted in FCS declaring an alert because the fire impacted safety-related equipment. The catastrophic failure of the replacement breaker and subsequent fire resulted in a large quantity of soot and smoke. The soot and smoke were sufficiently conductive that arcing occurred and the feeder breaker for the redundant train of electrical switchgear tripped. Operators took action to isolate equipment potentially affected by the fire. The event resulted in the loss of the spent fuel pool cooling function and could have resulted in the loss of a safety function or multiple failures in systems used to mitigate an event had the event occurred at power. The reactor was shutdown at the time of the fire.

The NRC determined that the event represented a finding of high safety significance (red finding). The basis for this determination was the high fire frequency given the short period of time that the replacement breaker had been in service, the significant damage caused by the failure, and the fact that the event affected both trains of safety equipment. The public was never endangered because the plant was in cold shutdown for a planned refueling outage at the time of the fire. Significantly less safety equipment is required in this plant condition to safely cool the fuel. However, had this event occurred while the plant was operating at power, the response to the event would have been much more complex.

Cause(s)—The direct cause of the fire was the high electrical resistance of the replacement breaker and the lack of proper cleaning and tightening of the electrical switchgear. Additionally, the area of the electrical connection was found to be full of hardened grease and copper oxide because of poor electrical maintenance practices by the licensee.

Actions Taken To Prevent Recurrence

Licensee—As a result of the event and other factors, OPPD has maintained FCS in a shutdown condition. Through its root cause analysis process, the licensee preliminarily determined that a wiring discrepancy caused the fire to spread to the opposite safety-related electrical train. The licensee also performed checks to ensure the wiring discrepancy is no longer present in the plant on the replacement equipment or other similar equipment.

NRC—The NRC transitioned FCS oversight from that described in Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program," to that described in IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition due to Significant Performance and/or Operational Concerns." The IMC 0350 process for FCS was implemented to:

- Establish a regulatory oversight framework as a result of significant performance problems and a significant operational event.
- Ensure the NRC communicates a unified and consistent position in a clear and predictable manner.
- Establish a record of actions taken and technical issues resolved.
- Verify that corrective actions are sufficient for restart.
- Provide assurance that, following restart, the plant will be operated in a manner that provides for adequate protection of public health and safety.

On February 26, 2013, the NRC issued a revised Confirmatory Action Letter (EA-13-020) "Confirmatory Action Letter-Fort Calhoun Station," (available at Agencywide Documents Access and Management System (ADAMS) Accession No. ML13057A287) for the purpose of confirming those actions that the NRC determined will need review or inspection before the restart of the plant. This revision supplemented two previously issued confirmatory action letters (ADAMS accession Nos. ML112490164 and ML12163A287) that confirmed actions that were necessary prior to restart. This revision was issued to incorporate three additional items to the Restart Checklist, that relate to (1) qualifications for containment electrical penetrations, (2) containment internal structure deficiencies, and (3) a number of safety system functional failures resulting in the associated performance indicator crossing into the white threshold. Prior to the NRC terminating the CAL and allowing FCS to restart, the NRC will verify that the licensee's corrective actions adequately address all of the items detailed on the restart checklist.

This event is open for the purpose of this report.

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

During this reporting period, three events at NRC licensees and 16 events at Agreement State licensees were significant enough to be reported as AOs, based on the criteria in Appendix A to this report.

AS12-03 Medical Event at Greenville Memorial Hospital in Greenville, South Carolina

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

Date and Place—September 15, 2009, Greenville, SC

Nature and Probable Consequences—Greenville Memorial Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment for liver cancer involving 1.7 GBq (45.9 mCi) of yttrium-90. The patient was prescribed to receive a total dose of approximately 13 Gy (1,300 rad) to the liver, but instead, received a dose of approximately 26 Gy (2,600 rad) to the liver. This delivered dosage was approximately 100 percent greater than the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On September 17, 2009, the licensee notified the South Carolina Department of Health and Environmental Control that following an infusion of radioactive yttrium-90, a postprocedure record review revealed that the patient was administered 1.7 GBq (45.9 mCi) of yttrium-90 versus the prescribed dose of 0.94 GBq (25.4 mCi). Upon investigation, it was discovered by the licensee that errors occurred both while preparing the treatment and estimating the activity from the written directive. Upon medical followup, the patient had good tumor response with no adverse medical effects.

Cause(s)—The cause of the medical event was human error in failing to administer the correct activity as stated on the written directive.

Actions Taken To Prevent Recurrence

Licensee—The licensee corrective actions included: (1) mandatory refresher training for all participants in this event, (2) implementation of a requirement to confirm the prescribed dose by two nuclear medicine technologists prior to administration, (3) implementation of a requirement for the written directive to be typed or printed with the dose amount highlighted, and (4) discussion of the event and corrective actions at the next meeting of the Radiation Safety Committee.

State—The South Carolina Department of Health and Environmental Control conducted an investigation on September 17, 2009, and determined that no items of non-compliance were noted. The State forwarded the final update of this event to the NRC on October 18, 2012.

This event is closed for the purpose of this report.

AS12-04 Medical Event at the Duke University Medical Center in Durham, North Carolina

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

Date and Place—October 22, 2010, Durham, NC

Nature and Probable Consequences—Duke University Medical Center (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) endobronchial brachytherapy treatment for small cell lung cancer. The treatment involved the use of 199.8 GBq (5.4 Ci) of iridium-192 split between two treatment catheters. The patient was prescribed to receive two doses of 10 Gy (1,000 rad) for a total dose of 20 Gy (2,000 rad) to the tumor site. However, the direction of the catheters was reversed during treatment, resulting in a dose of 20 Gy (2,000 rad) to the voice box (wrong treatment site). The patient and referring physician were informed of this event.

On October 22, 2010, the medical staff initially identified the locations of the two treatment catheters using computed tomography (CT) images. During the treatment, the direction of the catheters was mistakenly reversed. This changed the starting position of the HDR source and resulted in the dose being delivered to the voice box rather than targeted treatment site on the left side of the patient's airway. The patient exhibited minor swelling of the voice box, but no airway compromise, hoarseness, shortness of breath, or painful swallowing. The licensee concluded that the medical event would not have a significant medical effect on the patient. The patient was subsequently given the correct total dose in a followup treatment.

Cause(s)—The cause of the medical event was human error in that the oncology staff failed to correctly place and verify the position of the two treatment catheters. A contributing factor to the cause of the event is that the oncology staff infrequently uses two catheters to simultaneously deliver doses during HDR treatments.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included: (1) a root-cause analysis of the event, (2) development of a more detailed standard operational procedure for this type of treatment, (3) a revised HDR patient quality assurance form to include extra levels of verification, and (4) a new verification procedure. The licensee also provided training on the revised procedures for all radiation oncology staff approved to conduct HDR therapy.

State—The North Carolina Division of Radiation Protection conducted an investigation on December 14, 2010, and identified several procedural weaknesses in the licensee's HDR program. One item of noncompliance was issued and the State forwarded the final update of this event to the NRC on November 28, 2012.

This event is closed for the purpose of this report.

AS12-05 Medical Events at Our Lady of Bellefonte Hospital in Ashland, Kentucky

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

Date and Place—October 3, 2001 through February 24, 2009 (reported on December 13, 2010), Ashland, KY

Nature and Probable Consequences—The Kentucky Department of Public Health (KDPH) identified a medical event at Our Lady of Bellefonte Hospital (the licensee) associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 132.8 Gy (13,280 rad) to the prostate using 105 palladium-103 seeds, but instead, the patient received an approximate dose of 131 Gy (13,100 rad) to the penile bulb (glans) (wrong treatment site). The patient and referring physician were not informed of this event because the licensee believed that the treatment was satisfactory. However, the patient was subsequently informed of this event during a consultation at another medical treatment facility.

The licensee was unable to perform a dose assessment of the affected tissue due to the radiation oncologist's inadequate postprocedure seed implant records. The patient sought a second opinion from a different radiation oncologist, who performed a CT scan of the treatment site. Based on the results of this CT scan, the second radiation oncologist determined that the penile bulb received the majority of the prescribed dose. On November 30, 2010, KDPH investigated this event and the licensee's entire prostate brachytherapy treatment program. KDPH discovered 34 additional cases of improper prostate seed implantation performed by the same radiation oncologist between October 3, 2001, and February 24, 2009. KDPH documented procedural violations by the radiation oncologist including written directives not containing the prescribed or delivered doses, no records of postprocedure implant doses, and the lack of postprocedure CT scans.

Cause(s)—The cause of the medical events was human error in the failure of the radiation oncologist to follow the licensee's procedures and the failure of the licensee to maintain oversight of its brachytherapy program.

Actions Taken To Prevent Recurrence

Licensee—The corrective actions taken by the licensee included providing personnel with additional training, permanently suspending the brachytherapy program, and removing the radiation oncologist who performed the implant procedures from the license.

State—KDPH conducted an extensive investigation from November 30, 2010 through November 2, 2012, and cited the licensee for numerous violations in the oversight of its manual brachytherapy program. Additionally, the Kentucky Medical Board investigated the radiation oncologist for infractions that resulted in rescinding the Kentucky medical license.

This event is closed for the purpose of this report.

AS12-06 Medical Event at Banner Good Samaritan Medical Center in Phoenix, Arizona

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

Date and Place—December 22, 2010, Phoenix, AZ

Nature and Probable Consequences—Banner Good Samaritan Medical Center (the licensee) reported that a medical event occurred associated with a HDR mammosite treatment for breast cancer, involving approximately 139.5 GBq (3.8 Ci) of iridium-192. The patient was prescribed to receive a total dose of 34 Gy (3,400 rad) in 10 fractionated doses to the left breast; however, on the ninth treatment, a kink in one of the catheters apparently caused the source to punch through the catheter and slide along the skin tissue of the left breast. The patient received a dose of 20 Gy (2,000 rad) to the skin of the left breast (wrong treatment site). The patient and referring physician were informed of this event.

In preparation for the seventh treatment, the licensee had difficulty in attaching the transfer tube to the HDR unit, and one catheter kinked. During attempts to straighten and re-attach the transfer tube, the catheter broke off completely. The licensee used a technique that it developed to repair the catheter and test its integrity since the manufacturer provides no specific recommendations on how to deal with damaged catheters. In addition, the licensee determined that repairing the catheter was the best option, versus risking the surgical procedure to replace the catheter. During the ninth treatment, the patient reported a sensation of electricity on her left breast during the positioning of the source in one of the catheters. The remaining catheter treatment was completed without further complaints by the patient and the sources were retracted into the normal shielded position. On January 3, 2011, the prescribing physician noted very faint erythema over the lumpectomy site and no evidence of erythema where the source had been in contact with the skin. Later ulcerations developed and healed without further complication. The licensee concluded that there did not appear to be any skin effects from the ruptured catheter, and the patient gradually improved over time.

Cause(s)—The cause of the medical event was a material problem with the repaired catheter and ineffective procedures for handling a damaged catheter.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions included changes to the licensee's procedures so that the entrance site and catheters will be visible by camera and that the treatment will be interrupted upon any abnormal observation or response from the patient. In addition, the licensee procedures were revised so that if kinking or damage to a catheter is observed and the catheter shows any signs of weakening, the device will be replaced.

State—The Arizona Radiation Regulatory Agency conducted an investigation and determined that the licensee's corrective actions were adequate. No enforcement action was taken, and the State forwarded the final update of the event to the NRC on May 1, 2012.

This event is closed for the purpose of this report.

AS12-07 Medical Event at Highlands Regional Medical Center in Prestonsburg, Kentucky

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

Date and Place—March 17, 2009, (reported on January 14, 2011), Prestonsburg, KY

Nature and Probable Consequences—KDPH performed an inspection of Highlands Regional Medical Center (the licensee) manual brachytherapy program on January 14, 2011. KDPH identified one of the licensee's authorized users, a radiation oncologist, who the KDPH investigated in prostate brachytherapy seed implant AO medical events at Our Lady of Bellefonte Hospital in Ashland, Kentucky (AS12-05). KDPH discovered that on March 17, 2009, a patient prescribed to receive 100 Gy (10,000 rad) to the prostate instead received a dose of 160.8 Gy (16,080 rad). This delivered dosage was approximately 60 percent greater than the prescribed dosage to the patient. KDPH documented procedural violations by the radiation oncologist including written directives not containing the prescribed or delivered doses, no records of postprocedure implant doses, and the lack of postprocedure CT scans. The patient and referring physician were not informed of this event because the licensee believed that the treatment was satisfactory.

KDPH uncovered two additional improper prostate seed implantation events at the licensee's facility performed by the same radiation oncologist. These two additional events occurred between February 28, 2008, and April 3, 2008, and in both events the patients received less than the dose prescribed for the treatment. However, because of the radiation oncologist's inadequate postprocedure implantation records, final dose assessments of these events cannot be performed. The licensee's lack of oversight of the manual brachytherapy program caused these events to be undetected until the KDPH inspection.

Cause(s)—The cause of the medical event was human error in the failure of the radiation oncologist to follow the licensee's procedures and the failure of the licensee to maintain oversight of their brachytherapy program.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included providing personnel with additional training and removing the radiation oncologist who performed the implant procedures from the license. Additionally, the licensee's manual brachytherapy program has been suspended until the licensee can demonstrate complete regulatory oversight and compliance with Kentucky regulations.

State—KDPH conducted an extensive investigation from January 14, 2011 through November 28, 2012, and cited the licensee for numerous violations in the oversight of its manual brachytherapy program. Additionally, the Kentucky Medical Board investigated the radiation oncologist for infractions that resulted in rescinding his Kentucky medical license.

This event is closed for the purpose of this report.

AS12-08 Medical Event at Eastern Regional Medical Center in Philadelphia, Pennsylvania

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

Date and Place—January 19, 2011, Philadelphia, PA

Nature and Probable Consequences—Eastern Regional Medical Center (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment for liver cancer involving 1.42 GBq (38.3 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 117 Gy (11,700 rad) to the left lobe of the liver, but instead, received an approximate dose of 257 Gy (25,700 rad). This delivered dosage was about 120 percent greater than the prescribed dosage. The patient and referring physician were informed of this event.

On January 19, 2011, during a formal review, the licensee noted that the activity delivered to the left lobe of the liver was different than the activity that was prescribed by the doctor. Upon investigation, it was determined that a transcription error occurred while preparing the order form. The error was not recognized upon receipt of the yttrium-90, because the received amount of yttrium-90 was compared to the amount listed on the order form rather than the amount prescribed on the written directive. The licensee concluded that this elevated dose may result in an increased risk of atrophy to the left lobe of the liver.

Cause(s)—The cause of the medical event was human error in failing to correctly transcribe the activity from the written directive to the order form.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included the generation of a computer spreadsheet that populates fields based on initial calculations, written directives and the order form. In addition, several procedure modifications were implemented to ensure the correct dosage is ordered and received.

State—The Pennsylvania Department of Environmental Protection (PA DEP) conducted a reactive investigation on January 25, 2011, and identified one violation. PA DEP inspectors determined that the licensee failed to implement the procedures developed to provide high confidence that each yttrium-90 microspheres treatment was in accordance with the written directive. Specifically, the licensee's staff did not verify that the activity determined with a dose calibrator was within 10 percent of the prescribed activity on the written directive, nor were the decay calculations used to check that the activity at the time of treatment was as prescribed on the written directive.

This event is closed for the purpose of this report.

AS12-09 Medical Event at the University of Colorado Hospital in Aurora, Colorado

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

Date and Place—July 8, 2011, Aurora, CO

Nature and Probable Consequences—University of Colorado Hospital (the licensee) reported that a medical event occurred associated with a patient receiving treatment for Graves Disease. The patient was prescribed to receive a total dose of approximately 340 Gy (34,000 rad) to the thyroid gland using 740 MBq (20 mCi) of iodine-131, instead the patient received 3,748 MBq (101.3 mCi) of iodine-131 resulting in a dose of approximately 1,722 Gy (172,200 rad). This dosage was in excess of 400 percent greater than the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On July 8, 2011, the licensee reported to the Colorado Department of Health that a patient received the wrong dose of iodine-131. The licensee stated that the authorized user (AU) reviewed the procedure with the patient and then left the written directive and all associated paperwork with the technologists. The technologist who was administering the iodine-131 to the patient incorrectly assumed that the patient was receiving treatment for cancer and did not review the written directive. The technologist then decided to use a therapeutic dosage of iodine-131, which was intended and labeled for another patient. The AU discovered this error later that day, when they attempted to administer the therapeutic dosage of iodine-131 to the intended patient. On November 10, 2011, and February 8, 2012, the licensee reported that the patient's thyroid function tests indicated a normal thyroid function with a small interval change suggesting the patient is becoming hypothyroid. The difference in the incorrectly administered iodine-131 dosage is expected to cause hypothyroidism in the patient and result in the patient needing replacement thyroid hormone therapy. A less likely possibility is that patient's hyperthyroidism will reoccur and will need an additional dose of iodine-131.

Cause(s)—The cause of the medical event was human error in that the technologist did not properly review the written directive and label on the iodine-131 dose.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included the immediate suspension of the technician from active duty and an investigation, followed by procedure additions—including corroboration by two individuals for therapy doses. The technician was eventually allowed to return to work, but under the direct supervision of the lead technologist or supervisor.

State—The Colorado Department of Public Health and Environment (CDPHE) conducted interviews of the licensee's staff and reviewed the licensee's written report in July 2011. CDPHE issued a notice of violation (NOV) on August 17, 2011, and a followup Compliance Order on Consent on June 29, 2012.

This event is closed for the purpose of this report.

AS12-10 Medical Event at the Medical Center at Bowling Green in Bowling Green, Kentucky

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

Date and Place—November 16, 2011, Bowling Green, KY

Nature and Probable Consequences—The Medical Center at Bowling Green (the licensee) reported a medical event associated with a brachytherapy seed implant procedure to treat prostate cancer. The licensee scheduled back-to-back seed implant procedures, on consecutive days, for two patients who were prescribed a dose of 145 Gy (14,500 rad) to the prostate using 79 iodine-125 seeds. The licensee planned separate seed implant procedures for each patient and used the first patient's plan to correctly implant the seeds in the first patient. However, the licensee inadvertently reused the placement procedure for the first patient while placing the seeds in the second patient. This resulted in the incorrect placement of the seeds in the second patient and a dose to the urethra (wrong treatment site) of 310 Gy (31,000 rad). The second patient and referring physician were informed of this event.

On November 17, 2011, the licensee notified KDPH that the wrong permanent prostate brachytherapy implant treatment plan was used on a patient. The radiation oncologist identified the discrepancy immediately upon completion of the seed implants on the second patient. A postprocedure CT and magnetic resonance imaging (MRI) of the patient's prostate performed one month later revealed the patient received an approximate dose of 105.9 Gy (10,590 rad) to the prostate, which was 73 percent of the prescribed dose. The radiation oncologist placed additional seeds into the patient's prostate to improve coverage and comply with the treatment plan. The licensee concluded that the medical event would not have an adverse effect on the second patient.

Cause(s)—The cause of the medical event was human error in that the radiation oncologist deviated from standard operating procedures and did not verify the information on the prostate implantation plan.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included providing personnel with additional training on the modified process to ensure patients are treated using the correct prostate implant plan. Specifically, an individual will be assigned for printing the prostate implant plan, verifying the patient's identity, and signing the document. Subsequently, a second assigned individual will then verify the information and sign the document for confirmation.

State—KDPH conducted a reactive inspection on December 7, 2011, approved the licensee's corrective actions and did not issue any violations or penalties for this event.

This event is closed for the purpose of this report.

AS12-11 Medical Event at the University of Toledo in Toledo, Ohio

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

Date and Place—December 19, 2011, Toledo, OH

Nature and Probable Consequences—The University of Toledo (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for cervical cancer; involving 148.4 GBq (4 Ci) iridium-192. The patient was prescribed to receive a total dose of 16 Gy (1,600 rad) in four fractionated doses to the cervix (treatment site). It was later determined that the skin of the patient's right and left thigh (wrong treatment sites) received doses of 12.51 Gy (1,251 rad) and 12.74 Gy (1,274 rad), respectively. The patient and referring physician were informed of this event.

During a followup patient visit in January 2012, the attending physician noticed a reddening of the skin (erythema) on both the right and left upper thighs of the patient. Upon investigation, the licensee did not identify any errors with the treatment plan, but discovered a problem with the hardware used during the procedure. During the treatment, a tandem is inserted into the patient, and a catheter for the sealed source is inserted in the tandem. The vendor had recently switched to a new catheter model that was slightly larger in diameter and thicker than the original. During the procedure, the catheter got caught on a minor blockage in the tandem and was not fully inserted, and the source was approximately 9 centimeter (cm) away from the treatment site. The misplaced source resulted in a total dose of 13.94 Gy (1,394 rad) to the treatment site and excessive doses to the patient's thighs. As of March 21, 2012, the attending physician reported that the patient had fully recovered from the medical event. The patient reported no bowel or bladder problems, and the damaged skin areas had totally healed. The physician does not anticipate significant acute or long-term complications because of this medical event.

Cause(s)—The cause of the medical event was human error in that the licensee failed to recognize that the catheter was not fully inserted into the tandem during at least one of the fractionated doses. A contributing factor was the change in catheter construction, which allowed it to get caught on the blockage in the tandem.

Actions Taken To Prevent Recurrence

Licensee—The corrective action taken by the licensee includes marking the new catheters to provide a visual indication of full insertion into the tandem and inservice training for all staff involved in HDR treatments.

State—The Ohio Department of Health (ODH) conducted an onsite investigation and reviewed the incident causes and corrective actions. In February 2012, the ODH issued a notice to all Ohio licensees advising them to verify procedures to preclude a recurrence of this event.

This event is closed for the purpose of this report.

NRC12-02 Medical Event at Benefis Hospital in Great Falls, Montana

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

Date and Place—January 5, 2012, Great Falls, MT

Nature and Probable Consequences—Benefis Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for esophageal cancer. The treatment involved the use of 233.1 GBq (6.3 Ci) of iridium-192 and the patient was prescribed to receive a total dose of 7 Gy (700 rad) to the esophageal region (treatment site). However, it was determined that a 4 cm length of tissue in the nasal and nasopharyngeal sinus area (wrong treatment site) received a dose of 10 Gy (1,000 rad). The patient and referring physician were informed of this event.

On January 5, 2012, while planning the treatment, the authorized medical physicist (AMP) determined the placement of the source using a radio-opaque marker wire to simulate the source with imaging software. During the treatment, a nasogastric (NG) tube is inserted into the patient through the nostril, allowing for positioning of the HDR catheter and source at the treatment site. The NG tubes also have radio-opaque markers to aid in their placement in the patient, which the AMP mistook for the radio-opaque markers on the simulation wire. This error by the AMP was compounded by the lack of CT images of the patient's anatomy where the simulation wire was positioned. When the medical staff removed the HDR catheter and NG tube at the end of the procedure, they discovered that the HDR catheter had not been fully inserted into the NG tube. The licensee performed an investigation and determined that the dose was actually delivered to a location 29 cm away from the treatment site. The licensee concluded that the medical event would not have an adverse effect on the patient.

Cause(s)—The cause of the medical event was human error in that the AMP failed to recognize the source's correct placement relative to the treatment site.

Actions Taken To Prevent Recurrence

Licensee—The corrective action taken by the licensee included procedure modification such that catheter length measurements are performed before treatment and the NG tube and HDR catheter are introduced to the patient as a unit, rather than separately. Additionally, CT scans will be taken to cover the entire length of the HDR catheter during all HDR procedures.

NRC—The NRC conducted a special inspection on January 18, 2012, and contracted with a medical consultant to review the event. The NRC's medical consultant agreed with the hospital's analysis of this event, and the NRC issued a NOV to the licensee.

This event is closed for the purpose of this report.

AS12-12 Medical Event at Presbyterian Hospital in Charlotte, North Carolina

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

Date and Place—January 5 and 12, 2012, Charlotte, NC

Nature and Probable Consequences—Presbyterian Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for gastric cancer; the treatment involved 185.4 GBq (5 Ci) of iridium-192. The patient was prescribed to receive three fractionated doses of 7 Gy (700 rad) to the common bile duct (treatment site). However, it was determined that a 4 cm length of tissue in the common bile duct and liver (wrong treatment sites) received a dose of 14 Gy (1,400 rad). The patient and referring physician were informed of this event.

On January 18, 2012, while conducting the third fractionated HDR brachytherapy treatment for gastric cancer, the dosimetrist noticed that incorrect dwell location was used on the previous two fractioned treatments. On the previous fractionated treatment dates, January 5, 2012, and January 12, 2012, the dwell position on the HDR was mistakenly adjusted outward rather than inward. This resulted in treating only 1 cm of the desired treatment site of the common bile duct and delivered a dose of 14 Gy (1,400 rad) to 4 cm of the proximal portion of the bile duct and surrounding liver tissue. The licensee concluded that the medical event would not have an adverse effect on the patient.

Cause(s)—The cause of the medical event was human error in that the oncology staff presumed that the source position had been properly adjusted by the medical physics staff and did not notice this error until the third fractionated treatment.

Actions Taken To Prevent Recurrence

Licensee—The corrective action taken by the licensee included a procedure modification such that any catheter dwell position adjustments of greater than 5 millimeters (mm) mandate a replanning of the treatment protocol.

State—The North Carolina Division of Radiation Protection conducted a full inspection of the brachytherapy program (to include HDR) on February 16, 2012. There were no items of noncompliance, and the State reviewed and approved corrective actions. The State did not issue any violations or penalties for this event.

This event is closed for the purpose of this report.

NRC12-03 Medical Event at Avera McKennan Hospital in Sioux Falls, South Dakota

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

Date and Place—January 16 and 17, 2012, Sioux Falls, SD

Nature and Probable Consequences—Avera McKennan Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for breast cancer. The patient was prescribed to receive 10 fractionated doses of 3.4 Gy (340 rad) for a total dose of 34 Gy (3,400 rad) to the tumor site (treatment site). However, it was determined that the skin tissue over the rib cage (wrong treatment site) received a dose of 27.2 Gy (2,720 rad). The patient and referring physician were informed of this event.

On January 16, 2012, while conducting the fractionated HDR brachytherapy treatment for breast cancer, the medical staff identified that an incorrect treatment parameter length had been entered into the HDR. The programmed length was 10 cm too short and resulted in the source traveling to a location 10 cm short of the intended treatment site (inside the breast). This caused an unintended dose to the skin over the rib cage. This error was corrected and saved as a secondary treatment plan in the HDR console, which the staff used to correctly administer the second fractionated treatment. However, after the staff delivered the third fraction the following day (January 17, 2012), it was discovered that the original incorrect treatment plan had been inadvertently selected by the console operator, resulting in a second instance where the skin over the rib cage received an unintended dose. The licensee performed an investigation and the NRC contracted with a medical consultant, who determined that the patient received approximately 27.2 Gy (2,720 rad) of unintended skin dose and concluded that the event would not have an adverse effect on the patient. The patient experienced skin erythema, or reddening, as was expected from this level of skin exposure.

Cause(s)—The cause of the medical event was that the licensee failed to develop and implement effective procedures to ensure that patient treatment was in accordance with the written directive.

Actions Taken To Prevent Recurrence

Licensee—The corrective actions taken by the licensee included extensive revisions to the HDR procedures, including the development of requirements for independent verification of treatment parameter lengths, and staff training on these changes. The hospital also made organizational and personnel changes to improve the facility's safety culture.

NRC—The NRC conducted a special inspection from January 30 through February 2, 2012, and identified several procedural weaknesses in the licensee's HDR program. On October 3, 2012, the NRC issued a NOV and civil penalty to the licensee.

This event is closed for the purpose of this report.

AS12-13 Medical Event at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania

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

Date and Place—January 19, 2012, Philadelphia, PA

Nature and Probable Consequences—Thomas Jefferson University Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer for two patients. The first patient received a dose of 0.33 GBq (8.9 mCi) of yttrium-90 to the liver, but this was the dose prescribed for a second patient, which was 36 percent less than prescribed. The second patient received the dosage for the first patient, which was 0.514 GBq (13.9 mCi) or approximately 80 Gy (8,000 rad) and 64 percent greater than prescribed. The patients and referring physicians were informed of this event.

On January 20, 2012, the licensee reported that on the previous day the licensee administered the incorrect prescribed dosage of yttrium-90 to two patients. The licensee stated that the two patients were scheduled to be treated on the same day, in close time proximity, and that the worksheets were switched and each patient received the other patient's dose. The licensee concluded that the medical events would not have an effect on the two patients. However, the first patient received a higher dose than planned during the next scheduled treatment to compensate for the previous lower dosage described in this event. No adverse medical conditions are expected. The clinical judgment with respect to the second patient is that even though the dosage was 35 percent above that prescribed in the written directive, the activity was within levels acceptable for this particular patient and tumor size.

Cause(s)—The cause of the medical event was human error in that the medical staff did not verify the written directive before commencing the treatment, coupled with the erroneous transposition of the written directives in each of the patient's files.

Actions Taken To Prevent Recurrence

Licensee—The corrective action taken by the licensee includes developing and implementing written procedures to both minimize the chance of errors occurring in the microsphere dose preparation process and to identify and correct any such errors before administration. Independent checks by multiple individuals will be made to verify patient identity, treatment site, and prescribed dosage relative to the prepared dosage.

State—The PA DEP conducted a reactive investigation on January 26, 2012, and identified inadequacies in the administration procedure to provide assurances that each treatment is in accordance with the written directive. A NOV was issued by PA DEP; however, no order or final action was imposed because a revised dosage administration procedure was subsequently sent to PA DEP for review.

This event is closed for the purpose of this report.

AS12-14 Medical Event at the Intermountain Medical Center in Murray, Utah

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

Date and Place—February 2, 2012, Murray, UT

Nature and Probable Consequences—The Intermountain Medical Center (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer. The treatment plan prescribed 5.32 GBq (143.6 mCi) of yttrium-90 to deliver a total dose of 120 Gy (12,000 rad) to the right lobe of the liver. However, the patient received the dosage for a different patient. The dosage administered to the patient was 1.77 GBq (47.8 mCi) of yttrium-90, which was approximately 33 percent of the prescribed activity or 67 percent lower than the prescribed dose. The resulting dose to the patient's liver was 39.6 Gy (3,960 rads). The patient and referring physician were informed of this event.

On February 2, 2012, two patients were at the licensee's facility to receive treatment for liver cancer using yttrium-90 microspheres. The nuclear medicine technologist inadvertently selected the wrong yttrium-90 microsphere vial, and subsequently, administered to the first patient the dosage that was intended for the second patient. As a consequence, the first patient received an under dose of approximately 67 percent and because the licensee identified the error prior to administering any dose to the second patient, the licensee was able to treat the second patient with the correct dose. The licensee determined that the medical event would not have an effect on the first patient.

Cause—The cause of the medical event was human error, which resulted in the licensee administering the wrong radiopharmaceutical treatment dose to the patient.

Actions Taken To Prevent Recurrence

Licensee—The corrective actions taken by the licensee include a requirement for two individuals to sign off on the dosage vial, with the written directive present, before administering the dosage to the patient. In addition, the licensee committed to following protocol verification just before treatment to verify the patient's identification, site being treated, dose to be administered, and the correct identification on the dose vial.

State—The Utah Department of Environmental Quality, Division of Radiation Control conducted an investigation on February 6, 2012, and concluded its investigation on April 19, 2012. The State approved the licensee's corrective actions and did not issue any violations or penalties for this event.

This event is closed for the purpose of this report.

AS12-15 Medical Event at Abbott Northwestern Hospital in Minneapolis, Minnesota

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

Date and Place—February 2, 2012, Minneapolis, MN

Nature and Probable Consequences—Abbott Northwestern Hospital (the licensee) reported to the Minnesota Department of Health (MDH) that a medical event occurred associated with a SIR-Spheres (microspheres) treatment of liver cancer involving 1.55 GBq (41.9 mCi) of yttrium-90. A postprocedure scan of the patient identified a significant undesired amount of activity in the upper stomach (gastric fundus), spleen and small intestine (duodenum) (wrong treatment sites). The licensee estimated doses to these tissues of 44 Gy (4,400 rad), 35 Gy (3,500 rad), and 35 Gy (3,500 rad), respectively. The patient and referring physician were informed of this event.

On February 3, 2012, the licensee notified MDH that following an infusion of radioactive yttrium-90, a postprocedure CT scan of the patient revealed that some of the yttrium-90 was not in the liver as intended. The scan indicated that 10 to 15 percent of the yttrium-90 appeared in vessels involving the spleen and digestive track. The patient received followup diagnostic scans to determine a baseline for future treatment and the long term prognosis. On February 6, 2012, after consultation with international and domestic experts, the patient was administered the radio-protective agent amifostine. The licensee concluded that the event may result in unintended, permanent functional damage and some form of future medical intervention was likely needed. A special review group including surgeons, radiation oncologists, and interventional radiologists are managing the care of the patient on an ongoing basis.

Cause(s)—The licensee stated that they had not anticipated any adverse reactions to this treatment, and that the treatment was correctly planned and administered. However, the licensee hypothesized that the cause may have been the result of temporary blood vessel contractions in the patient due to the passage of the microspheres.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions were not indicated as the licensee followed appropriate therapy procedures and the treatment had no unusual implications. Additionally, based upon the large number of this type of treatment that the licensee has performed, it appears that this medical event is a rare occurrence.

State—On February 6, 2012, MDH performed an onsite investigation of the medical event. MDH concluded that licensee procedures were appropriately followed and no violations were issued.

This event is closed for the purpose of this report.

AS12-16 Medical Event at Carolina East Medical Center in New Bern, North Carolina

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

Date and Place—May 29, 2012, New Bern, NC

Nature and Probable Consequences—Carolina East Medical Center (the licensee) reported that a medical event occurred associated with a manual brachytherapy treatment for prostate cancer. The treatment consisted of 27 needles containing 65 pre-stranded seeds of iodine-125 with each seed containing 12.6 MBq (0.34 mCi). The physician prescribed a total dose of 145 Gy (14,500 rad) to the prostate; however, it was determined during the post implant seed count that all of the seeds were implanted in the penile bulb (glans) (wrong treatment site). The resulting dose to the penile bulb was 145 Gy (14,500 rad). The patient and referring physician were informed of this event.

On May 29, 2012, after completion of the implantation procedure, the licensee performed a CT scan of the patient to verify the placement of the implanted seeds. The licensee confirmed that all of the seeds were improperly implanted in the penile bulb. The patient was informed the following day, since he had been under the effects of general anesthesia during and after the procedure. The patient and his family were counseled at length by the AU within a week of the occurrence of the medical event. The AU reported that the patient tolerated the brachytherapy procedure well, without acute toxicity. The AU reported that anticipated side effects from this event will be similar to the anticipated side effects from a typical permanent prostate brachytherapy implant. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause(s)—The cause of the medical event was the incorrect identification of the prostate during ultrasound imaging resulting in the improper placement of the brachytherapy seeds.

Actions Taken To Prevent Recurrence

Licensee—The AU compiled a report and discussed corrective actions with the urologist and the authorized medical physicist. The licensee revised the procedures to include a mandatory "time out" period during implant procedures, and a quality assurance procedure for pre-plan ultrasounds. Additional licensee corrective actions include, using single shot fluoroscopy, in addition to ultrasound, to verify placement of the brachytherapy seed needle at the base of the prostate. Contrast and other additional enhancements may be used in conjunction with the fluoroscopy to ensure more accurate imaging results.

State—The North Carolina Division of Radiation Protection conducted an investigation on June 12, 2012. Two items of noncompliance were noted: (1) the licensee failed to have documented procedures to ensure that a therapy is administered in accordance with the written directive, and (2) the licensee failed to have a program commensurate with licensed activities. Enforcement actions are pending the licensee's responses to the State.

This event is open for the purpose of this report.

AS12-17 Medical Events at Wheaton Franciscan Healthcare-All Saints in Racine, Wisconsin

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

Date and Place—July 15, 2005 through May 20, 2010 (reported on July 19, 2012), Racine, WI

Nature and Probable Consequences—Wheaton Franciscan Healthcare-All Saints (the licensee) reported 15 medical events associated with prostate brachytherapy seed implant procedures, which occurred between July 2005 and May 2010. The medical events involved permanent implant seeds of iodine-125 where the total dose delivered differed from the prescribed dose by 20 percent or more. The 15 medical events involved 13 patients, including seven patients who received a rectal (wrong treatment site) dose that exceeded the prescribed prostate dose by more than 10 Gy (1,000 rads). The patients and physicians were informed of these events.

The Wisconsin Department of Health Services (WDHS) identified the medical events during a routine inspection and followed up with a reactive inspection on July 18, 2012. WDHS inspectors determined that the licensee was not reviewing prostate brachytherapy cases against the medical event criteria. Instead, the licensee was using established dose-based criteria based upon the postoperative CT scans of the events. The events involved prostate procedures where the doses were less than 80 percent or greater than 130 percent of the prescribed dose, or procedures where the doses to 2 cubic centimeters (cm^3) of the rectum or bladder were greater than the prescribed prostate dose. The AU's review of each of the medical events concluded that the posterior rows of seeds were placed too close to the rectal mucosa. The licensee has evaluated all prostate implants performed since 2001. The licensee concluded that the medical events would not have an adverse effect on the patients and is monitoring their medical progress.

Cause(s)—The cause of the medical events was human error in that the licensee was not providing adequate oversight of the permanent implant prostate brachytherapy program.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions include: (1) revising the prostate implant procedures to include the use of stranded seeds, (2) allowing only the AU to insert the needles into the prostate, and (3) a secondary check of the needle position prior to deploying the seeds. Additionally, the AU is now the only individual who contours the images on the postoperative CT scan, which is reviewed by the medical physicist to improve accuracy.

State—WDHS conducted a reactive inspection on July 18, 2012, and did not cite the licensee because of the licensee's self-identified and implemented process improvements prior to the inspection. No additional cases have met the medical event reporting criteria.

This event is closed for the purpose of this report.

NRC12-04 Medical Event at Deaconess Hospital in Evansville, Indiana

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

Date and Place—August 15, 2012, Evansville, IN

Nature and Probable Consequences—Deaconess Hospital (the licensee) reported that a medical event occurred associated with an HDR mammosite brachytherapy treatment for breast cancer. The patient was prescribed to receive 10 fractionated doses for a total dose of 34 Gy (3,400 rad) to the breast tumor site. However, it was determined that a 4.2-cm length of skin and fatty breast tissue (wrong treatment sites) received a dose of 34 Gy (3,400 rad). The patient and referring physician were informed of this event.

Between March 5 and 9, 2012, the patient received two HDR mammosite treatments per day to the right breast for a total prescribed dose of 34 Gy (3,400 rad). During a followup appointment on June 11, 2012, it was noted that the catheter insertion site had not healed. A plastic surgeon performed surgical removal of the entire skin and breast tissue area affected by the treatment. The surgical pathology report revealed a final diagnosis of fat necrosis with granulation tissue radiation effect. Upon reviewing the pathology report, the prescribing physician requested complete review of the treatment plan by a qualified consultant. The consultant discovered that the unintended dose to the skin and fatty breast tissue was the result of the incorrect positioning of the HDR source. The possibility of long term effects are low, but nonetheless additional skin ulceration and breast tissue necrosis could occur.

Cause(s)—The cause of the medical event was human error in that the medical physicist was not familiar with the treatment planning system for the HDR mammosite device. A contributing factor to the cause of the event was the licensee's ineffective independent check of the treatment plan prior to commencing the procedure.

Actions Taken To Prevent Recurrence

Licensee—The corrective actions taken by the licensee includes the independent review, by a qualified third party, of HDR treatment plans prior to delivery for the first five plans provided by each physician or physicist. Additionally, the licensee requires the performance of an additional independent check that verifies the physical orientation of any channel (catheter) used in an HDR procedure. Finally, the licensee implemented appropriate training and continuing medical education programs for all staff participating in HDR procedures.

NRC—The NRC conducted a special inspection on August 22, 2012, and contracted with a medical consultant to review the event. The NRC's medical consultant agreed with the hospital's analysis of this event. On January 31, 2013, the NRC issued a NOV to the licensee.

This event is closed for the purpose of this report.

AS12-18 Medical Event at the Anderson Regional Medical Center in Meridian, Mississippi

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

Date and Place—September 10, 2012, Meridian, MS

Nature and Probable Consequences—Anderson Regional Medical Center (the licensee) reported that a medical event occurred associated with an iodine-131 treatment for thyroid carcinoma. The patient was prescribed to receive a total dose of 25 Gy (2,500 rad) to the thyroid using 3.7 GBq (100 mCi) of iodine-131. Instead, the patient received 6.03 GBq (162.8 mCi) of iodine-131 for an approximate dose of 40 Gy (4,000 rad) to the thyroid, which was about 160 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On September 10, 2012, the licensee reported that a patient was administered 6.03 GBq (162.8 mCi) of iodine-131, instead of the prescribed 3.7 GBq (100 mCi). An investigation performed by the licensee revealed that the nuclear medicine technologist misinterpreted the patient's admission order as a written directive. Specifically, the nuclear medicine technologist incorrectly interpreted the AU's name and 5.55 GBq (149.9 mCi) of iodine-131 activity on the patient's admission order as the written directive for the patient's treatment. The written directive for the patient's treatment was never received by the Nuclear Medicine Department. The doctor indicated that the patient was previously treated using a prescribed dose of 100 mCi, and that the thyroid would be fully saturated with iodine-131. Additionally, the doctor believes that the thyroid would not have significant uptake of the excess iodine-131 and this excess would be quickly excreted from the patient. Therefore, the licensee concluded that this elevated dose would not result in any adverse health effects to the patient.

Cause(s)—The medical event was caused by human error coupled with a new communication process, in which written directives were not directly communicated to the Nuclear Medicine Department.

Actions Taken To Prevent Recurrence

Licensee—The licensee restored its previous written directive communication policy, which required the communication of written directives directly from the AU to the Nuclear Medicine Department and required written directives for iodine-131 on a specific therapy form.

State—The Mississippi Division of Radiological Health conducted an investigation on September 19, 2012, and cited the licensee with a violation, for its failure to follow written directive procedures. The investigation revealed this violation was an isolated incident during a two month period where the change in written directive communication policy took place.

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

(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* (FR) 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 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 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 that results in the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to Title 10 of the Code of Federal Regulations (10 CFR) Part 20, "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 Part 110, "High Risk Radioactive Material, Category 2." Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.

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

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

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

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

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

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

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

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

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

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

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

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100, Reactor Site Criteria, or 5 times the dose limits of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities, Appendix A, "General Design Criterion for Nuclear Power Plants," General Design Criterion (GDC) 19, 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.

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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."

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

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

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

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

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

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

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

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

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

B. For Fuel Cycle Facilities

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.

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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 1×10^{-3}.

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

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

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

2. Represents either
   a. A dose or dosage that is at least 50 percent greater than that prescribed, or
   b. A prescribed dose or dosage that
      (i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or
      (ii) Is delivered by the wrong route of administration; or
      (iii) Is delivered to the wrong treatment site; or
      (iv) Is delivered by the wrong treatment mode; or
      (v) Is from a leaking source or sources; or
      (vi) Is delivered to the wrong individual or human research subject.

IV. Other Events of Interest

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

APPENDIX B
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, updated information became available for three abnormal occurrence (AO) events that the U.S. Nuclear Regulatory Commission (NRC) had previously reported in NUREG-0090, Volume 34, "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2011," dated May 2012 (see Agencywide Documents Access and Management System (ADAMS) Accession No. ML12142A194). These events involved a human exposure to radiation event at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas; a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama; and a medical event at Lovelace Medical Clinic in Albuquerque, New Mexico.

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

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

Background—Caribbean Inspection & NDT Services Inc. (the licensee) reported that a radiographer trainee received an overexposure to his right hand. The radiographer trainee stated that while he was conducting radiography operations in the field, he removed a radiography camera guide tube from the radiography camera and noticed the 2.7 terabecquerals (TBq) (73 curies (Ci)) iridium-192 source was not fully retracted. Later, the radiographer trainee presented himself to a Houston, Texas hospital with observable deterministic effects, which included blistering of the thumb, index and middle fingers, which correspond to an exposure range of 20–30 sieverts (Sv) (2000 to 3000 rem) to the extremities. The trainee's dosimeter indicated that he received 14.1 mSv (1.41 rem) whole body exposure. His doctors initially conferred with the Radiation Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, regarding his medical treatment. The trainee received medical care at an area hospital and was released. The FY 2011 AO report discusses the full details of the event under AS11-02. The final dose assigned to the radiographer trainee by the licensee was 27 Sv (2,703 rem) to the extremities for the year 2011.

Update on Cause(s)—The Texas Department of State Health Services (DSHS) and licensee determined that the overexposure occurred; however, the root cause was never identified.

Update on Actions Taken To Prevent Recurrence

Licensee—The licensee conducted an investigation; however, the essential details of the event were never discovered, despite significant efforts by the licensee and the State. As a result, the root cause was never identified. The licensee took actions that included training their radiographers on the known circumstances of the event and the importance of performing surveys. The licensee replaced the radiation safety officer, as a result of his response to the event. In addition, the licensee performed dose rate studies to confirm dose calculations for the individual.

State—The State of Texas attempted to depose individuals involved in the event to obtain their testimony under oath, but was unable to do so. Nevertheless, on January 20, 2012, Texas issued a notice of violation (NOV) letter to the licensee, and on January 26, 2012, issued a civil penalty. DSHS and REAC/TS are following the condition of the radiographer trainee, who has since developed subsequent blistering and an open wound of his right index finger.

This event is closed for the purpose of this report.

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

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

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

The NRC identified several other performance deficiencies including the licensee's failure to establish adequate programs to ensure that motor-operated valves are capable of performing their design-basis safety functions. This failure to effectively maintain and inspect these valves within the program contributed to the performance deficiency. The licensee's corrective action program and root cause evaluation also did not appear to address the broader issues associated with programs to ensure the continued capability of motor-operated valves to perform their design-basis safety function. The FY 2011 AO report discusses the full details of the event under NRC11-02.

Update on Actions Taken To Prevent Recurrence

NRC—NRC staff initiated a supplemental inspection at the Browns Ferry Nuclear Power Station beginning on September 12, 2011. This inspection is currently being conducted in accordance with inspection procedures, and is including extensive reviews of programs and processes not inspected as part of the NRC's baseline inspection program. The inspection also includes an assessment of the Browns Ferry Nuclear Power Station's safety culture. Parts 1 and 2 of this supplemental inspection were completed and inspection reports were issued on November 17, 2011, and February 28, 2012, respectively (available at ADAMS Accession No. ML113210602 and ML12059A314). The results of these two inspections will be combined with the results from Part 3 of the inspection, which will be conducted in accordance with Inspection Procedure (IP) 95003, "Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs, or One Red Input," (available at ADAMS Accession No. ML102020551). The reports will assist the NRC in determining the breadth and depth of safety, organizational, and programmatic issues at Browns Ferry Nuclear Power Station. On February 15, 2013, the NRC received written notification from the licensee on its readiness to support Part 3 of a supplemental inspection in accordance with IP 95003. The red finding is being held open past 4 quarters pending completion of Part 3 of IP 95003. The NRC staff plans to begin this inspection in the spring of 2013. Based on a review of the inspection results, the NRC will provide further clarification regarding specific actions TVA will need to take following completion of Part 3 of IP 95003.

The NRC will provide a report on the final results of the Part 3 of IP 95003 as an update in Appendix B of the FY 2013 AO Report to Congress.

This event is open for the purpose of this report.

Medical Event at Lovelace Medical Clinic in Albuquerque, New Mexico (previously reported as AS11-09 in NUREG-0090, Volume 34)

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

Background—The Lovelace Medical Clinic (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for endometrial carcinoma. The patient was prescribed to receive a total dose of 21 gray (Gy) (2,100 rad) in three fractionated doses to the treatment site, but instead, the skin tissue on the patient's thigh received 30.6 Gy (3,060 rad). The licensee determined that the medical event was caused by either improper placement or workers inadvertently moving the catheter while adjusting the patient for better alignment with the treatment device. The licensee's corrective actions included revising the procedures to ensure that the catheter is correctly positioned before the start of the treatment. In addition, the licensee required staff training to address the procedure updates. The licensee concluded that no long-term medical effects are expected for the patient. The FY 2011 AO report discusses the full details of the event under AS11-09.

Update on Actions Taken To Prevent Recurrence

State—The New Mexico Radiation Control Bureau inspected the licensee and reviewed this medical event, its cause and the licensee's corrective actions. On July 10, 2010, New Mexico issued a NOV to the licensee for failing to follow written directives and incompatible Quality Management Program Brachytherapy and Gamma Knife medical event reporting requirements. The State of New Mexico anticipates issuing enforcement actions with civil penalties in early spring 2013. The NRC will provide an update for this event in Appendix B of the FY 2013 AO report to Congress.

This event is open for the purpose of this report.

APPENDIX C
OTHER EVENTS OF INTEREST

This appendix discusses other events of interest that do not meet the abnormal occurrence (AO) criteria in Appendix A but 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. These include a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

EOI-01 Bracco Diagnostics, Inc.: CardioGen-82 Radioisotope Generator Strontium-82 and Strontium-85 Breakthrough

The NRC included this event in this report because the public perceived it to be of high health and safety significance. However, the 2011 discovery of strontium-82 and strontium-85 breakthrough and administration to patients of levels higher than the regulatory breakthrough levels for these radionuclides from CardioGen-82 radioisotope generators manufactured by Bracco Diagnostics, Inc. (BD) was actually of low safety significance. The event was of low safety significance because all doses were at or below the medical event reporting threshold in Title 10 of the *Code of Federal Regulations* (10 CFR) section 35.3045. Additionally, BD voluntarily withdrew the product from the market on July 25, 2011. At the time, there were over 100 users of the CardioGen-82 generators. The U.S. Food and Drug Administration (FDA) and the NRC maintained oversight.

On February 17, 2011, and March 8, 2011, two patients—one in Florida and one in Nevada—received cardiac stress tests, using rubidium-82 from a CardioGen-82 generator for positron emission tomography (PET) scans. In late spring or early summer 2011, both patients were detected at different security checkpoints upon reentry to the United States and determined to have higher than expected levels of strontium. The patients were referred to Oak Ridge National Laboratory (ORNL) to undergo sensitive whole body counting in July 2011. The whole body counting indicated the presence of strontium-85 and strontium-82 and expected doses of 49 millisievert (mSv) (4.9 roentgen equivalent man (rem)) for the Nevada patient and 21 mSv (2.1 rem) for the Florida patient.

Testing was conducted by the Nevada Radiation Control Program on 203 additional patients, who were either imaged at about the same time as the Nevada patient was stopped at the border, imaged with generators that had recorded breakthrough, or imaged on days that had no recorded breakthrough information. Thirty seven of these 203 additional patients had higher predicted whole body activity levels than the patient that received whole body counting at ORNL. Because the patient who received the whole body counting at ORNL received 4.9 rem, any of the 37 patients had a high probability of reaching the dose threshold for being a medical event as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, “Medical Use of Byproduct Material,” which is 5 rem. The results of these survey scans were compared to the Nevada patient who received the whole body counting at ORNL.

BD, the manufacturer of the CardioGen-82 generator, tested additional patients at the Florida site who received the same cardiac stress test scans at about the same time as the Florida patient that was stopped at the border. About 20 additional patients were reported to have increased strontium-82 and 85 radiation exposures, which included one additional Florida patient stopped at the border during the summer of 2011.

FDA, the NRC, the Centers for Disease Control, the State of Nevada, the State of Florida, and BD began collecting and analyzing data to determine the extent of this event. Nevada Heart and Vascular Center reported that three out of 203 patients treated between February 11 and April 7, 2011 were confirmed to have received whole body exposures of 55.4 mSv (5.54 rem), 56.6 mSv (5.66 rem), and 58.3 mSv (5.83 rem). None of the patients from Florida exceeded the effective dose equivalent threshold for medical events of 50 mSv (5 rem). The FDA determined that there were generator manufacturing procedural issues and high customer use conditions that could result in breakthrough events, and that customer quality control steps may need to be performed more frequently in certain situations.

In February 2012, BD returned the generators to the market with FDA-approved revised package labeling, which included enhanced testing information to help minimize the risk for exposure to unintended levels of strontium radiation and enhanced monitoring of the quality control data by the manufacturer. The revised drug safety communication is found at http://www.fda.gov/Drugs/DrugSafety/ucm265278.htm and the revised package insert is found at http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019414s014lbl.pdf. In addition, technologists were trained by BD on updated policies concerning strontium breakthrough testing and an online worksheet was developed to simplify and monitor the breakthrough recording process.

EOI-02 Davis-Besse Nuclear Power Station: Shield Building Laminar Cracking

The NRC included this event in this report because the public, as well as local and national media, perceived it to be of high health and safety significance. However, as described below, the Davis-Besse Nuclear Power Station (DBNPS) shield building laminar cracking is actually of low safety significance. Specifically, the building continues to be able to perform its safety functions despite the cracking. Additionally, plant safety was always maintained by FirstEnergy Nuclear Operating Company (the licensee), and the NRC maintained oversight.

The DBNPS is located approximately 34 kilometers (21 miles) east-southeast of Toledo, Ohio and consists of a single Babcock & Wilcox designed pressurized water reactor. On October 10, 2011, a previously existing crack was discovered in the unit's shield building wall. At the time of discovery, licensee contractors were performing hydro-demolition activities to create an opening for replacement of the existing reactor pressure vessel closure head. The licensee subsequently performed impact response testing and confirmatory core boring to determine the extent of the shield building wall cracking. These laminar cracks exist in the area of the shield building flute shoulders, around the main steam line penetrations, and in various locations near the top of the building wall. The flute (vertical cutouts) shoulders extend out from the thick cylindrical shield building structural wall to form flutes at regular intervals around the building for aesthetic purposes. The flute shoulders are not credited for structural support of the shield building. However, the cracks are located next to and parallel to the outer structural rebar mat of the cylindrical structural wall (deeper into the concrete than the flute shoulders) and were therefore of structural concern because of the potential impact on the concrete/rebar bonding strength.

The DBNPS containment system is designed to provide protection for the public from radiological consequences of hypothetical accidents including a break of the largest reactor coolant piping. The containment vessel is made of one and a half inch thick welded steel and sits inside the shield building separated by about four and a half feet of void space (annulus). The containment vessel provides the primary means to contain the post-accident environment and was designed to withstand and hold against accident pressure. The identified cracking does not involve the containment vessel. The shield building surrounds the containment vessel and provides for: (1) protection of the containment vessel from environmental impacts, (2) a controlled release of the atmosphere between the containment and shield building during accidents, and (3) shielding from radiation sources within the shield building. In the event of radioactive leakage from the containment vessel during an accident, the shield building allows the emergency ventilation system to draw a suction from the annulus region and filter that leakage. In addition, the shield building protects the containment vessel from external environmental hazards such as tornado winds and tornado driven missiles and must also function to withstand earthquakes.

After extensive review by NRC structural experts, and additional efforts by the licensee's staff and structural contractors, the NRC staff independently concluded that the licensee had provided sufficient rationale to demonstrate that the shield building remained capable of performing its safety functions. The inspection report, "Davis-Besse Nuclear Power Station Reactor Vessel Head Replacement and Shield Building Cracking Inspection Report" 05000346/2012007, dated May 7, 2012, is available at the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML12128A443). To publicly document its conclusion and provide continued long-term confidence, the NRC issued confirmatory action letter (CAL) 3-11-001 on December 2, 2011 (available at ADAMS Accession No. ML11336A355), before plant restart, which included licensee commitments to provide a root

cause analysis and corrective actions, a long term monitoring plan, and specific short term monitoring efforts to ensure the cracking would not worsen in the interim. This NRC conclusion and its basis were discussed during a public meeting held on January 5, 2012 (meeting summary available at ADAMS Accession No. ML12030A141).

The NRC staff completed its inspection of the licensee's root cause efforts and planned corrective actions on May 9, 2012 (NRC Inspection Report 05000346/2012009, "Inspection to Evaluate the Root Cause Evaluation and Corrective Actions for Cracking in the Reinforced Concrete Shield Building of the Containment System," dated June 21, 2012, and available at ADAMS Accession No. ML12173A023). Prior to the licensee completing the root cause analysis, the NRC inspection team observed and evaluated the comprehensive and systematic approach of the licensee's root cause efforts; independently observed the cracks in the shield building access opening, core bores, and core samples; inspected at offsite vendor testing labs; evaluated the inputs, assumptions, and modeling for associated shield building structural calculations; interviewed licensee root cause staff; and reviewed the licensee's root cause analysis report. The NRC team confirmed that the licensee's root cause analysis team, as augmented with vendor subject matter experts, was appropriately trained, followed site procedures for root cause investigations, and had considered relevant site and external operating experience.

The NRC staff concluded that the licensee had provided a sufficient basis for the causes of the shield building laminar cracking related to the environmental factors associated with a 1978 blizzard, the lack of an exterior moisture barrier, and the structural design elements of the shield building. In particular, wind driven heavy rains caused moisture to soak into the building wall, quickly followed by a rapid and sustained drop to below freezing temperatures during the severe blizzard. This resulted in initiation and propagation of cracks along the flute shoulders and some areas of denser rebar. The licensee's corrective actions include the application of a moisture sealant to the shield building exterior, periodic monitoring of the sealant condition on that and other buildings, more extensive impulse response testing and core boring to provide additional confirmation of the extent of cracking, and a long term monitoring program to ensure, regardless of cause, that additional cracking, if it occurs, will be quickly identified and addressed. The NRC staff concluded that the identified corrective actions were sufficient to maintain safety. The NRC conclusions and their bases with respect to root cause and corrective actions were discussed during a public meeting held on August 9, 2012 (meeting summary available at ADAMS Accession No. ML12243A283). The NRC staff is implementing a followup inspection plan to verify completion of licensee corrective actions.

EOI-03 Byron Generating Station, Unit 2: Design Vulnerability Discovered in the Electrical Distribution System Following Reactor Trip from a Loss of Offsite Power

This event is being included in this report because it caused the NRC to increase its attention to and oversight of the Byron Generating Station, Unit 2, and because the event identified a design vulnerability that has potential generic implications to other commercial nuclear power plants. The Exelon Generation Company, LLC (the licensee) always maintained plant safety, and the NRC maintained oversight.

The Byron Generating Station is located about 27 kilometers (17 miles) southwest of Rockford, Illinois, and consists of two Westinghouse-designed four-loop pressurized water reactors. On January 30, 2012, an electrical insulator failed in the Byron Generating Station 345 kilovolt (kV) switchyard, resulting in the loss of offsite power, an automatic reactor trip of Unit 2, and the licensee declaring a notice of unusual event (NOUE). The failed insulator physically supported the "C" phase electrical conductor, one of three electrical phases supplying 345kV to the two Unit 2 station auxiliary transformers (SATs). The NRC responded to the NOUE by staffing the Region III Incident Response Center and entering the Monitoring Mode.

Following the insulator failure, Byron Unit 2 automatically tripped from full power because of an undervoltage condition on two of the four reactor coolant pumps (RCPs). The loss of the "C" phase of offsite power, however, did not result in an automatic undervoltage protection signal, which was a previously unidentified design vulnerability in the undervoltage protection scheme. Additionally, as a result of this design vulnerability in the undervoltage protection scheme, the emergency diesel generator did not automatically start, rendering all major running and standby electrical safety-related equipment unavailable. These conditions existed for approximately eight minutes, until control room operators took manual actions to separate the unit from the degraded offsite power source by opening the SAT feeder breakers. After the control room operators separated the unit from the degraded offsite power source, both emergency diesel generators started and provided electrical power to safety-related equipment. The licensee determined that no significant degradation occurred to the RCP seals based upon the time it took for the control room operators to open the SAT feeder breakers and the estimated time (approximately 13 minutes) for the RCP seal water volume to be depleted. The licensee removed reactor decay heat using the diesel-driven auxiliary feedwater pump and steam generator power-operated relief valves while the primary system cooled down in the natural circulation mode of operation. On January 31, 2012, Byron Unit 2 entered Mode 5, cold shutdown. The licensee completed repairs to the failed insulators, returned the Byron Unit 2 SATs to their normal alignment after completing the required oil sampling and inspections, and exited the NOUE on January 31, 2012.

The NRC Region III office performed a risk evaluation of this event and dispatched a special inspection team (SIT) to the site to review circumstances surrounding this event. The SIT charter included the development of the sequence of events related to the Byron Unit 2 reactor trip, the determination of a root cause of the trip, an assessment of operator responses to the events, a review of the licensee's root cause determination plan and schedule, and a review of the circumstances surrounding a number of equipment problems associated with the January 30, 2012, event. The inspectors used information from the plant computer and sequence of events recorder; interviewed licensee personnel who responded to the event; performed physical walkdowns of plant equipment and the switchyard; reviewed procedures, maintenance records, and various technical documents; and reviewed corrective action program documentation and causal evaluations. Following the inspection, the NRC identified a number

of unresolved items requiring additional followup and inspection. The most significant of these was the determination of whether the event that occurred was required to be addressed as defined in the licensee's design and licensing basis.

The staff was concerned with this aspect of the design and licensing basis because the licensee did not perform an operability determination upon discovery of the design vulnerability. In response to the staff's concern, the licensee stated that their procedures did not require an operability determination be performed since the non-conforming condition was not within the scope of structures, systems, and components considered in the operability determination process. The licensee's decision to not perform an operability determination was based largely on the fact that the event was outside of their current licensing basis. At the end of this inspection, a detailed NRC review of the current licensing basis was in progress.

The complete Byron Generating Station, Unit 2, SIT report entitled "Byron Unit 2—NRC Special Inspection Team Report 05000455/2012008," is available through ADAMS at Accession No. ML12087A213. In response to this event, the staff issued NRC Bulletin 2012-01, "Design Vulnerability in Electric Power System," (available at ADAMS Accession No ML12074A115) which required all operating reactor licensees to comprehensively address their compliance to General Design Criterion 17, "Electric Power Systems," the principal design criteria in each licensee's updated final safety analysis report, and the design criteria for protection and safety systems under 10 CFR Part 50.55a. The NRC is currently evaluating the Bulletin responses of all operating reactor licensees and combined license holders for new reactors. This event is also discussed in NRC Information Notice 2012-03, "Design Vulnerability in Electric Power System" (available at ADAMS Accession No ML120480170).

EOI-04 San Onofre Nuclear Generating Stations: Unusual Steam Generator Tube Wear and Unit 3 Steam Generator Tube Leak

The NRC included this event in this report because it received significant media and Congressional attention, and the public perceived it to be of high health and safety significance. San Onofre Nuclear Generating Station (SONGS), Units 2 and 3, have been shut down since January 2012 due to steam generator (SG) issues identified on two units that remain unresolved. Although the SG issues at SONGS are of regulatory significance and the NRC has placed the plant under Inspection Manual Chapter (IMC) 0351 ("Implementation of the Reactor Oversight Process at Reactor Facilities in an Extended Shutdown Condition for Reasons Other Than Significant Performance Problems"), the Southern California Edison Company (the licensee) always maintained plant safety, and the NRC maintained oversight.

SONGS, Units 2 and 3, are located approximately 74 kilometers (46 miles) Southeast of Long Beach, California, and are Combustion Engineering-designed pressurized water reactors. On January 31, 2012, SONGS, Unit 3, was operating at full power when control room operators received a high radiation alarm for the condenser air ejector monitor. This indicated a tube leak in one of the two SGs, and the operators entered the abnormal operating procedure for reactor coolant system (RCS) leakage. Once the leak rate was determined to be approximately 75 gallons per day (gpd) with an increasing rate of leakage exceeding 30 gpd per hour, a rapid power reduction was commenced in accordance with plant procedures. Operators manually tripped the reactor from 35 percent power, as directed by procedure, and entered into the emergency operating procedures for standard post-trip actions. The operators identified which SG had the tube leak, isolated the affected SG (identified as SG3E0-88), and cooled down the plant. The release of radioactive material from the leaking SG to the environment resulted in an estimated maximum off-site radiation dose of 4.52E-4 microseiverts (μSv) or 0.000452 mrem to a member of the public. The annual regulatory limit to a member of the public is 1 mSv/year (100 mrem/year).

On February 16, 2012, NRC Region IV performed an evaluation to determine if a reactive inspection was needed and it was determined that a reactive inspection was not needed at that time. The Region IV staff recommended that a baseline inspection focusing on event followup to review the licensee's response to the initial indications of the tube leak and to verify that the licensee's actions to assess the material conditions of the SG tubes were appropriate. Experts from several NRC offices were sent to the site to assist with these inspection efforts. During the followup inspection of the Unit 3 SG tubes, the licensee discovered unexpected wear in both SGs, including significant tube-to-tube wear in 129 tubes. Three tubes had wall thinning in excess of 99 percent, with many others also experiencing significant wear. The tube-to-tube wear was identified as the cause of the tube leak and resulted from thermal-hydraulic conditions that were more challenging than predicted and insufficient tube support.

The licensee commenced in situ pressure testing on March 13, 2012, of the 129 total tubes identified by eddy current testing as requiring this additional testing. Eddy current testing is a normal part of the SG tube integrity program, and the in situ pressure testing is performed when flaw indications exceed established criteria. The in situ testing is used to demonstrate the structural integrity of SG tubes. The licensee completed the in situ test of Unit 3 SG tubes and eight SG tubes failed.

On March 14, 2012, NRC Region IV and NRC Headquarters staff consulted on the need for a special inspection, in light of the significant SG tube wear and unexpected wear mechanisms observed during initial inspections of the Unit 3 SG tubes. The staff reviewed the need for a

reactive inspection and identified that the risk warranted the performance of an Augmented Inspection Team (AIT) inspection and that three deterministic criteria for AIT performance were also met. These criteria were: (1) a major deficiency in design, construction, or operation having major safety implications, (2) degradation that led to a significant loss of primary coolant pressure boundary, and (3) a loss of SG integrity reported as principal safety barriers being seriously degraded. The NRC AIT was sent to the SONGS site on March 16, 2012 (available at ADAMS Accession No. ML12075A258).

These SGs were manufactured by Mitsubishi Heavy Industries (MHI) and had been in service since the beginning of the operating cycle (approximately 1 year of power operation for Unit 3). The AIT charter included steps for conducting inspections at MHI and any of their associated subcontractors, to assess the possible effects that the manufacturing process had on the SGs. Separate from the AIT, during the period of October 9 through 17, 2012, a vendor inspection was conducted at MHI with personnel from NRC's Office of New Reactors and Region IV. The focus of the inspection was on potential long-term repair options for the SGs. During this inspection, the Region IV personnel were able to meet with various MHI engineers and managers to discuss design concerns associated with the replacement SGs. The AIT report was issued on July 18, 2012 (available at ADAMS Accession No. ML12188A748), and it concluded that plant operators responded to the January 31, 2012, SG tube leak in accordance with procedures and in a manner that protected public health and safety. The NRC identified 10 unresolved items, some of which concerned SG design and design control. Eight of the 10 unresolved items were closed during an AIT followup inspection that concluded in September 2012.

On March 27, 2012, the NRC also issued CAL 4-12-001, "Confirmatory Action Letter–San Onofre Nuclear Generating Station, Units 2 and 3, Commitments to Address Steam Generator Tube Degradation," (available at ADAMS Accession No. ML12087A323) to ensure that SONGS Unit 2, shutdown since January 10, 2012, will not enter startup mode (Mode 2), and SONGS Unit 3 will not enter hot shutdown (Mode 4), until the cause of the abnormal wear is determined and actions are taken to prevent the loss of SG tube integrity.

The licensee submitted a response to the CAL on October 2, 2012, which described its proposed actions to address SG tube degradation on Unit 2 and its return to service. The Unit 2 SG tubes did not experience wear as significant as the tube wear experienced in the Unit 3 SG. The licensee has not yet announced any plans for returning Unit 3 to service. The NRC conducted a portion of its inspection of the licensee's actions for the Unit 2 SG tube degradation during the week of December 3, 2012, and the inspection activities are still in progress. Before it makes any restart decision, the NRC will conduct additional inspection activities and analyses, and convene public meetings near the plant as the process progresses.

EOI-05 Palisades Nuclear Plant: Leak from the Safety Injection Refueling Water Tank

The NRC included this event in this report because it received significant media attention and the public perceived it to be of high health and safety significance. However, as described below, the Palisades Nuclear Plant leak from the safety injection refueling water tank (SIRWT) was of low safety significance since the tank was able to perform its function and the leaks did not affect other plant equipment. Additionally, plant safety was always maintained by Entergy Nuclear Operations, Inc. (the licensee), and the NRC continued to maintain its oversight.

Palisades Nuclear Plant is located approximately 8 kilometers (5 miles) south of South Haven, Michigan and is a Combustion Engineering design consisting of a two loop pressurized water reactor. On June 12, 2012, with Palisades operating at 100-percent reactor power, leakage from the SIRWT exceeded the licensee's administrative threshold established at 31 gpd. The licensee shut down the plant before the leakage from the SIRWT exceeded a value that would indicate a flaw that could challenge its structural integrity and function. The SIRWT is a large aluminum water tank located on the roof of the Palisades Auxiliary Building, above the main control room and is a safety-related tank. The SIRWT is designed to provide two engineered safeguards system functions: (1) it has an inventory of a minimum of 250,000 gallons of borated water available to the reactor coolant system for emergency core cooling, and (2) it is the primary source of net positive suction head to high- and low-pressure safety injection pumps and containment spray pumps.

With the plant shutdown and the SIRWT drained, the licensee performed various inspections of the tank using nondestructive examinations to identify the leaks. During inspection activities, the licensee identified weld flaws in various tank locations, including the SIRWT base, base-wall, under SIRWT base floor, and nozzles. The examinations revealed the existence of thru-wall flaws, including a flaw on a SIRWT nozzle. This nozzle has been replaced and the thru-wall leaks were repaired; the plant restarted on July 10, 2012. Post-repair leak rates have diminished to 0.05 gpd or less, which may be residual leakage from pre-repair conditions, rainwater, or a small leak from the SIRWT.

On July 17, 2012, the NRC issued CAL EA-12-155, “Confirmatory Action Letter—Palisades Nuclear Plant Commitments To Address Safety Injection Refueling Water Tank and Control Room Concrete Support Structure Leakage” (available at ADAMS Accession No. ML12199A409). The CAL confirms commitments made by the licensee to ensure frequent monitoring of the SIRWT. This will ensure prompt detection of flaw growth and address criteria for plant shutdown before the SIRWT is structurally challenged. In addition, the CAL discusses actions that have been taken, or are planned to be taken, by the licensee to address some leakage that has been seen in the control room from the SIRWT. This leakage has been minor, and the SIRWT is currently not leaking into the control room, and it is not impacting the equipment in the control room. The licensee is taking actions to ensure that the leakage into the control room is repaired promptly to prevent additional degradation of the control room barrier.

EOI-06 Seabrook Station, Unit 1: Concrete Degradation—Distress from Alkali-Silica Reaction

The NRC included this event in this report because it caused the agency to increase its attention to or oversight of concrete degradation from alkali-silica reaction (ASR). However, as described below, the staff is reviewing the concrete degradation from ASR at Seabrook Station, Unit 1, for long-term effects and to determine if the affected structures are capable of performing their safety functions. Additionally, NextEra Energy Seabrook, LLC., (the licensee) always maintained plant safety, and the NRC maintained oversight.

In June 2009, the licensee for the Seabrook Station, Unit 1, a Westinghouse-designed four loop pressurized-water reactor located about 21 kilometers (13 miles) south of Portsmouth, New Hampshire confirmed that certain concrete structures at Seabrook Station, Unit 1, were showing signs of degradation. In August 2010, through several engineering evaluations and interactions with concrete experts, the licensee determined that the degradation identified in certain concrete structures was the result of ASR. ASR is a slow chemical reaction in which cement and aggregate, if exposed to excessive water from the environment, can react to form an alkali-silica gel within the concrete. The alkali-silica gel can then expand within the concrete, resulting in very small cracks that can potentially weaken the affected concrete structure. At Seabrook Station, Unit 1, certain below-grade concrete structures have experienced ground-water infiltration, which, in turn, has induced ASR.

The NRC has interacted with the licensee to ensure that the significance of the impacts is properly categorized and that the effect of ASR is addressed. The NRC has reviewed design documentation and engineering evaluations of the affected structures, and has conducted focused inspections of the affected structures. Based on these efforts, the NRC staff has determined that there are no immediate safety concerns attributable to ASR, and that the affected structures are capable of performing their safety-related functions. This determination takes into account the safety margins built into the affected structures, the fact that ASR is present in a limited section of the affected structures, and the licensee's implementation of a dedicated monitoring program that would provide warning of further degradation of the affected structures. Seabrook Station, Unit 1, is the first plant in the U.S. nuclear industry to exhibit ASR; therefore, the NRC has a particular interest in ensuring that a rigorous evaluation of this issue is completed and that any significant lessons learned are made available to the U.S. nuclear industry. On November 18, 2011, the NRC issued NRC Information Notice 2011-20, "Concrete Degradation by Alkali-Silica Reaction," (available at ADAMS Accession No. ML112241029) to provide the U.S. nuclear industry with information related to the ASR identified at Seabrook Station, Unit 1.

On May 16, 2012, the NRC issued CAL 1-2012-002, "Confirmatory Action Letter—Seabrook Station, Unit 1—Information Related to Concrete Degradation Issues" (available at ADAMS Accession No. ML121254172). The CAL documented the licensee's commitments to provide additional information to the NRC regarding its upcoming testing, evaluations, and other activities in response to the concrete degradation. On July 19, 2012, the NRC Office of Nuclear Reactor Regulation and Region I chartered the Seabrook Alkali-Silica Reaction Issue Technical Team (SAITT) (available at ADAMS Accession No. ML121250588) to provide coordination of the onsite inspections, in-office technical reviews, and other associated evaluations and assessments involving the licensee's review and resolution of the ASR issues at Seabrook Station, Unit 1.

As part of the followup activities from the SAITT, on September 14, 2012, the NRC issued a press release announcing that the agency will “deviate” from its reactor oversight process to conduct additional inspections of concrete degradation at Seabrook Station, Unit 1, in New Hampshire (available at ADAMS Accession No. ML12258A391).

EOI-07 Halliburton Energy Services: Reported Loss and Recovery of a Well Logging Source

This event is being included in this report because it was perceived by the public to be of high health and safety significance and the event received significant media coverage. However, as described below, the loss and subsequent recovery of the category 3 americium-beryllium (Am-Be) well logging source by Halliburton Energy Services (the licensee) was actually of low safety significance. The Texas Department of State Health Services (DSHS) maintained regulatory oversight of the search efforts and the NRC followed the event through its communications with DSHS.

On September 11, 2012, the licensee reported to the DSHS that a 555 GBq (15 Ci) Am-Be well logging source, which had been used earlier that day at a well site near Pecos, Texas, could not be located by their well logging crew upon arrival at a second well site near Odessa, Texas. The well logging crew left the Pecos site and travelled approximately 209 kilometers (130 miles) towards Odessa without stopping. When the crew went to remove the Am-Be well logging source they discovered that the source transport container lock and plug were not in place and that the source was missing. The well logging crew returned to the well site near Pecos and searched for the source, but did not find it.

The licensee conducted extensive search efforts along the roadway between the two well logging sites. The licensee did not find the source along the roadway and conducted two additional searches of the well logging site in Pecos. The licensee stated that it completed a review of the truck's black box and confirmed that the truck did not stop while traveling between the two well sites. Additionally, the licensee stated that the three individuals who conducted the well logging operations when the source was lost were interviewed by individuals from the Federal Bureau of Investigation working with the Department of Transportation.

DSHS notified their local inspectors of the event and included a copy of the latest dose rate readings for the Am-Be well logging source. DSHS conducted extensive search efforts, and augmented its search efforts with the Texas Military Forces' Sixth Civil Support Team and the US Environmental Protection Agency's Aerial Spectrophotometric Environmental Collection Technology (ASPECT) aircraft. Local police and the well site lease holder were notified of the lost well logging source along with its description. The licensee issued a press release which provided a description of the source and actions to take if found, and stated that it would offer a reward. Additionally, the logging truck used during the event was stripped down in an attempt to locate the lost source.

On October 5, 2012, DSHS was notified by the licensee that the missing Am-Be well logging source had been recovered by a member of the public. The missing source was located along a road approximately 8 miles from the Pecos wellhead. The well logging crew did not report traveling on that road on the day the source was lost. The licensee estimated that the member of the public who found the source received a whole body dose of 0.518 mSv (51.8 mrem) based on his description of time and proximity to the source. This exposure is below the 1 mSv (100 mrem) limit to individual members of the public in 10 CFR section 20.1301.

EOI-08 Honeywell Metropolis Works: Vulnerability of Feed Materials Building Process Equipment to Seismic or Tornado Events and Inadequacy of Emergency Response Plan

The NRC included this issue in this report because it caused the NRC to increase its attention to and oversight of the Honeywell Metropolis Works (the licensee) facility due to identified vulnerabilities in the ability of the feed materials building (FMB) process equipment to withstand a credible seismic event or tornado. Additionally, the potential chemical release from an event was inconsistent with assumptions used to develop its Emergency Response Plan (ERP).

The licensee's facility is located on approximately 1,000 acres of land in Massac County at the southern tip of Illinois, along the northern bank of the Ohio River near the town of Metropolis, IL. The licensee converts uranium into uranium hexafluoride (UF_6) for the nuclear industry. The conversion process involves the use of some hazardous chemicals in both liquid and gaseous forms. The NRC requires that the licensee have an effective ERP to protect both the public and on-site workers in the event hazardous chemicals and/or nuclear material are released from the process equipment to the environment.

On May 21 through 24, 2012, an NRC inspection at the licensee's facility was conducted as part of the NRC's followup to the Fukushima Daiichi nuclear plant accident using Temporary Instruction (TI) 2600/015, "Evaluation of Licensee Strategies for the Prevention and/or Mitigation of Emergencies at Fuel Facilities" (available at the NRC's ADAMS Accession No. ML111030453). The objective of the TI inspection was to independently verify that the licensee is adequately prepared to prevent and/or mitigate the consequences of selected safety/licensing basis events, and to evaluate the adequacy of those emergency prevention and/or mitigation strategies for dealing with the consequences of selected beyond safety/licensing basis events. The inspection identified significant concerns related to the assumed amount of UF_6 and hydrogen fluoride that could potentially be released during credible seismic events or tornadoes and used as a basis for the site ERP. Specifically, the inspection identified that the process equipment in the licensee's FMB lacks seismic restraints, supports, and bracing that would assure process equipment integrity during certain credible seismic events or tornadoes. The results of the inspection are documented in TI 2600/015 Inspection Report 40-3392/2012-006 (available at ADAMS Accession No. ML12222A163).

On July 13, 2012, the NRC issued a confirmatory action letter, CAL 02-2012-012, "Confirmatory Action Letter—Honeywell Facility Commitments To Resolve Safety Concerns Before Restarting NRC Licensed Operations" (available at ADAMS Accession No. ML12195A212), acknowledging that the licensee voluntarily suspended all NRC licensed operations involving a phase change of solid UF_6 or quantities of liquid UF_6 beyond the bases for its ERP. The NRC concluded that significant actions are necessary to provide reasonable assurance of public health and safety prior to resuming operations. On October 15, 2012, the NRC issued a confirmatory order (available at ADAMS Accession No. ML12289A863) that required the licensee to: (1) submit documentation to the NRC to include; (i) an evaluation of external events that clearly defines and provides the safety bases for seismic and wind design, (ii) documentation of structures, systems, or components relied upon to protect workers and the public for both intermediate and high consequence events, (iii) documentation regarding the definitions of intermediate consequence event and high consequence event for non-radiological releases, and (iv) documentation of definitions of unlikely and highly unlikely for seismic and wind events; (2) submit a revised ERP; (3) provide documentation of the design bases for the proposed plant modifications; (4) develop and implement quality assurance measures for the plant modifications; (5) implement the proposed plant modifications prior to resuming facility

operations; (6) demonstrate the adequacy of its revised ERP by conducting an onsite exercise at least 15 days prior to resuming facility operations; (7) obtain NRC written approval to resume plant operations, and to notify the NRC at least 30 days before resuming facility operations; and (8) submit a revised Integrated Safety Analysis summary no later than six months after restart.

The licensee responded to the order in November 2012, and NRC accepted the response for detailed review.

The licensee must implement the corrective actions identified in the confirmatory order. NRC will review and inspect these corrective actions to verify that the licensee's design and implementation meets the licensing basis before authorizing restart.

APPENDIX D
GLOSSARY

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

Authorized User—as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.2, "Definitions," a physician, dentist, or podiatrist who (1) meets the requirements in 10 CFR 35.59, "Recentness of Training," and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 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 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.

Breakthrough—occurs when the elution extracted from a radioisotope generator contains some of the parent radionuclide or other undesirable contaminant from within the generator. The maximum acceptable level of breakthrough for clinical use of radioisotope generators is specified in 10 CFR 35.204.

[1]**Catheter**—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.

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

[1]**Computed Tomography (CT)**—radiography in which a three-dimensional image of a body structure is constructed by a computer from a series of cross-sectional images made along an axis.

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

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

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 ($H_E = \Sigma\, w_T\, H_T$).

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

[1]**Endobronchial**—located within either of the two primary divisions of the trachea that lead respectively into the right and the left lung.

[1]**Endometrial Carcinoma**—a cancer that starts in the endometrium, the lining of the uterus (womb).

[2]**Esophageal cancer**—a malignant tumor of the esophagus.

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.

[2]**Gastric Cancer**—a malignant tumor of the stomach.

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

[1]**Graves Disease**—a common form of hyperthyroidism characterized by goiter and often a slight protrusion of the eyeballs.

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).

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

[1]**Magnetic Resonance Imaging (MRI)**—a noninvasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

[3]**Mammosite Treatment**—a minimally invasive radiation therapy technique used to treat breast cancer. This technique uses brachytherapy to deliver radiation directly to the site of the tumor bed from inside the body. A soft balloon, attached to a thin catheter, is inserted into the cavity where the tumor was removed. The balloon is inflated and a computer-controlled machine delivers the radiation down the catheter into the balloon, where it irradiates the tumor bed.

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

[3] This term is not defined in 10 CFR, a management directive, an inspection procedure, or an NRC policy statement. Rather, this term is defined based on the definitions in the online WebMD (http://www.webmd.com).

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

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

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

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

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

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

Member of the Public—as defined in 10 CFR 20.1003, any individual except when that individual is receiving an occupational dose.

[2]**Nasogastric**—referring to the passage from the nose to the stomach.

[1]**Nasopharyngeal**—of, relating to, or affecting the nose and pharynx or the nasopharynx.

Occupational Dose—as defined in 10 CFR 20.1003, the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," from voluntary participation in medical research programs, or as a member of the public.

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.

[2]**Prostate Gland**—a gland within the male reproductive system that is located just below the bladder.

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

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

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

Radiation Safety Officer (RSO)—as defined in 10 CFR 35.2, an individual who (1) meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59, "Recentness of Training"; or (2) is identified as a radiation safety officer on (i) a specific medical use license issued by the Commission or Agreement State; or (ii) a medical use permit issued by a Commission master material licensee.

[2]**Radiation Therapy (Radiotherapy)**—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."

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

[4]**Radioisotope Generator**—separation systems containing a relatively long-lived parent radionuclide that produces a short-lived daughter in its decay scheme. The daughter can be periodically extracted (milked) by means of an appropriate eluting agent.

[2]**Radiologist**—a physician specialized in radiology, the branch of medicine that uses ionizing and non-ionizing radiation for the diagnosis and treatment of disease.

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

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

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

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

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

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

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

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

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

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[4] This term is not defined in 10 CFR, a management directive, an inspection procedure, or an NRC policy statement. Rather, this term is defined based on the definitions in the online medical dictionary (http://www.online-medical-dictionary.org).

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

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

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

APPENDIX E
CONVERSION TABLE

Radioactivity and Ionizing Radiation

QUANTITY	FROM METRIC UNITS	TO NON-SI UNITS	DIVIDE BY
(Radionuclide) Activity	megabecquerel (MBq)	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