

characteristics (mainly slope) making it very suitable for calibrating the laser altimeters that will be on NASA's ICESat-2.

The desired flight lines cross small portions of the Barwick Valley Antarctic Specially Protected Area, and the management prohibits overflight at altitudes less than 2500 ft. NASA is seeking a permit to fly through ASPA 123 six times at an altitude of 1500 ft. or higher. While flying over the ASPA, NASA will be using airplane mounted instruments to collect laser, radar, gravity, and magnetic data and aerial photography. There is no plan to land the aircraft in the ASPA and data collection would not disturb the ground surface in the ASPA.

Location

ASPA 123 Barwick and Balham Valleys

Dates

October 26, 2013 to November 30, 2013

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NUCLEAR REGULATORY COMMISSION

[NRC-2013-0094]

Report to Congress on Abnormal Occurrences: Fiscal Year 2012, Revision 1; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 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 (Pub. L. 104-68) requires that AOs be reported to Congress annually. During Fiscal Year (FY) 2012, 22 events that occurred at facilities licensed by the NRC and/or Agreement States were determined to be AOs.

This report describes four events at NRC-licensed facilities. The first event at an NRC-licensed facility was an occurrence at a commercial nuclear power plant and the other three events occurred at NRC-licensed medical institutions and are medical events as defined in part 35 of Title 10 of the Code of Federal Regulations (10 CFR). The report also describes 18 events at

Agreement State-licensed facilities. Agreement States are the 37 States that currently have entered into formal agreements with the NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA-licensed material at facilities located within their borders. 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 and occurred at medical institutions. As required by Section 208, the discussion for each event includes the date and place, the nature and probable consequences, the cause or causes, and the actions taken to prevent recurrence. Each event is also described in NUREG-0090, Volume 35, "Report to Congress on Abnormal Occurrences: Fiscal Year 2012," issued May 2013 (ADAMS Accession No. ML13149A083). The report was revised to include editorial corrections and reissued in August 2013 as NUREG-0090, Volume 35, Revision 1, "Report to Congress on Abnormal Occurrences: Fiscal Year 2012" (ADAMS Accession No. ML13225A395). This report is available electronically at the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/>.

Three major categories of events are reported in this document—I. For All Licensees, II. For Commercial Nuclear Power Plant Licensees, and III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events. The full report, which is available on the NRC's Web site, provides the specific criteria for determining when an event is an AO. It also discusses "Other Events of Interest," which do not meet the AO criteria but have been determined by the Commission to be included in the report. The event identification number begins with "AS" for Agreement State AO events and "NRC" for NRC AO events.

I. For All Licensees

A. Human Exposure to Radiation From Licensed Material

During this reporting period, two events involving Agreement State-licensees were significant enough to be reported as AOs. 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, "For 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

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.

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

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 total effective dose equivalent (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. The DSHS cited both the licensee and radiographer trainer with several violations associated with this event.

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.

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

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 while the plant was operating 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 (CAL) (EA-13-020) "Confirmatory Action Letter—Fort Calhoun Station," (available at the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML13057A287) to confirm 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.

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

C. Medical Licensees

During this reporting period, three events at NRC licensees and 16 events at Agreement State-licensees were significant enough to be reported as AOs.

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

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.

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

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 the 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.

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

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. The KDPH discovered 34 additional cases of improper prostate seed implantation performed by the same radiation oncologist between October 3, 2001, and February 24, 2009. The 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—The 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.

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

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 an 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.

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

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

Nature and Probable Consequences—The KDPH performed an inspection of Highlands Regional Medical Center (the licensee) manual brachytherapy program on January 14, 2011. The 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). The 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. The 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.

The 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—The 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 the Kentucky medical license.

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

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 PA DEP conducted a reactive investigation on January 25, 2011, and identified one violation. The 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.

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

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. The CDPHE issued a notice of violation

(NOV) on August 17, 2011, and a followup Compliance Order on Consent on June 29, 2012.

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

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 the 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 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—The 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.

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

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.

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

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.

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

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 fractionated 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.

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

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.

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

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 event 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 patient's file.

Actions Taken To Prevent Recurrence

Licensee—The corrective actions taken by the licensee include 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.

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

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(s)—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.

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

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. The MDH concluded that licensee procedures were appropriately followed and no violations were issued.

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

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.

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

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. The 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 (cm³) 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 any adverse effects 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—The 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.

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

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 include 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.

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

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.

Dated at Rockville, Maryland, this 28th day of August, 2013.

For the Nuclear Regulatory Commission,
Annette Vietti-Cook,
Secretary of the Commission.

[FR Doc. 2013-21477 Filed 9-3-13; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

Sunshine Act Meetings

TIME AND DATE: Wednesday, September 11, 2013, at 11 a.m.

PLACE: Commission Hearing Room, 901 New York Avenue NW., Suite 200, Washington, DC 20268-0001.

STATUS: Part of this meeting will be open to the public. The rest of the meeting will be closed to the public. The open session will be audiocast. The audiocast may be accessed via the Commission's Web site at <http://www.prc.gov>. A period for public comment will be offered following consideration of the last numbered item in the open session.

MATTERS TO BE CONSIDERED: The agenda for the Commission's September 11, 2013 meeting includes the items identified below.

PORTIONS OPEN TO THE PUBLIC:

1. Report on legislative activities.
2. Report on handling of ate and service inquiries from the public.
3. Report from the Office of General Counsel on the status of Commission dockets.

4. Report from the Office of Accountability and Compliance.
5. Report from the Office of the Secretary and Administration.
6. Report on the Public Representative program pursuant to 39 U.S.C. 505.

PORTION CLOSED TO THE PUBLIC:

7. Discussion of pending litigation.

CONTACT PERSON FOR MORE INFORMATION: Stephen L. Sharfman, General Counsel, Postal Regulatory Commission, 901 New York Avenue NW., Suite 200, Washington, DC 20268-0001, at 202-789-6820 (for agenda-related inquiries) and Shoshana M. Grove, Secretary of the Commission, at 202-789-6800 or shoshana.grove@prc.gov (for inquiries related to meeting location, access for handicapped or disabled persons, the audiocast, or similar matters).

By direction of the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013-21506 Filed 8-30-13; 11:15 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-70276; File No. SR-FINRA-2013-036]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change Relating to Wash Sale Transactions and FINRA Rule 5210 (Publication of Transactions and Quotations)

August 28, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 thereunder, ² notice is hereby given that on August 15, 2013, Financial Industry Regulatory Authority, Inc. (“FINRA”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to add Supplementary Material .02 to FINRA Rule 5210 (Publication of Transactions and Quotations) to emphasize that wash sale transactions are generally non-bona fide transactions and that members have

an obligation to have policies and procedures in place to review their trading activity for, and prevent, wash sale transactions.

Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

5000. SECURITIES OFFERING AND TRADING STANDARDS AND PRACTICES

* * * * *

5200. QUOTATION AND TRADING OBLIGATIONS AND PRACTICES

5210. Publication of Transactions and Quotations

No Change.

• • • Supplementary Material:

.01 Manipulative and Deceptive Quotations. No Change.

.02 *Wash Sales. Transactions in a security that involve no change in the beneficial ownership of the security, commonly known as “wash sales,” generally are non-bona fide transactions for purposes of Rule 5210. Members must have policies and procedures in place that are reasonably designed to review their trading activity for, and prevent, wash sale transactions. Transactions that originate from unrelated algorithms or separate and distinct trading strategies within the same firm would generally be considered bona fide transactions and would not be considered wash sales, even if the transactions did not result in a change of beneficial ownership, unless the transactions were undertaken for manipulative or other fraudulent purposes. Algorithms or trading strategies within the most discrete unit of an effective system of internal controls at a member firm are presumed to be related (e.g., within an aggregation unit, or individual trading desks within an aggregation unit separated by reasonable information barriers, as applicable). This Supplementary Material does not change members' existing obligations under NASD Rule 3010 and FINRA Rule 2010.*

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II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.