

NUCLEAR REGULATORY COMMISSION  
REPORT TO CONGRESS ON ABNORMAL OCCURRENCES  
FISCAL YEAR 2009  
DISSEMINATION OF INFORMATION  
[NRC-2010-0238]

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event which 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 104-68) requires that AOs be reported to Congress annually. During Fiscal Year 2009, nine events that occurred at facilities licensed or otherwise regulated by the NRC and/or Agreement States were determined to be AOs. The report describes three events at NRC-licensed facilities. All three NRC- licensee events were medical events, as defined in Title 10, Part 35, of the *Code of Federal Regulations* (10 CFR Part 35). The report also describes six events at Agreement State-licensed facilities. [Agreement States are those States that 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.] Currently, there are 37 Agreement States. The first two Agreement State-licensee events involved radiation exposure to an embryo/fetus. The other four 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, nature and probable consequences, the cause or causes, and the actions taken to prevent recurrence. Each event is also being described in NUREG-0090, Vol. 32, "Report to Congress on Abnormal

Occurrences: Fiscal Year 2009.” This report is available electronically at the NRC Web site <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/>.

There are three major categories of events 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, available on the NRC Web site, provides the specific criteria for determining when an event is an abnormal occurrence (AO) and discusses “Other Events of Interest” that do not meet the AO criteria but which the Commission has determined should 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 at Agreement State-licensed facilities were significant enough to be reported as abnormal occurrences (AOs). Although both of these events occurred at medical facilities, they both involved unintended exposures to individuals who were not the patient. Therefore, these events belong under the criteria I.A, “For All Licensees” category as opposed to the criteria III.C, “For Medical Licensees” category.

#### **AS09-01 Human Exposure to Radiation at Chester County Hospital in West Chester, Pennsylvania**

Date and Place – March 30, 2009, West Chester, Pennsylvania

Nature and Probable Consequences – Chester County Hospital (the licensee) reported that a therapeutic dose of 2,001.7 MBq (54.1 mCi) of iodine-131 resulted in a dose to an embryo/fetus

of 119 mSv (11.9 rem). On March 30, 2009, the patient was given a pregnancy test and it yielded a negative result. Based on the negative pregnancy test, the licensee administered the iodine-131 to the patient.

On May 13, 2009, the patient informed the authorized user that she was pregnant. The administration of iodine-131 was given to the patient approximately 5 days post-conception, a time period at which the thyroid had not developed. The hospital discovered the pregnancy at 9.5 weeks gestation, at which time the thyroid had developed. Due to residual iodine-131 in the patient's system, both a whole body and an organ dose exposure occurred. The hospital calculated a total whole body dose to the embryo/fetus of 119 mSv (11.9 rem) and a fetal thyroid dose of 9.7 mSv (0.97 rem). The hospital recommended that the patient consult with a genetic counselor for any potential health effects to the embryo/fetus.

Cause(s) – The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

#### Actions Taken to Prevent Recurrence

Licensee – The licensee is providing additional instructions to its staff to strongly emphasize to patients the risks associated with being pregnant prior to the administration of radioiodine treatments.

State – The State conducted a follow-up inspection and did not take any enforcement action regarding this event.

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**AS09-02      Human Exposure to Radiation at Loyola University Medical Center  
in Maywood, Illinois**

Date and Place – September 21, 2009, Maywood, Illinois

Nature and Probable Consequences – Loyola University Medical Center (the licensee) reported that the administration of 925 MBq (25 mCi) of iodine-131 resulted in a dose to an embryo/fetus of 67 mSv (6.7 rem). Prior to the administration of iodine-131, a urinary pregnancy test was conducted by the licensee on September 21, 2009, and it yielded a negative result. On September 29, 2009, the patient notified the licensee that she took a home pregnancy test and it was positive. The patient's pregnancy was confirmed by an independent clinic that administered a second pregnancy test.

The administration of iodine-131 was given to the patient at 2 to 3 weeks gestation (as determined by a consulting physician), a time period at which the thyroid had not developed. Shortly thereafter, the pregnancy ended. The licensee calculated a total whole body dose of 67 mSv (6.7 rem) to the embryo/fetus. There was no dose to the fetal thyroid since the pregnancy had ended before the thyroid had developed.

Cause(s) – The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

Actions Taken to Prevent Recurrence

Licensee – The licensee reviewed its established patient selection criteria, screening methods, and testing protocols for any procedural changes. A more sensitive pregnancy test for women

capable of bearing children will now be conducted no more than a few days prior to the dose administration.

State – After consulting an expert, the State determined that the administration occurred before the development of the thyroid. The State also performed independent calculations that verified the estimate of the fetal dose by the licensee. The State reviewed and accepted the licensee’s formal report on October 14, 2009.

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## **II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES**

During this reporting period, no events at commercial nuclear power plants in the United States were significant enough to be reported as AOs.

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

### **C. Medical Licensees**

During this reporting period, three events at NRC-licensed or regulated facilities and four events at Agreement State-licensed facilities were significant enough to be reported as AOs.

#### **AS09-03 Medical Event at St. Vincent’s Medical Center Inc., in Jacksonville, Florida**

Date and Place – September 10-17, 2008, Jacksonville, Florida

Nature and Probable Consequences – St. Vincent’s Medical Center Inc., (the licensee) reported that a medical event occurred associated with a high dose-rate (HDR) mammosite treatment for breast cancer containing 199.8 GBq (5.4 Ci) of iridium-192. A patient was prescribed to receive 34 Gy (3,400 rad) to the right breast but received 34 Gy (3,400 rad) to the skin of the left breast.

On October 16, 2008, the patient notified her physician of erythema on her left breast. During a records review, the medical physicist determined that an error in programming the catheter length in the HDR device caused the source to stop 10 cm short of the intended tumor site in the right breast. Due to this programming error, the dose intended for the right breast was delivered to the skin of the left breast. The authorized user concluded that no chronic health effect to the patient is expected.

Cause(s) – The medical event was caused by human error in failing to verify that the correct catheter length was entered into the treatment planning system.

#### Actions Taken to Prevent Recurrence

Licensee – The licensee committed to taking several corrective actions as a result of the medical event that include (1) utilizing a catheter length worksheet to determine and verify the mammosite catheter length, (2) documenting the mammosite catheter length by two individuals – one physicist and either a dosimetrist, physicist, or radiation therapist – during simulation treatment set-up, (3) providing procedures for the medical physicist and authorized user on documenting the catheter length on the catheter worksheet during the review of the treatment control unit and treatment plan, and (4) conducting a second measurement of the catheter length to verify that the length agrees with the data in the treatment control unit.

State – The Florida Bureau of Radiation Control conducted an investigation and reviewed the licensee’s corrective actions and found the corrective actions to be adequate.

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**NRC09-01      Medical Event at Saint Mary’s Medical Center in Huntington, West Virginia**

Date and Place – October 15, 2008, Huntington, West Virginia

Nature and Probable Consequences – Saint Mary’s Medical Center (the licensee) reported that a medical event occurred associated with the administration of a 5.55 GBq (150 mCi) iodine-131 capsule for thyroid cancer. A patient was prescribed to receive 10.12 Gy (1,012 rad) to the esophagus but received 18 Gy (1,800 rad) to the esophagus. The patient and the referring physician were informed of this event.

During the administration, the patient attempted to swallow the capsule, but it became lodged in an obstruction in the upper portion of the esophagus. Licensee staff provided the patient with soda and applesauce to help dissolve the capsule, and after 2.5 hours the capsule passed the obstruction. Since the capsule was lodged in the patient’s upper portion of the esophagus for longer than expected, an estimated dose of 18 Gy (1,800 rad) was received to a small area of esophageal tissue. If the capsule had not become lodged in the upper portion of the patient’s esophagus, the esophagus would have received the intended dose of 10.12 Gy (1,012 rad) instead of 18 Gy (1,800 rad). The dose to the esophagus exceeded the intended dose by 78 percent.

On October 22, 2008, the event was discussed with the patient during a follow-up visit with the prescribing physician. The prescribing physician indicated that potential health effects from this administration could include esophagitis and radiation fibrosis.

Cause(s) – The cause of the medical event was human error in failing to recognize that the esophageal obstruction might interfere with the patient’s ability to swallow the iodine-131 capsule.

Actions Taken to Prevent Recurrence

Licensee – The licensee modified its procedure to include a pre-therapy esophageal dilation for patients known to have difficulty swallowing. In addition, patients known to have this difficulty may be administered liquid iodine-131 for treatment.

NRC – NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee’s corrective actions taken to prevent recurrence of similar events. The medical consultant concluded that no significant adverse health effect to the patient is expected. The NRC concluded an inspection on February 6, 2009, and one non-cited violation was issued to the licensee on February 10, 2009.

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**AS09-04      Medical Event at Presbyterian Hospital of Dallas in Dallas, Texas**

Date and Place – December 2, 2008, Dallas, Texas



Nature and Probable Consequences – Presbyterian Hospital of Dallas (the licensee) reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife) containing 125.8 TBq (3,400 Ci) of cobalt-60. A patient being treated for trigeminal neuralgia was prescribed to receive 80 Gy (8,000 rad) to the fifth intracranial nerve but received 14.95 Gy (1,495 rad) to the seventh intracranial nerve. The patient and the referring physician were informed of this event.

An error in entry of information into the treatment planning system caused the wrong nerve to receive treatment. The error was identified by the neurosurgeon 9 minutes into the 45-minute treatment. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The medical event was caused by the misidentification of the anatomical target site listed on the written directive.

#### Actions Taken to Prevent Recurrence

Licensee – The licensee modified its written procedure to include verification of the target site, by the neuroradiologist, for each treatment. In addition, an updated written directive will document the new procedure to ensure that the correct treatment site is targeted and treated in each procedure.

State – The State will conduct a review of at least 20 percent of the past treatment cases to ensure that this error had not previously occurred.

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**AS09-05      Medical Event at Cancer Care Northwest PET Center in Spokane,  
Washington**

Date and Place – April 14, 2009, Spokane, Washington

Nature and Probable Consequences – Cancer Care Northwest PET Center (the licensee) reported that a medical event occurred associated with a HDR brachytherapy treatment for prostate cancer containing 185 GBq (5 Ci) of iridium-192. During patient treatment, the aluminum connector to needle 13 became detached from the plastic guide tube and a dose of 12.5 Gy (1,250 rad) was delivered to a small area of the patient's inner thigh (wrong treatment site). The patient and the referring physician were informed of this event.

The source wire for needle 13 hung about 6 inches past the disconnected guide tube, which resulted in the skin dose. The licensee conducted several follow-up examinations of the patient's inner thigh and noted that no skin reddening or injury has occurred and the patient is not experiencing any pain in this area. Therefore, the licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The cause of the medical event was the source wire, for needle 13, snagged on the seam between the aluminum connector and the plastic guide tube during retraction.

Actions Taken to Prevent Recurrence

Licensee – The licensee committed to taking several actions as a result of the medical event that include (1) requiring the staff to sign the patient quality assurance list when they check the applicators, transfer guide tubes, and aluminum connectors; (2) inspecting the guide tube

catheters daily and examining the aluminum connectors prior to patient use; and (3) revising the refresher training to include new procedures for staff prior to patient treatment.

State – The State conducted follow-up inspection activities from April-May 2009, and reviewed the licensee's corrective actions. The State found the licensee's corrective actions adequate and did not take any enforcement action regarding this event.

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**AS09-06      Medical Event at The Urology Center in Cincinnati, Ohio**

Date and Place – May 11, 2009, Cincinnati, Ohio

Nature and Probable Consequences – The Urology Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 144 Gy (14,400 rad) to the prostate using 64 iodine-125 seeds as permanent implants. Instead, the patient received an approximate dose of 76 Gy (7,600 rad) to the urethra and bulb of the penis (unintended sites). The patient and the referring physician were informed of this event.

According to the licensee, an interpretation of the ultrasound image of the patient's prostate resulted in 30 of the 64 seeds delivered to the prostate while the other 34 seeds were delivered outside the prostate. Due to the patient's prostate being smaller than normal, the prostate received 68 Gy (6,800 rad) of the prescribed dose and the urethra and bulb of the penis (unintended sites) received approximately 76 Gy (7,600 rad). Prior to the seeds being implanted, the urologist and radiation oncologist should have consulted on the ultrasound image of the patient's prostate to determine the correct seed placement. The licensee concluded that

no significant adverse health effect on the patient is expected. On May 19, 2009, the patient returned for a second treatment to compensate for the original underdosing to the prostate.

Cause(s) – The cause of the medical event was the misinterpretation of the correct size of the patient’s small prostate gland by ultrasound.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions taken by the licensee included instituting a new policy requiring agreement by both the urologist and radiation oncologist on seed placement for all prostate glands measuring 20 cubic centimeters or less. On May 26, 2009, the licensee submitted a written report of this event to the Ohio Department of Health, Bureau of Radiation Protection (ODH BRP).

State – On June 12, 2009, ODH BRP conducted an inspection of this event and determined that the licensee had followed the correct procedures for administrations requiring a written directive. ODH BRP reviewed the licensee’s corrective actions for this event and found the corrective actions to be adequate.

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**NRC09-02      Medical Event at Gamma Knife Center of the Pacific in Honolulu, Hawaii**

Date and Place – July 2, 2009, Honolulu, Hawaii

Nature and Probable Consequences – Gamma Knife Center of the Pacific (the licensee) reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit

(gamma knife) containing 104.86 TBq (2,834 Ci) of cobalt-60. A patient being treated for multiple brain metastatic sites was prescribed to receive 24 Gy (2,400 rad) to seven discrete brain sites using an 8 mm collimator. However, an 18 mm collimator was used to treat two of the discrete brain sites, resulting in a dose of 24 Gy (2,400 rad) to additional brain tissue. The patient and the referring physician were informed of this event.

The patient received treatment to the first and second discrete brain sites and after receiving treatment to the second discrete site, it was discovered that an 18 mm collimator was used to deliver treatment instead of the prescribed 8 mm collimator. The larger collimator caused the volume of each of the two discrete sites to increase by 2.45 cubic meters, resulting in a dose of 24 Gy (2,400 rad) to additional brain tissue. After the 18 mm collimator was discovered, it was replaced with the 8 mm collimator and the patient received treatment to the five remaining discrete sites as prescribed. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s) – The cause of the medical event was human error in failing to check the collimator size prior to patient treatment.

#### Actions Taken to Prevent Recurrence

Licensee – Corrective actions taken by the licensee included (1) sending a notice to all authorized users, neurosurgeons, and medical physicists reiterating that they should each independently check the collimator size prior to patient treatment and (2) revising procedures to have a second independent verification of all treatment parameters, including the collimator size, by a treatment team member.

NRC – NRC conducted an onsite inspection and hired a medical consultant to review the event. The conclusions from the onsite inspection and medical consultant's review are ongoing.

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**NRC09-03      Medical Event at the Veterans Affairs San Diego Health Care System  
in San Diego, California**

Date and Place – September 21, 2009, San Diego, California

Nature and Probable Consequences – The Department of Veterans Affairs (the licensee), National Health Physics Program (NHPP) reported that a medical event occurred at the Veterans Affairs (VA) San Diego Health Care System associated with a therapeutic dosage of iodine-131 for the treatment of metastatic thyroid cancer. A patient was prescribed to receive 6.9 GBq (187 mCi) of iodine-131 to the metastatic sites around the body but received 6.1 GBq (166 mCi) to the stomach (wrong treatment site). The patient and the referring physician were informed of this event.

On September 21, 2009, a dosage of 6.9 GBq (187 mCi) of iodine-131 was administered to the patient through an existing feeding tube. Daily radiation measurements indicated small decreases in radiation readings that were consistent with the physical decay of iodine-131, but not consistent with the biological elimination of iodine-131. On September 25, 2009, the feeding tube was replaced and a subsequent investigation revealed that the majority of the dosage, 6.1 GBq (166 mCi), was administered to the wrong orifice of the feeding tube. As a result, the dosage remained in the balloon of the feeding tube and irradiated the patient's stomach, resulting in an approximate dose of 16 Gy to 19 Gy (1,600 rad to 1,900 rad) to the stomach.

Cause(s) – Three root causes were identified for this medical event: (1) inadequate training of staff, (2) inadequate procedures, and (3) an inadequate procedure on the verification that administrations involving feeding tubes were being administered in accordance with a written directive.

Actions Taken to Prevent Recurrence

Licensee – Corrective actions taken by the licensee included (1) immediate suspension of any further gastric tube administrations until the direct cause of the medical event was identified, (2) suspension of one individual's participation in administrations requiring a written directive, (3) informal training of the nuclear medicine technologists by the Radiation Safety Officer, and (4) development of draft written policies and procedures on the administration of iodine-131 through a gastric tube.

NRC – The NRC Region III Office conducted a reactive inspection on November 3, 2009, and also contracted a medical consultant to review this event. Based on the results of the inspection, five apparent violations of NRC's regulations were identified. Enforcement action is pending and the medical consultant's review is on-going.

Dated at Rockville, Maryland, this 12<sup>th</sup> day of July, 2010.

For the U.S. Nuclear Regulatory Commission.

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Annette L. Vietti-Cook,  
Secretary of the Commission.