For the Nuclear Regulatory Commission.

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NUCLEAR REGULATORY COMMISSION

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Report to Congress on Abnormal Occurrences; Fiscal Year 2010; 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 2010, fifteen events that occurred at facilities licensed or otherwise regulated by the NRC and/or Agreement States were determined to be AOs.

This report describes eight events at NRC-licensed facilities. The first event involved radiation exposure to an embryo/fetus. The other seven events occurred at NRC-licensed or regulated medical institutions and are medical events as defined in Title 10, Part 35, of the *Code of Federal Regulations* (10 CFR part 35). The report also describes seven 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 two Agreement State-licensee events involved radiation exposure to an embryo/fetus. The other five 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 being described in NUREG–0090, Vol. 33, ''Report to Congress on Abnormal Occurrences: Fiscal Year 2010.'' This report is available electronically at the NRC 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 Web site, provides the specific criteria for determining when an event is an AO. It also discusses ''Other Events of Interest,'' which does not meet the AO criteria but has 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, one event at an NRC-licensed or regulated facility and two events at Agreement State-licensed facilities were significant enough to be reported as AOs. Although these events occurred at medical facilities, they involved unintended exposures to individuals who were not patients. Therefore, these events belong under the criteria I.A, ''For All Licensees'' category as opposed to the criteria III.C, ''For Medical Licensees'' category.

AS10–01 Human Exposure to Radiation at Mohamed Megahy MD, Ltd in Maryville, Illinois

Date and Place—May 1, 2007 (reported on June 17, 2010), Maryville, Illinois.

Nature and Probable Consequences—Mohamed Megahy MD, Ltd (the licensee) indicated that on May 1, 2007, a patient was given 3,807 MBq (102.9 mCi) of iodine-131 as a treatment for the recurrence of thyroid cancer. On June 11, 2007, the licensee was contacted by the patient's obstetrician/gynecologist (OB/GYN) who advised them that the patient was 25–27 weeks (6 months) pregnant at the time of the iodine-131 administration. At the time of administration, the patient indicated to the licensee that she was not pregnant, and the licensee did not perform an independent test.

In June 2010, the Illinois Emergency Management Agency was contacted by the licensee and requested to make a dose estimate to a fetus as a result of administration of iodine-131 to a patient who was later found to be pregnant. When the Illinois Emergency Management Agency requested additional information to determine the appropriate parameters of the event, the licensee advised the Illinois Emergency Management Agency that the administration had occurred 3 years earlier. The Illinois Emergency Management Agency calculated an estimated dose to the fetus of 860 mSv (86 rem) and the fetal thyroid of over 1,000,000 mSv (100,000 rem). A full-term child was subsequently born in August 2007 without a thyroid. The child was immediately placed on replacement hormone therapy and continues such treatment.

Cause(s)—The cause of the event was found to be a combination of miscommunication and failure of the licensee to conduct an independent confirmatory pregnancy test.

Actions Taken To Prevent Recurrence

Licensee—The licensee has subsequently made procedural changes to the interview process for screening patients for iodine-131 treatment. This policy includes a confirmatory negative pregnancy test. In addition, the licensee identified the significant delay in reporting the event to the Illinois Emergency Management Agency as not knowing the reporting requirement for this type of event.

State—The Illinois Emergency Management Agency conducted an investigation of the event and issued a Notice of Violation (NOV) for the licensee's failure to report the event. The Illinois Emergency Management Agency is considering rulemaking to require the performance of testing to determine pregnancy prior to administration of iodine-131.

AS10–02 Human Exposure to Radiation at Mercy Medical Center in Durango, Colorado

Date and Place—March 16, 2010, Durango, Colorado.

Nature and Probable Consequences—Mercy Medical Center (the licensee) reported that a therapeutic dose of 1,110 MBq (30 mCi) of iodine-131 for hyperthyroidism resulted in a dose to an embryo of 80 mGy (8 rem) whole body. Prior to the treatment, the patient informed the licensee's staff that she was not pregnant and the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, the licensee administered iodine-131 to the patient.

On April 26, 2010, the patient performed a home pregnancy test that resulted in a positive test result. The patient's pregnancy was confirmed with a positive blood serum pregnancy test on April 27, 2010. The patient's OB/GYN estimated that conception

occurred on March 13, 2010 (about 1 week pregnant at the time of administration). A consulting medical physicist reviewed the case and estimated the embryonic exposure (whole body) at 53 to 92 mGy (5.3 to 9.2 rem). The possibility of embryonic thyroid exposure was also investigated and determined to be insignificant due to the early stage of embryonic development. At this dose and administration time in relation to the embryonic development (blastogenesis), the licensee determined that no adverse impact will be likely on subsequent embryonic or fetal development and that subsequent health risks were unlikely. The patient was informed of the dose estimates and potential risks and she elected to continue the pregnancy.

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

Actions Taken To Prevent Recurrence

Licensee—To help prevent recurrence, the licensee added additional questions to the screening process to help identify patients that might be pregnant even though all procedures to prevent this occurrence were followed.

State—The State conducted an investigation and concurs with the licensee that a reasonable standard of care was met and, consequently, no enforcement action is warranted.

NRC10–01 Human Exposure to Radiation at Tripler Army Medical Center in Honolulu, Hawaii

Date and Place—June 7, 2010, Honolulu, Hawaii.

Nature and Probable Consequences—Tripler Army Medical Center (TAMC) (the licensee) reported that a female patient underwent a therapeutic administration of iodine-131 for thyroid ablation therapy. Prior to the treatment, the patient informed the licensee's staff that she was not pregnant and the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, the licensee administered iodine-131 to the patient.

On July 8, 2010, the patient became aware that she was pregnant and informed the licensee and her physician. On August 3, 2010, an ultrasound was performed on the patient and a determination was made that the actual date of conception was June 1, 2010 (about 1 week pregnant at time of administration). The TAMC radiation safety officer (RSO) estimated the embryonic dose to be 41.27 cGy (41.27 rad) and concluded that the exposure of the embryo in the first 2 weeks following conception is not likely to result in malformation or embryo/fetal death despite the fact that the central nervous system and the heart are beginning to develop in the third week. The NRC contracted with a medical consultant to perform an independent medical evaluation of this embryo/fetal overexposure event. The consultant's report agreed with the TAMC conclusions with the exception that the medical consultant did not want to rule out the chance of embryo/fetal malformation.

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

Actions Taken To Prevent Recurrence

Licensee—The patient consent form has been updated to reflect that the pregnancy test may not show a positive result until the embryo has implanted, which may not occur until 7–10 days after conception. In future consultations, the clinic plans to ask the patient to refrain from any action that may lead to pregnancy during the period immediately prior to therapeutic radioisotope administration.

NRC—The NRC conducted an inspection on October 13–14, 2010, and concluded there were no violations of NRC requirements associated with this event.

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.

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

C. Medical Licensees

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

AS10–03 Medical Event at Mercy St. Vincent Medical Center in Toledo, Ohio

Date and Place—November 8, 2005 (reported on March 3, 2010), Toledo, Ohio.

Nature and Probable Consequences—Mercy St. Vincent Medical 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 160 Gy (16,000 rad) to the prostate using 67 iodine-125 seeds. Instead, the patient's sigmoid colon received at least the full prescription dose of 160 Gy (16,000 rad) and a significant portion of the bladder base including the region of the urethral orifices received at least 108 Gy (10,800 rad) (wrong treatment sites). The patient and referring physician were informed of this event.

On March 3, 2010, the Ohio Department of Health (ODH) performed an inspection of the licensee and noted that the licensee had not reported this medical event to the State and the NRC. The licensee had not identified the medical event as a reportable event and did not investigate it to determine a cause. Subsequently, the licensee reported the medical event to the NRC. The licensee confirmed that 13 of the permanent iodine-125 seeds were improperly positioned in the bladder and subsequently removed from the patient's bladder immediately after the procedure. A post-implant dose calculation showed that the prostate received a dose of 15.43 Gy (1,543 rad), or 9.6 percent of the prescribed dose. The patient chose to then receive an external beam treatment with a linear accelerator to treat the tumor. About 13 months after the brachytherapy procedure, the patient developed rectosigmoid bleeding that required hospitalization and argon laser coagulopathy. In August 2010, ODH ordered an independent medical expert evaluation of the event. The independent medical expert concluded that the subsequent delivery of external beam radiotherapy may have contributed to the rectosigmoid damage, but the high dose from the brachytherapy procedure almost certainly was the primary cause of the damage.

Cause(s)—The cause of the medical event was the failure of the licensee to adequately visualize the prostate prior to the implant procedure.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions taken by the licensee included training of the RSO, medical physicist, clinical director, and radiation oncologists on ODH regulations concerning medical events. New procedures were also developed for brachytherapy seed implant procedures.

State—In March 2010, ODH conducted a special inspection of the licensee and issued an NOV. The NOV required the licensee to perform a self

audit of all brachytherapy cases performed since November 2004, which revealed seven additional medical events that were not reported. In June 2010, an Adjudication Order and administrative penalty of $25,000 were issued to the licensee.

NRC10–02 Medical Event at Chippenham & Johnston-Willis Medical Center in Richmond, Virginia

Date and Place—December 16, 2008, Richmond, Virginia.

Nature and Probable Consequences—Chippenham & Johnston-Willis (CJW) Medical Center (the licensee) reported a medical event with its gamma stereotactic radiosurgery (GSR) unit. A patient being treated for trigeminal neuralgia (inflammation of the nerve) was prescribed a treatment of 40 Gy (4,000 rad) to the right trigeminal nerve but received the treatment dose to the left trigeminal nerve (wrong treatment site). The patient and referring physician were informed of this event.

The licensee noted that on the day of the treatment, the top portion of the written directive correctly documented the prescribed treatment site; however, while the staff was preparing the daily patient treatment log, it was inadvertently annotated that the dose was to be delivered to the left trigeminal nerve. This error was carried through by the medical physicist during preparation of the patient's treatment plan and completion of the bottom part of the written directive. Upon completion of the procedure and after reviewing the patient's file, the treatment team identified the inadvertent treatment of the left trigeminal nerve. The NRC contracted medical consultant concluded that although no actual consequences resulted, an unlikely injury to the brain stem was possible due to high radiation dose to a tiny volume of the brain stem tissue and an increased risk of cataract formation.

Cause(s)—The cause of the medical event was the licensee's failure to have adequate procedures that verify the location of treatment sites and ensure that any inconsistencies in the written directives are resolved prior to administration.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised their GSR treatment procedures to affirm that (1) a ''Physician Order'' will be the primary source of documentation of the treatment site and will accompany the patient through the entire course of the treatment, (2) the radiation oncologist and the neurosurgeon will independently verify and document the treatment site, (3) the nurse and the medical physicist will confirm that the treatment site identified by the radiation oncologist in the written directive and the neurosurgeon's ''physician order'' both match, (4) the neurosurgeon will mark the treatment site with ink in the presence of a nurse, and (5) a ''Time-Out'' process involving independent verification of the final treatment plan by each of the four members of the clinical team (who are required to sign-off their presence and acceptance of time-out in the presence of the patient before moving ahead with the treatment) will be used with the patient or the patient's authorized representative to confirm the treatment site.

NRC—The NRC initiated an inspection on December 18, 2008. The NRC completed the inspection on November 30, 2009, and issued one Severity Level III violation to the licensee on January 21, 2010.

NRC10–03 Medical Event at Virtua Health System in Marlton, New Jersey

Date and Place—January 19, 2009, Marlton, New Jersey.

Nature and Probable Consequences—Virtua Health System (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 145 Gy (14,500 rad) to the prostate using 93 iodine-125 seeds. Instead, the patient received an approximate dose of 12.2 Gy (1,220 rad) to the rectum (wrong treatment site). The patient and referring physician were informed of this event.

On January 19, 2009, the urologist inserted needles in the patient's prostate gland under transrectal ultrasound guidance while the radiation oncologist left the operating room to obtain the radioactive seeds. The licensee's staff (including the authorized medical physicist [AMP]) questioned the accuracy of prostate visualization prior to implantation of the seeds but took no action to resolve the question. On February 23, 2009, following a post-implant computed tomography (CT) scan, it was noted that some mispositioning of the sources occurred and the patient was notified that additional treatment may be necessary. On March 19, 2009, the AMP reviewed the case and determined that 100 percent of the seeds were implanted outside of the prostate, which received about 10 Gy (1,000 rad). The NRC contracted with a medical consultant who concluded that although the probability of long-lasting negative health effects to the patient is low, an increased risk of impotency and fibrosis was possible due to the high radiation dose.

Cause(s)—The cause of the medical event was failure of the medical implant team to adequately visualize and identify the prostate prior to the implant.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised its policy and procedures to require that (1) all members of the implant team be present before the patient is brought to the operating room and placed under anesthesia, (2) the AMP be included in the pre-implantation ultrasound, (3) the authorized user consult with the urologist before needle insertion, (4) both the radiation oncologist and the urologist agree on the positioning and the visualizing of the target anatomy, (5) any objection or question by an implant team member is cause for stopping the implant and performing a review, and 6) the implant be stopped if there are any ultrasound image questions. The licensee's staff was also trained on the revised procedures, the definition and reporting requirements of a medical event, and the communication of any CT scan abnormalities or seed misplacement to the RSO.

NRC—The NRC initiated an inspection on March 20, 2009. The NRC completed the inspection on August 26, 2009, and issued one Severity Level III violation to the licensee on October 21, 2009.

NRC10–04 Medical Event at Nanticoke Memorial Hospital, Seaford, Delaware

Date and Place—March 5, 2009 (reported on July 15, 2009), Seaford, Delaware.

Nature and Probable Consequences—Nanticoke Memorial Hospital (the licensee) reported that a medical event occurred involving a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 145 Gy (14,500 rad) to the prostate using 61 iodine-125 seeds. Instead, the patient received an approximate prostate dose of 26 Gy (2,600 rad) (18 percent of the prescribed dose) and a dose of 139 Gy (13,900 rad) to unintended tissue (wrong treatment site). The patient and referring physician were informed of this event.

The seeds were implanted under ultrasound guidance using an axial view; however, following the implant, the urologist performed a cystoscopy to remove 22 of the seeds from the bladder. When the patient returned to the hospital for a post-implant CT scan, the images revealed that 32 seeds were displaced superiorly to the prostate and 7 seeds were implanted in the prostate.

The NRC contracted with a medical consultant who concluded that no significant adverse health effects to the patient were expected.

Cause(s)—The cause of the medical event was due to a miscalculation of the prostate depth in relation to the skin surface due to possible patient movement during the procedure.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised its prostate implant procedure to include the use of both the axial and sagittal views of an ultrasound probe to determine prostate depth. In addition, the licensee revised its medical event policy to ensure timely reporting of medical events and to clearly state the parameters under which a medical event must be reported. The licensee provided training on the revised policies and procedures to its staff.

NRC—The NRC initiated an inspection on July 19, 2009. The NRC completed the inspection on January 6, 2010, and issued one Severity Level III violation to the licensee on February 2, 2010.

AS10–04 Medical Event at Hoag Memorial Hospital Presbyterian in Newport Beach, California

Date and Place—March 20, 2009, Newport Beach, California.

Nature and Probable Consequences—Hoag Memorial Hospital Presbyterian (the licensee) reported that a medical event occurred associated with its GSR unit. A patient being treated for an acoustic neuroma was scheduled to receive between 11 and 18 Gy (1,100 and 1,800 rads) to an intended neuroma volume of 0.08 cm^3 but, due to an unintended shift in the treatment volume of about 2 mm, only about one-half of the neuroma received the treatment dose and an adjacent temporal bone volume of 0.04 cm^3 received the treatment dose (wrong treatment site). The other half of the neuroma received between 3 and 11 Gy (300 and 1,100 rads). The patient and physician were informed of this event.

The unintended shift in treatment volume occurred due to a misaligned fiduciary marker (indicator) box during a CT scan used in the treatment planning process. The misalignment occurred because one alignment pin of four on the indicator box was not fully seated in the stereotactic frame attached to the patient's head, resulting in the indicator box not being correctly aligned. The alignment pin error was not detected until the conclusion of the treatment. The additional dose to the temporal bone because of the alignment error is not expected to result in any significant adverse health effect to the patient.

Cause(s)—The medical event is believed to have been caused by human error in not ensuring the CT indicator box was properly installed at the time of the CT scan. It is not known if the improper installation occurred when the technologist positioned the indicator box in the stereotactic frame or whether the indicator box became misaligned during patient positioning in preparation for the CT scan.

Actions Taken To Prevent Recurrence

Licensee—The licensee has retrained all CT technologists concerning the proper placement of the CT indicator box. Also, because use of CT imaging for GSR treatment is infrequent (normally MRI is used), the licensee now requires that a GSR qualified medical physicist verify the placement of the CT indicator box immediately prior to all CT imaging that will be used for GSR treatment planning.

State—On June 22, 2009, the California Department of Public Health (CDPH) issued an NOV related to this event. Subsequently, CDPH received dosimetry information which they used to interpret the event as not meeting the AO criteria; however, CDPH was not certain of this determination and asked the NRC for a final determination. On July 1, 2010, after the NRC Medical Radiation Safety Team (MSRT) had performed a careful analysis of the event along with the dosimetry data, the NRC determined that the event met the AO criteria.

AS10–05 Medical Event at Marshfield Clinic in Marshfield, Wisconsin

Date and Place—June 2005 to May 2007, (reported on July 8, 2010) Marshfield, Wisconsin.

Nature and Probable Consequences—In July 2010, the Marshfield Clinic (the licensee) reviewed all prostate brachytherapy cases performed under its license in the past 7 years. The review resulted in the identification of nine medical events involving permanent implants of iodine-125 for prostate brachytherapy where the total dose delivered differed from the prescribed dose by 20 percent or more, or another organ received at least 50 percent more dose than intended. The three medical events involved planned doses to the prostate of 120 Gy (12,000 rad), 160 Gy (16,000 rad), and 160 Gy (16,000 rad). The licensee assumes an identical planned dose to the urethra. However, these treatments resulted in actual doses to the urethra of 191.6 Gy (19,160 rad), 258.1 Gy (25,810 rad), and 242.6 Gy (24,260 rad), which were overdoses of 59.7, 61.3, and 51.6 percent, respectively. The licensee notified the affected patients and referring physicians.

The authorized user physicians had previously determined that patients would not suffer significant health effects for urethral doses below 400 Gy (40,000 rad). Because the urethra penetrates through the center of the prostate and the prostate itself is a small gland, a balance exists between reducing the dose to the urethra and delivering the prescribed dose to the prostate. The doses delivered to the patients in question were well within the 400 Gy (40,000 rad) urethral tolerance dose, and the licensee considered the treatments to be clinically acceptable.

Cause(s)—The licensee suspects that the implants deviated from their intended tracks after insertion into the prostate, causing the seeds to be deposited closer to the urethra.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions included developing a procedure for ensuring that treatments were delivered in accordance with the written directive, planning treatments to D90 (minimum dose received by 90 percent of CT-defined prostate volume) values of 100–110 percent, using the same written directive form at each site that performs brachytherapy, increasing ultrasound and fluoroscopy visualization during prostate implants and providing additional training to personnel.

State—The Wisconsin Department of Health Services determined that Marshfield Clinic did not have a procedure for evaluating whether the dose delivered in a prostate brachytherapy treatment was in accordance with the written directive. In addition, the licensee did not have criteria for identifying a medical event for prostate brachytherapy. The licensee has been cited for several items of noncompliance.

NRC10–05 Medical Event at Yale New-Haven Hospital, New Haven, Connecticut

Date and Place—August 5, 2009, New Haven, Connecticut.

Nature and Probable Consequences—Yale New-Haven Hospital (the licensee) reported that a medical event occurred associated with its GSR unit. A patient being treated for brain metastases was prescribed 18 Gy (1,800 rad). However, while treating a patient earlier in the day, an equipment malfunction occurred with the GSR unit that resulted in a positioning shift of the x-axis by 4.5 mm. The positioning shift in the x-axis

resulted in an underdose to the treatment site and an overdose to a wrong treatment site. The patient and physician were informed of this event.

The malfunction occurred following the treatment of the first patient on August 5, 2009. The automatic positioning system (APS) malfunctioned and, after discussion with the GSR manufacturer, the position error codes were cleared by the AMP. A second patient was treated for multiple brain metastases later that day. The GSR service personnel noted on August 5, 2009, that the APS positioning was off by about 5 mm. After further evaluation, the manufacturer determined that a position shift (offset) occurred when licensee personnel accepted an error message concerning position deviation. The NRC contracted with a medical consultant who concluded that no clinically significant side effects from radiation damage to the wrong treatment sites would be expected.

Cause(s)—The cause of the medical event was failure of licensee personnel to verify that the APS coordinates were in accordance with the written directive.

Actions Taken To Prevent Recurrence

Licensee—The licensee issued a memorandum to all personnel involved in GSR treatments to require visual verification of the physical coordinates against the electronic coordinates before the start and at the end of each treatment run. The licensee also retrained all GSR personnel on the importance of fully understanding error conditions and reviewing unexpected errors with other staff involved in the treatment (e.g., radiation oncologist, AMP, etc.) prior to clearing any unexpected error.

NRC—The NRC initiated an inspection on August 13, 2009. The NRC completed the inspection on April 7, 2010, and issued one Severity Level III violation to the licensee on May 21, 2010.

NRC10–06 Medical Event at Valley Hospital in Paramus, New Jersey

Date and Place—July 29, 2009, Paramus, New Jersey.

Nature and Probable Consequences—Valley Hospital (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 65 Gy (6,500 rad) to the prostate using 46 cesium-131 seeds. Instead, the licensee determined that an unintended volume (30.1 ml) of soft tissue received 100 percent of the prescribed prostate dose. The patient and referring physician were informed of this event.

On August 6, 2009, the patient returned to the hospital for a post-implant CT scan. The images revealed that the seeds were implanted in soft tissue 4 to 5 cm from the prostate. Post-implant dosimetry calculations indicated that none of the prostate received the prescribed dose of 6,500 cGy (6,500 rad). The NRC contracted with a medical consultant who concluded that the additional dose can increase the risk of soft tissue fibrosis or increase the risk of impotency.

Cause(s)—The cause of the medical event was the licensee's failure to identify the position of the prostate due to the patient's unusual anatomy and obesity.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised their prostate implant procedures to include steps to ensure that the prostate and surrounding anatomy is adequately visualized prior to implant.

NRC—The NRC initiated an inspection on August 13, 2009. The NRC completed the inspection on October 29, 2009, and determined that no violations of NRC requirements occurred.

NRC10–07 Medical Event at Christiana Care Health Center in Wilmington, Delaware

Date and Place—January 18, 2010, Wilmington, Delaware.

Nature and Probable Consequences—Christiana Care Heath Center (the licensee) reported that a patient was prescribed a high dose-rate (HDR) mammosite (brachytherapy) multi-lumen catheter treatment of 34 Gy (3,400 rad) over a 5-day period to the left breast. The patient received an average dose of 17 Gy (1,700 rad) to 100 cm^3 of unintended breast tissue; 68 Gy (6,800 rad) to 7.5 cm^3 of unintended skin and underlying tissue; and 3.4 Gy (340 rad) to 35 cm^3 of intended breast tissue. The patient and referring physician were informed of this event.

On February 22, 2010, during a follow-up examination, the patient complained about skin reddening on the external breast. In reviewing the treatment plan, it was discovered that the AMP performed measurements using a source position simulator (SPS) measurement tool following a CT scan to determine the treatment distance for each catheter. The catheter distances were recorded and confirmed with two manufacturer representatives that were present at the time of the treatment. However, it was noted that an incorrect measurement caused the placement of the radioactive source 10 cm proximal to the intended position. The NRC contracted medical consultant concluded that the dose that was administered to the unintended left breast tissue is unlikely to result in any significant or unusual adverse effect. However, a significant risk exists that local tumor recurrence could occur if additional intervention is not performed.

Cause(s)—The cause of the medical event was human error in the failure to identify that the measurement tool was functioning improperly and to identify an incorrect measurement distance.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised its procedures for HDR brachytherapy to require a double-check of all patient measurements, a daily and monthly quality assurance requirement to confirm that the SPS tool is functioning properly, and a process to ensure that all members of the treatment team agree on the specifics of the treatment. In addition, the licensee acquired a new SPS tool, developed and posted a reference table at the HDR control console, provided training on revised procedures to staff involved in the HDR program (to be repeated annually), and implemented a ''New Product'' committee to review all new product plans.

NRC—The NRC conducted an inspection on July 12, 2010, and issued one Severity Level III violation to the licensee on August 24, 2010.

AS10–06 Medical Event at Mary Bird Perkins Cancer Center in Baton Rouge, Louisiana

Date and Place—March 15, 2010, Baton Rouge, Louisiana.

Nature and Probable Consequences—Mary Bird Perkins Cancer Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 145 Gy (14,500 rad) to the prostate using iodine-125 seeds. Instead, the patient received a dose of 39.55 Gy (3,955 rad) to the rectum, 40.94 Gy (4,094 rad) to the urethra, and 6 Gy (600 rad) to the bladder (wrong treatment sites). The patient and referring physician were informed of this event.

During the review of this event, the licensee determined that a positioning error occurred and the dose was delivered about 3.0 cm away from the targeted prostate gland. The estimated dose to the prostate gland was 12.88 Gy (1,288 rad). The licensee concluded that

no significant adverse health effect to the patient is expected.

Actions Taken To Prevent Recurrence

Licensee—The licensee modified its procedure to insert the needles that hold the prostate in place prior to obtaining the ultrasound images instead of immediately before the seed needles are inserted. In addition, the sagittal image will be captured at the time of planning image acquisition and confirmed periodically throughout the case, and the radiation oncologist will personally confirm the location of the reference base prior to dispensing the first seed.

State—The Louisiana Department of Environmental Quality conducted an investigation, reviewed the licensee's corrective actions, and found the corrective actions to be adequate.

AS10–07 Medical Event at Mayo Clinic in Rochester, Minnesota

Date and Place—March 23, 2010, Rochester, Minnesota.

Nature and Probable Consequences—The Mayo Clinic (the licensee) reported a medical event associated with an HDR biliary treatment for liver carcinoma containing 329 GBq (8.9 Ci) of iridium-192. A patient was prescribed to receive four fractionated doses totaling 16 Gy (1,600 rad) to the liver. The treatment to the liver should have produced an estimated dose to the duodenum (wrong treatment site) of 1.2 Gy (120 rad) but as a result of the event it received a dose of about 10 Gy (1,000 rad). The patient and referring physician were informed of this event.

During the second fractioned treatment, the measurement cable was inserted into the catheter and it was noted that it extended about 17 cm beyond the programmed treatment distance used during the first fractioned treatment. It was concluded that the measurement wire on the first treatment had met with some resistance at a tight bend and that it was not at the end of the catheter. This resulted in overdosing the duodenum (wrong treatment site). Upon discovery of the treatment distance error and overdose, the licensee changed the written directive to add a fifth fractioned treatment to correct for the underdose of the liver. A lesser total dose to the liver was given because of concerns regarding the dose already received by the duodenum. 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 HDR unit.

Actions Taken To Prevent Recurrence

Licensee—The licensee committed to taking several corrective actions including the imaging of inserted catheters prior to treatments and performing catheter length checks prior to HDR treatments.

State—On April 6, 2010, the Minnesota Department of Health (MDH) staff performed a reactive inspection of the licensee's HDR program. The MDH approved the licensee's corrective actions and did not take enforcement action.

NRC10–08 Medical Event at Providence Hospital in Novi, Michigan

Date and Place—August 30, 2010, Novi, Michigan.

Nature and Probable Consequences—Providence Hospital (the licensee) reported that a medical event occurred associated with an anal brachytherapy treatment using 32 seeds containing iodine-125. The intended dose was 90 Gy (9,000 rad) to the tumor. Instead, the patient's seminal vesicle received 19.79 Gy (1,979 rad) more than intended and the bladder received 3.68 Gy (368 rad) more than intended. The patient and referring physician were informed of this event.

On September 1, 2010, a follow-up CT scan showed that the permanent implants had been inserted about 4 cm from the intended location. The licensee reported that the tumor near the anus and rectum received a maximum dose of 8 Gy (800 rad). The licensee calculated the dose difference to the surrounding tissue as a result of the improper permanent implant placement. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The licensee determined that the cause of the event was that they did not use tissue markers to confirm source placement and the insertion needle did not have a visible mark to ensure proper depth placement.

Actions Taken To Prevent Recurrence

Licensee—Procedures were modified to administer sources as prescribed in the written directive as follows: (1) Any interstitial procedure that requires the use of fluoroscopy alone will be done with the use of tissue markers to confirm source placement, and (2) interstitial procedures that use fluoroscopy alone will have needle depth verified. The licensee completed training of licensee staff on the event and the corrective actions by October 1, 2010.

NRC—The NRC's Region III staff reviewed and concurred on the licensee's corrective actions. The NRC has retained the services of an independent medical consultant to determine if any significant health effects to the patient are expected.

Dated at Rockville, Maryland, this 23rd day of June, 2011.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Acting Secretary of the Commission.

[FR Doc. 2011–16266 Filed 6–28–11; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

[OMB–3420–0011; OPIC–115]

Submission for OMB Review

AGENCY: Overseas Private Investment Corporation (OPIC).

ACTION: Request for approval.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency has prepared an information collection for OMB review and approval. {Comments were solicited in the 60 day notice, posted on [October 2, 2007], and no comments were received.}

DATES: This 30-day notice is to inform the public, that this collection is being submitted to OMB for approval.

ADDRESSES: Copies of the subject form may be obtained from the Agency submitting officer.

FOR FURTHER INFORMATION CONTACT: OPIC Agency Submitting Officer: Essie Bryant, Record Manager, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527; (202) 336–8563.

Summary Form Under Review

Type of Request: Revised form.
Title: Application for Financing.
Form Number: OPIC–115.
Frequency of Use: Once per investor per project.
Type of Respondents: Business or other institution (except farms); individuals.
Standard Industrial Classification Codes: All.
Description of Affected Public: U.S. companies or citizens investing overseas.
Reporting Hours: 9 hours per project.
Number of Responses: 190 per year.
Federal Cost: $12,754.
Authority for Information Collection: Sections 231, 234(a), 239(d), and 240A of the Foreign Assistance Act of 1961, as amended.