expenses in a model pagophilic species, the Weddell seal, as a function of size and body condition on a small temporal scale for specific environments, activities and swim speeds.

The applicant requests a modification to her permit to allow:

(1) Increase the number of seals from 40–55 (pup through adult) over the life of the permit. The addition of the 15 additional seals takes into account the loss of tags and incomplete datasets from irretrievable equipment. The additional seals will allow a minimum of 10 complete datasets from each age class (pup, juvenile, and adult).

(2) Authorization to conduct a full necropsy with collection of blood and tissue samples for import into the U.S. for post-mortem analysis.

*Location:* ASPA 121–Cape Royds, and McMurdo Sound.

*Dates:* October 2, 2012 to February 28, 2013.

**Nadene G. Kennedy,**

*Permit Officer, Office of Polar Programs.*

[FR Doc. 2012–15118 Filed 6–20–12; 8:45 am]

**BILLING CODE 7555–01–P**

## NATIONAL SCIENCE FOUNDATION

### Notice of Permits Issued Under the Antarctic Conservation Act of 1978

**AGENCY:** National Science Foundation.

**ACTION:** Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

**SUMMARY:** The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

**FOR FURTHER INFORMATION CONTACT:** Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

**SUPPLEMENTARY INFORMATION:** On May 16, 2012, the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on June 15, 2012 to:

Paul J. Ponganis, Permit No. 2013–004.

**Nadene G. Kennedy,**

*Permit Officer.*

[FR Doc. 2012–15123 Filed 6–20–12; 8:45 am]

**BILLING CODE 7555–01–P**

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

**AGENCY:** U.S. Nuclear Regulatory Commission.

**ACTION:** Notice of Meeting.

**SUMMARY:** NRC will convene a teleconference meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on July 9, 2012. The purpose of the meeting will be to discuss the radium-223 chloride subcommittee report. NRC will also convene a regular meeting of the ACMUI on September 20–21, 2012. A sample of agenda items to be discussed during the public session includes: (1) Reducing occupational dose limits; (2) status of data collection on patient release; (3) status update on 10 CFR part 35 rulemaking; (4) status update on proposed regulatory changes for permanent implant brachytherapy programs; (5) follow-up on ACMUI reporting structure; and (6) update on domestic production of molybdenum-99. The regular meeting agenda is subject to change. The current agendas for both meetings and any updates will be available prior to the meetings at *http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda* or by emailing Ms. Ashley Cockerham at the contact information below.

*Purpose:* Discuss issues related to 10 CFR Part 35 Medical Use of Byproduct Material.

*Date and Time for Teleconference Meeting:* July 9, 2012, from 11:00 a.m. to 12:00 p.m.

*Date and Time for Regular Meeting Closed Session:* September 20, 2012, from 8:30 a.m. to 11:30 a.m. This session will be closed for ACMUI training.

*Date and Time for Regular Meeting Open Sessions:* September 20, 2012, from 1:00 p.m. to 5:00 p.m. and September 21, 2012, from 8:30 a.m. to 12:00 p.m. Regular meeting times are subject to change.

*Address for Regular Meeting:* U.S. Nuclear Regulatory Commission, Two White Flint North Building, Room T2–B3, 11545 Rockville Pike, Rockville, Maryland 20852.

*Public Participation:* Any member of the public who wishes to participate in the meetings in person or via phone should contact Ms. Cockerham using the information below. The regular meeting on September 20–21 will also be webcast live at *http://video.nrc.gov.*

*Contact Information:* Ashley Cockerham, email: *ashley.cockerham@nrc.gov,* telephone: (240) 888–7129.

**Conduct of the Meeting**

Leon S. Malmud, M.D., will chair the meeting. Dr. Malmud will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit an electronic copy to Ms. Cockerham at the contact information listed above. All submittals must be received five business days prior to the meeting and must pertain to the topic on the agenda for the meeting.

2. Questions and comments from members of the public will be permitted during the meeting at the discretion of the Chairman.

3. The draft transcripts will be available on ACMUI's Web site (*http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/)* within 30 business days of the meeting. A meeting summary will be available on ACMUI's Web site (*http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-summaries/*) within 30 business days of the meeting.

4. Persons who require special services, such as those for the hearing impaired, should notify Ms. Cockerham of their planned attendance.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, Part 7.

Dated: June 14, 2012.

**Andrew L. Bates,**

*Advisory Committee Management Officer.*

[FR Doc. 2012–15173 Filed 6–20–12; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

**[NRC–2012–0128]**

### Report to Congress on Abnormal Occurrences; Fiscal Year 2011; 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) 2011, 24 events that occurred at facilities licensed by the NRC and/or Agreement States were determined to be AOs.

This report describes five events at NRC-licensed facilities. The first event involved radiation exposure to an embryo/fetus, and the second was an event of high safety significance at a commercial nuclear power plant. The other three events occurred at NRC-regulated medical institutions and are medical events as defined in Title 10 of the Code of Federal Regulations (10 CFR) part 35. The report also describes 19 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, the second event involved an exposure to the extremities of a radiographer, and the third event involved a stolen radiography camera. 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 being described in NUREG–0090, Vol. 34, ''Report to Congress on Abnormal Occurrences: Fiscal Year 2011.'' 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 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-regulated facility and three events at Agreement State-licensed facilities were significant enough to be reported as AOs. Although two of 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.

NRC11–01 Human Exposure to Radiation at Portsmouth Naval Medical Center in Portsmouth, Virginia

*Date and Place*—January 12, 2011, Portsmouth, Virginia.

*Nature and Probable Consequences*—The U.S. Department of the Navy (the licensee) reported that a female patient at the Naval Medical Center in Portsmouth, Virginia (NMCP), received 3,630 MBq (98 mCi) of iodine-131 for thyroid ablation therapy. On the day of the treatment the patient informed NMCP staff that she was not pregnant and NMCP 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, NMCP staff administered iodine-131 to the patient.

On January 27, 2011, the patient became aware that she was pregnant and informed the physician who had administered the treatment. An obstetrician estimated that conception had occurred somewhere around January 7–10, 2011, and that a pregnancy test administered on January 12, 2011, would not have been sensitive enough to produce a positive result. The NMCP estimated the dose to the embryo to be 21.3 cGy (21.3 rem) and notified the Naval Radiation Safety Committee that the patient may have been pregnant before the therapy. The NMCP staff estimated a slight increased risk of early pregnancy failure and this was discussed with the patient. The NMCP staff subsequently refined the dose estimate to 24.7 cGy (24.7 rem). The NRC contracted with a medical consultant who estimated a fetal/embryo dose of 27 cGy (27 rem) and stated that embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, the 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 close proximity of conception, which resulted in a negative pregnancy test result, to the administration of the iodine-131.

Actions Taken To Prevent Recurrence

*Licensee*—The NMCP revised the initial consultation procedures for the prescribing physician to stress the importance of discussing with the patient the need for sexual abstinence at least 10 days before therapeutic dose administration.

*NRC*—The NRC conducted an inspection on February 2, 2011, through June 2, 2011, and there were no violations of the NRC's requirements associated with this event.

AS11–01 Human Exposure to Radiation at Montefiore Medical Center in New York City, New York

*Date and Place*—September 22, 2006 (reported on April 27, 2011), New York City, New York.

*Nature and Probable Consequences*—Montefiore Medical Center (the licensee) reported that a female patient received 3,519 MBq (95 mCi) of iodine-131 for thyroid ablation therapy. Before the treatment, the licensee interviewed the patient and ascertained that she was not pregnant. 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 December 22, 2006, the patient returned to the licensee for a followup visit. Following that visit, the nuclear medicine department staff was informed by another section of the medical center that the patient was pregnant. The licensee confirmed the pregnancy with the patient's obstetrician/gynecologist. The ultrasound performed by the patient's obstetrician/gynecologist revealed that the patient was approximately 2–3 weeks pregnant at the time of the iodine-131 treatment. The licensee estimated that the fetus received about 25 cGy (25 rem) of radiation exposure 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 fully formed at the time of the treatment. The patient was advised to see a genetic specialist to discuss the possible consequences to the fetus from this exposure. Although the licensee claimed that it had originally reported the event to the New York City Office of Radiological Health in 2006, the

office had no record of the report. The New York City Office of Radiological Health identified the missing report in April 2011, and subsequently notified the NRC on June 15, 2011.

*Cause(s)*—The cause of this event was the close proximity of conception to the iodine-131 treatment and a false negative result on a pregnancy test done before the administration of the treatment.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee's corrective actions included additions to its Safety Precaution Form stressing the necessity of sexual abstinence before the treatment and recommending that patients also take precautions to avoid getting pregnant for 6 months after the treatment.

*State*—The New York City Office of Radiological Health conducted an inspection on June 16, 2011, and determined that the licensee had followed acceptable protocols before the administration of iodine-131. Consequently no civil penalties or enforcement action for this event are warranted.

AS11–02 Human Exposure to Radiation at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas

*Date and Place*—September 12, 2011, Port Lavaca, Texas.

*Nature and Probable Consequences*—Caribbean Inspection & NDT Services Inc. (the licensee) reported that a radiographer trainee received an overexposure to his right hand and was seeking medical attention. The radiographer trainee stated that on September 12, 2011, while conducting radiography operations in the field, he removed a radiography camera guide tube from the Amersham 660 D radiography camera. The radiographer trainee stated that he noticed the 2.7 TBq (73 Ci) iridium-192 source was not fully retracted and protruding from the camera about 2 inches. The radiographer trainee stated that he may have brushed the source with his hand when he removed the guide tube.

On September 19, 2011, the radiographer trainee presented himself to a Houston, Texas hospital with observable deterministic effects, which included blistering of the thumb, index and middle fingers. These types of effects correspond to an exposure range of 20–40 Sv (2000 to 4000 rem) to the extremities. His doctors initially conferred with the Radiation Emergency Assistance Center/Training Site in Oak Ridge, TN regarding his medical treatment. The trainee is continuing his treatment at the Houston, Texas hospital as an out-patient. The licensee stated that the results of the trainee's dosimeter indicated that he received 14.1 mSv (1.41 rem) whole body exposure based on the film badge he was wearing at the time of the event.

*Cause(s)*—The State of Texas is currently investigating the cause of this event.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee is conducting an investigation to determine the exact nature and cause of this event. Pending the results of this investigation the licensee will determine corrective action and inform the State of the circumstances of the event and the corrective actions.

*State*—Texas Department of State Health Services, Radiation Control Program is currently investigating this incident, which includes collecting information from the physicians, the licensee, and the individuals involved in the event. Pending the results of this investigation and the depositions performed through the General Counsel, the Texas Department of State Health Services will determine the probable causes of the event and review the licensee's corrective actions and consider what, if any, civil penalties and enforcement actions to pursue.

AS11–03 Stolen Radiography Camera at Acuren Inspection, Inc., in La Porte, Texas

*Date and Place*—July 19, 2011, La Porte, Texas.

*Nature and Probable Consequences*—Acuren Inspections Inc. (the licensee) reported the theft of a radiography camera containing 1.25 GBq (33.7 Ci) of iridium-192. On July 19, 2011, the licensee discovered that their radiography truck had been broken into, and the radiography camera, associated equipment, and portable generator had been stolen. The alarm system on the truck was then tested and determined to be operational; however, the alarm had not been set at the time of the theft. Attempts to locate the camera included the use of portable radiation detection equipment on vehicles, Austin Police Department/6 Civil Support Team helicopter flyovers of the area, and a U.S. Department of Energy fly-over survey between the cities of Austin and San Antonio, using a fixed wing plane.

It should be noted that at the time this event was reported to the NRC, the radioactive material in the camera was at a level considered to be risk-significant. However, as of October 1, 2011, the radioactive material had decayed to a level considered to not be risk-significant. The radioactive source has not been recovered at the time of this report.

*Cause(s)*—Licensee failure to use the vehicle alarm system.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee conducted a company-wide review of the incident with all employees, inspected all their trucks to verify the alarm systems were operating, and required all employees to view a video that showed the proper way to lock and secure radioactive material.

*State*—The Texas Department of State Health Services conducted an inspection on July 21, 2011, and determined that the radiographer had failed to activate the alarm system on the truck containing the radiography camera. The licensee and the radiographers involved were cited for the violation.

**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.

NRC11–02 Commercial Nuclear Power Plant Event at Browns Ferry Nuclear Plant, Unit 1, in Athens, Alabama

*Date and Place*—October 23, 2010, Athens, Alabama.

*Nature and Probable Consequences*—The Tennessee Valley Authority (TVA) (the licensee) reported a commercial nuclear power plant event at Browns Ferry Nuclear Plant, Unit 1, a boiling-water reactor designed by General Electric. On October 23, 2010, during a refueling outage, it was discovered that a residual heat removal (RHR) low pressure coolant injection (LPCI) flow control valve failed while the licensee was attempting to establish shutdown cooling. The flow control portion of the valve, called the disc, was found stuck in the seat of the valve. The disc had become separated from the valve stem and could no longer be controlled by the valve motor operator. The RHR system is primarily used for LPCI during accident conditions and for cooling while the reactor is shut down. As a result of the flow control valve failure, Loop II of the RHR system could not have performed its safe shutdown functions and was declared inoperable. The licensee promptly placed the other loop of the RHR system (Loop I) into service and, as a result, the failure of the flow control valve did not involve an actual safety consequence or impact the health and safety of the public.

However, the NRC reviewed this event under its significance determination process and determined that the licensee's history with regards to this valve performance issue represented a finding of high safety significance (red finding). The basis for this finding was that the flow control valve's failure (condition) caused a weakness in the licensee's fire mitigation strategy, resulting in a significant increase in the core damage frequency. The licensee's fire mitigation strategy limits the availability of alternative sources of reactor coolant inventory makeup and both loops of LPCI could potentially be unavailable in some accident scenarios. Automatic valve function was lost, as well as the ability of plant operators to manually use this loop of the RHR system.

The public was never actually endangered because no event requiring use of the RHR system occurred. However, the RHR system is counted on for core cooling during certain accident scenarios, and the flow control valve failure left it inoperable, which could have led to core damage had an accident involving a series of unlikely events occurred. The NRC determined that this event did not represent an immediate safety concern, because the licensee staff had, as part of its immediate corrective actions, implemented repairs and modifications in accordance with design requirements that returned the flow control valve to an operational condition (the red finding was for licensee performance deficiencies resulting in a past inoperability).

*Cause(s)*—The immediate cause for this condition was separation of the valve disc from the stem/skirt, with the disc wedged into the seat in the closed position. The licensee determined that part of the root cause was a valve manufacturing defect that resulted in undersized disc skirt threads at the disc connection to the valve stem. In addition, the NRC identified several other performance deficiencies on the part of the licensee. Specifically, the NRC determined that the licensee's failure to establish adequate programs to ensure that motor-operated valves continue to be capable of performing their design-basis safety functions was a performance deficiency. The NRC also concluded that TVA should have foreseen the results of not including these valves within the scope of the program described in Generic Letter 89–10, ''Safety-Related Motor-Operated Valve Testing and Surveillance,'' dated June 28, 1989, and should have corrected the problem. This failure to effectively maintain and inspect these valves within the program contributed to the performance deficiency. The licensee's corrective action program and root cause evaluation also did not appear to address the broader issues associated with programs to ensure the continued capability of motor-operated valves to perform their design-basis safety function.

Actions Taken To Prevent Recurrence

*Licensee*—The TVA reported this condition under 10 CFR 50.73, ''Licensee Event Reporting System,'' and under 10 CFR part 21, ''Reporting of Defects and Noncompliance Process.'' In addition, TVA has presented corrective actions related to the flow control valve failure and corrective actions that are planned to address long-term fire strategies at the Browns Ferry Nuclear Power Station. The flow control valve was repaired promptly, and inspections were performed on all similar valves for Units 1, 2, and 3 to verify their functional capability. The TVA informed the NRC of plans to reduce operator manual actions; implement procedural changes related to fire strategy; install modifications as a result of its review of National Fire Protection Association Standard 805, ''Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants,'' and continue to reduce fire risk at the station.

*NRC*—The NRC assessed the performance of Browns Ferry Nuclear Power Station, Unit 1, to be in the Multiple/Repetitive Degraded Cornerstone Column of the NRC's Action Matrix beginning in the fourth quarter of Calendar Year 2010. This finding resulted in increased NRC oversight at Browns Ferry Nuclear Power Station, including a supplemental inspection to evaluate safety, organizational, and programmatic issues at the plant. The NRC staff initiated the supplemental inspection at the Browns Ferry Nuclear Power Station beginning on September 12, 2011. This inspection is being conducted in accordance with inspection procedures, and will include extensive reviews of programs and processes not inspected as part of the NRC's baseline inspection program. The inspection will also include an assessment of the Browns Ferry Nuclear Power Station's safety culture. Part 1 of this supplemental inspection was completed and an inspection report was issued on November 17, 2011 (available at Agencywide Documents Access and Management System (ADAMS) Accession No. *ML113210602*). The results of this inspection will be combined with the results from Parts 2 and 3 of the Browns Ferry Inspection Procedure 95003 (available at ADAMS Accession No. *ML102020551*), and will assist the NRC in determining the breadth and depth of safety, organizational, and programmatic issues at Browns Ferry Nuclear Power Station. The NRC will report on the final supplemental inspection results as part of the FY 2012 AO report to Congress.

## 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 NRC-regulated facilities and 16 events at Agreement State-licensed facilities were significant enough to be reported as AOs.

AS11–04 Medical Event at Western Pennsylvania Hospital in Allegheny, Pennsylvania

*Date and Place*—February 23, 2009, Allegheny, Pennsylvania.

*Nature and Probable Consequences*—The Western Pennsylvania Hospital (the licensee) reported that a medical event occurred associated with a high-dose-rate (HDR) mammosite treatment for breast cancer; the treatment consisted of 184.2 GBq (4.9 Ci) of iridium-192. The patient was prescribed to receive 34 Gy (3,400 rad) in 10 fractionated doses, but instead, received a dose of 50 Gy (5,000 rad) to the skin tissue around the catheter entry point (wrong treatment site). The patient's physicist notified the patient and the referring physician of this event.

Before starting the treatment on February 23, 2009, the medical staff performed a check to verify the catheter length and treatment calculations. In addition, the treatment procedure required daily CT scans to verify the treatment site. On February 27, 2009, a different therapy physicist identified a potential error in the patient's chart and contacted the patient's physicist. On March 3, 2009, the patient's physicist checked the other therapy physicist's findings and discovered there had been a 3 cm error in the placement of the source during treatment. This incorrect distance resulted in the intended site receiving only 30 percent of the intended dose and the skin tissue receiving the full dose. The patient received followup care for erythema of the skin tissue and the licensee concluded that this medical event would not have a significant medical effect on the patient.

*Cause(s)*—The medical event was caused by human error in the placement of the source during treatment.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee revised all mammosite policies and procedures to strengthen the accuracy of measurement, planning, treatment, and quality control. Specifically, the licensee modified the mammosite worksheet to add the expected catheter length beside the block where the measured catheter length is recorded, and required that the catheter measurement wire be kept in place during CT simulation following catheter measurement.

*State*—The Pennsylvania Department of Environmental Protection investigated the incident on March 18, 2009, 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 November 14, 2011.

AS11–05 Medical Event at the University of Pennsylvania in Philadelphia, Pennsylvania

*Date and Place*—January 21, 2010, Philadelphia, Pennsylvania.

*Nature and Probable Consequences*—The University of Pennsylvania (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 65 iodine-125 seeds. Instead, the seeds were inadvertently placed outside the intended treatment site (wrong treatment site). The patient received an approximate dose of 161 Gy (16,100 rad) to the penile bulb (glans) (wrong treatment site). The patient and referring physician were informed of this event.

On January 21, 2010, the iodine-125 seeds were implanted in the patient's prostate using real time dosimetry under ultrasonic guidance. The written directive called for a therapeutic radiation dose of 145 Gy (14,500 rad) to the prostate volume, plus 5 mm of margin. On February 23, 2010, the patient returned for a 30 day post implant CT scan, which revealed that the implanted seeds were ''in an appropriate pattern,'' but outside the intended target volume, which resulted in unintended dose to the penile bulb (glans). The licensee concluded that the medical event would not have a significant medical effect on the patient.

*Cause(s)*—The medical event is presumed to have been caused by misuse of a new ultrasound unit.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee's Radiation Oncology Department suspended all prostate brachytherapy treatments pending an additional quality assurance review. Upon completion of the quality assurance review, the licensee modified its prostate brachytherapy treatment procedures. As of January 2012, the licensee has not yet resumed prostate brachytherapy treatments after implementation of these modified procedures.

*State*—The Pennsylvania Department of Environmental Protection investigated the incident on April 15, 2010, 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 November 14, 2011.

AS11–06 Medical Event at University Community Hospital in Tampa, Florida

*Date and Place*—February 14, 2010, Tampa, Florida.

*Nature and Probable Consequences*—The University Community Hospital (the licensee) reported that two patients were prescribed single-channel HDR brachytherapy treatments of 34 Gy (3,400 rad). An actual average dose of 17 Gy (1,700 rad) to the first patient, and 26 Gy (2,600 rad) to the second patient, were delivered to the target area of the breast, and some parts of the planned volume received greater than 700 percent (first patient) and 220 percent (second patient) of the prescribed dose. In addition, other areas of the breast not in the target region received up to 136 Gy (13,600 rad) in the first patient and 75 Gy (7,500 rad) in the second patient. The maximum skin dose was calculated to be 42.5 Gy (4,250 rad) to the first patient and 75 Gy (7,500 rad) to the second patient. The patients and their referring physicians were informed of the events.

On February 14, 2010, the licensee noted that the source within the mammosite catheter was erroneously positioned approximately 2 to 2.5 cm away from the tumor. This was the result of the operator entering the wrong dwell position into the planning system. The licensee concluded that no significant adverse health effects to the patients are expected.

*Cause(s)*—The cause of the medical events was human error involving entering the wrong position of the reference end of the catheter into the planning system.

Actions Taken To Prevent Recurrence

*Licensee*—Corrective actions included implementing various quality assurance steps to ensure that the correct treatment calculations and data are used for future treatments. Additional procedural guidance will be created with detailed instructions.

*State*—The Florida Bureau of Radiation Control initiated an inspection on February 18, 2010. The State completed the inspection on March 1, 2010, 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 February 1, 2011.

AS11–07 Medical Event at Coral Springs Clinic in Coral Springs, Florida

*Date and Place*—March 11, 2010, Coral Springs, Florida.

*Nature and Probable Consequences*—The Coral Springs Clinic (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for basal cell carcinoma of the ear. The patient was prescribed 14 fractionated doses of 2.5 Gy (250 rad) to the ear, but instead, the patient received 22.5 Gy (2,250 rad) on the second fractionated treatment dose. The patient and referring physician were informed of this event.

While starting the treatment the radiation therapist accidentally pushed the incorrect button on the HDR device, which was the ''auto radiography'' button rather than the ''treatment'' button on the machine control console. This resulted in the patient receiving approximately 9 times the intended dose for that fraction of the treatment. Further treatments were canceled. The patient and doctor were notified of the incident. The licensee concluded that no significant health effects to the patient are expected as a result of this incorrect dose.

*Cause(s)*—The medical event was caused by human error in that the radiation therapist failed to push the correct button on the HDR device.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee immediately disabled the autoradiograph function on the HDR and other similar devices. The licensee modified its procedures to include the use of an independent mechanical timer and provided additional training to its entire clinical staff.

*State*—The Florida Bureau of Radiation Control initiated an inspection on April 27, 2010, 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 October 10, 2011.

AS11–08 Medical Event at Rhode Island Hospital in Providence, Rhode Island

*Date and Place*—April 23, 2010, Providence, Rhode Island.

*Nature and Probable Consequences*—The Rhode Island Hospital (the licensee) reported that a medical event occurred during a thyroid diagnostic uptake scan. The patient was prescribed to receive 7.4 MBq (200 μCi) of iodine-123, but was administered 148 MBq (4 mCi) of iodine-131. The administration resulted in a dose of approximately 3,108 cGy (3,108 rad) to the patient's thyroid, rather than the estimated 7 cGy (7 rad) that would have resulted from the iodine-123 administration. The patient and referring physician were informed of this event.

The patient's physician handed the patient a written prescription for the iodine-123 scan, but the physician's office faxed an incorrect order to the hospital for an iodine-131 scan. On April 23, 2010, the patient presented the correct written prescription slip, for the iodine-123, to the licensee's admitting receptionist. The receptionist refused the written prescription, because she thought the hospital already had the correct prescription in its records. The patient was administered the iodine-131, and the whole body scan was performed. The nuclear medicine technologist noticed something was wrong based on the scan results. The impact of this event on the patient was not reported by the licensee.

*Cause(s)*—The cause of this medical event was human error and failure of the licensee staff to follow existing written procedures and protocols.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee reviewed existing written protocols and training procedures used for the nuclear medicine technologists. The licensee's corrective actions included modifying the procedures and conducting refresher training for the nuclear medicine technologists. In addition, the licensee developed a thyroid interview and patient assessment history sheet and now requires a pathology report for all thyroid cancer patients before iodine-131 doses are administered.

*State*—The Rhode Island Department of Health, Radiation Control Program, conducted an investigation of this medical event on April 30 through May 20, 2010, and issued a Notice of Violation (NOV) to the licensee. The Rhode Island Department of Health also issued a regulatory citation regarding the licensee's failure to follow established procedures and forwarded the final update of the event to the NRC in September 2011.

AS11–09 Medical Event at Lovelace Medical Clinic in Albuquerque, New Mexico

*Date and Place*—May 4, 2010, Albuquerque, New Mexico.

*Nature and Probable Consequences*—The Lovelace Medical Clinic (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for endometrial carcinoma; the treatment consisted of 129.7 GBq (3.5 Ci) of iridium-192. The patient was prescribed to receive a total dose of 21 Gy (2,100 rad) in three fractionated doses to the vaginal cuff, but instead, the skin tissue on the patient's thigh received 30.6 Gy (3,060 rad). The patient and referring physician were informed of this event.

On May 4, 2010, the patient received the third fractionated dose of 7 Gy (700 rad) and, 1 week later, noticed the appearance of two somewhat painful dark spots on the skin of her thigh. On May 18, 2010, the patient notified the licensee of the appearance of the spots on her skin and was examined by the prescribing physician the next day. The prescribing physician did not diagnose the spots as radiation erythema at this time, but asked the patient to return for a followup examination approximately a week later. On May 26, 2010, the physician identified two circular areas with a diameter of approximately 1 cm, which were determined to be radiation erythema. The average skin dose to the patient's thigh was calculated to be 30.6 Gy (3,060 rad) and the thigh dose at a depth of 2.5 cm was calculated to be 4.08 Gy (408 rad). The licensee concluded that no long-term medical effects are expected for the patient.

*Cause(s)*—The medical event was caused by either improper placement or workers inadvertently moving the catheter while adjusting the patient for better alignment with the treatment device.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee revised its procedures to ensure that the catheter is correctly positioned before the start of the treatment. In addition, the licensee required staff training to address the procedure updates.

*State*—The New Mexico Radiation Control Bureau is conducting a long-term investigation of the event and the licensee's corrective actions and is still considering what, if any, enforcement actions to pursue.

AS11–10 Medical Event at Lancaster General Hospital in Lancaster, Pennsylvania

*Date and Place*—June 3, 2010, Lancaster, Pennsylvania.

*Nature and Probable Consequences*—The Lancaster General Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for ovarian cancer; the treatment consisted of 310.8 GBq (8.4 Ci) iridium-192. The patient was prescribed to receive 7.2 Gy (720 rad) in five fractionated doses, but instead during one of the fractionated treatments received a dose of 19 Gy (1,900 rad) to the small bowel (wrong treatment site). The patient and referring physician were informed of this event.

On June 15, 2010, before starting the second treatment, the medical staff noted that an incorrect target area had been previously entered into the HDR device for the first treatment on June 3, 2010. The medical staff noted that the intended treatment area in the written directive differed from the actual area treated by approximately 3 cm. This error in treatment area resulted in a dose of 19 Gy (1,900 rad) to the small bowel. The licensee concluded that the medical event would not have a significant medical effect on the patient.

*Cause(s)*—The medical event was caused by human error in that the licensee entered the incorrect target area into the HDR device.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee implemented corrective measures including procedure modifications to discontinue using the part of the HDR software that allows for treatment offsets to occur.

*State*—The Pennsylvania Department of Environmental Protection investigated the incident on June 21, 2010, 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 November 14, 2011.

AS11–11 Medical Event at the Greater Baltimore Medical Center in Baltimore, Maryland

*Date and Place*—July 9, 2010, Baltimore, Maryland.

*Nature and Probable Consequences*—The Greater Baltimore Medical Center (the licensee) reported that a medical event occurred associated with a manual brachytherapy treatment for cervical cancer. The patient was prescribed to receive 35 Gy (3,500 rad) to the cervix over the course of 73 hours using 1.635 GBq (44.2 mCi) of cesium-137. While the sources were being

inserted into the patient, one of the cesium-137 sources fell out of the Fletcher-Suit applicator and into the patient's hospital gown. Consequently, the skin tissue on the patient's buttocks received a dose of 10.5 Gy (1,050 rad) from the errant source. The patient and referring physician were informed of this event.

Sometime after the sources had been inserted into the patient, the patient removed the hospital gown, folded it, placed it with the trash, and donned a clean gown. On July 9, 2010, the oncologist and medical physicist removed the sources from the patient and discovered that one of the six sources was missing. The oncologist and radiation safety officer subsequently located the source wrapped in the soiled hospital gown in a bag designated for radioactive waste. The source was retrieved and transported back to the Radiation Oncology Department's source storage room. The licensee noticed no erythema of the patient's skin and concluded that no clinically significant side effects would be expected from the radiation exposure to the skin.

*Cause(s)*—The cause of the medical event was the failure of the source attachment to the applicator, coupled with failure of the licensee to establish appropriate procedures to prevent the occurrence of the medical event.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee plans to discontinue the use of the Fletcher-Suit applicator used during this treatment and exclusively use the Fletcher-Suit-Delclos applicator. The licensee also plans to revise procedures for brachytherapy applicators and provide improved training to the staff.

*State*—The Maryland Department of the Environment, Radiological Health Program conducted an investigation on July 27, 2010, and August 18, 2010. On October 18, 2010, the Department issued a letter and NOV to the licensee and forwarded the final update of the event to the NRC in July 2011.

NRC11–03 Medical Event at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi

*Date and Place*—August 4, 2008 (reported on September 8, 2010), Jackson, Mississippi.

*Nature and Probable Consequences*—The U.S. Department of Veterans Affairs (the licensee) reported that a medical event involving prostate cancer brachytherapy seed implants occurred at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 104 iodine-125 seeds. However, the seed placement resulted in an approximate dose of 233 Gy (23,300 rad) to the patient's rectum (wrong treatment site). The patient and referring physician were informed of this event.

In September 2010, the medical center staff completed a followup comprehensive external review and reanalysis of posttreatment dose parameters for all prostate seed implants performed at the G.V. (Sonny) Montgomery VA Medical Center for the period between February 2005 and August 2008. Upon an evaluation of the updated dose information generated by external review, medical center staff, working with the National Health Physics Program, discovered this event. No adverse effect to the patient is expected from the implant procedure, and the licensee continues to monitor the progress of the patient.

*Cause(s)*—The cause of the medical event was an anatomical anomaly of the patient. The patient had an unusually thin tissue layer between the prostate gland and rectum, which resulted in a small area of the rectum receiving a higher than expected dose.

Actions Taken To Prevent Recurrence

*Licensee*—The U.S. Department of Veterans Affairs, working with the National Health Physics Program and the medical center's staff, performed an initial review of all prostate brachytherapy seed implant procedures for the period between February 2005 and August 2008. The initial review of this program resulted in the suspension of and eventual termination of the medical center's prostate brachytherapy implant program in August 2009. The followup comprehensive external review and reanalysis of the program identified this event, which the medical center reported to the licensee and the NRC.

*NRC*—In August 2010, the NRC issued an NOV and Proposed Imposition of Civil Penalties to the licensee, based on the results of the initial evaluation and analysis of several events associated with the licensee's prostate brachytherapy implant program. The licensee was cited for failure to have adequate written procedures and failure to verify that the administered doses were in accordance with written directives. The NRC has not taken any additional actions based on the identification of this event.

NRC11–04 Medical Event at Community Hospitals of Indiana in Indianapolis, Indiana

*Date and Place*—October 6, 2010, Indianapolis, Indiana.

*Nature and Probable Consequences*—The Community Hospitals of Indiana (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for breast cancer; the treatment consisted of 340.4 GBq (9.2 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 postsurgical cavity in the left breast following excision of a cancerous tumor (treatment site). It was determined that the first eight treatment fractions resulted in a portion of the treatment site receiving a dose of 266 Gy (26,600 rad). In addition, a portion of the patient's skin on the left breast and the chest muscle tissue (tissue other than the treatment site) received doses of 105 Gy (10,500 rad) and 1,002 Gy (100,200 rad), respectively. The patient and referring physician were informed of this event.

On October 6, 2010, following the eighth fractionated treatment dose, an error was discovered in the treatment plan by the medical physicist who remembered that he had not changed a default entry in the treatment planning system. This error caused the source placement to be flipped 180 degrees along the applicator's long axis which resulted in a portion of the treatment site at the tip end of the applicator receiving less than the prescribed dose, and a portion of the treatment site at the connector end of the applicator receiving more than the prescribed dose. The licensee concluded that no long-term medical effects are expected for the patient. The NRC contracted with a medical consultant who determined that the overall impact to the patient is minimal.

*Cause(s)*—The medical event was caused by human error in that the medical physicist failed to change a default entry in the treatment planning system as required by the licensee's procedure.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee revised its written directive form to remind staff to change the default entry in the treatment planning system as applicable, added a step to its procedure for multicatheter HDR breast treatments to verify that the default was changed as applicable, and trained its staff on the revised written directive form. In addition, the licensee evaluated all of the other HDR breast treatments that

were conducted in 2010 to verify that the applicators were accurately reconstructed in the treatment planning computer.

*NRC*—The NRC conducted a reactive inspection on October 18–20, 2010, with continued in-office review through January 18, 2011, and issued two NOVs to the licensee on March 1, 2011, and April 20, 2011, respectively.

AS11–12 Medical Event at Cleveland Clinic Foundation in Cleveland, Ohio

*Date and Place*—October 26, 2010, Cleveland, Ohio.

*Nature and Probable Consequences*—The Cleveland Clinic Foundation (the licensee) reported, to the Ohio Department of Health (ODH) that a medical event occurred associated with a radioembolization brachytherapy treatment for liver cancer; the treatment consisted of 3.96 GBq (107 mCi) of yttrium-90. A postprocedure scan of the patient identified significant undesired activity in the duodenum (wrong treatment site). The licensee estimated that approximately 0.37 GBq (10 mCi) of activity was present in the duodenum, with a dose to the duodenum of approximately 90 Gy (9,000 rad). The patient and physician were informed of this event.

Approximately 3 weeks before the therapy, the patient was scanned for extra hepatic shunting by injecting technetium-99m into the hepatic artery. No shunting to the duodenum was identified during this procedure. On October 26, 2010, the interventional radiologist correctly inserted the catheter into the patient and its placement was confirmed by a second interventional radiologist. During the radioembolization treatment, the patient complained of pain, which resulted in the medical staff performing a postprocedure SPECT/CT scan of the patient. The SPECT/CT scan identified undesired yttrium-90 activity in the duodenum. The patient was hospitalized for observation and possible intervention as a result of the dose to the duodenum. Some ulceration of the duodenum bulb was observed, but no evidence of perforation or bleeding was detected. The licensee is continuing to monitor the patient for health effects from the radiation exposure.

*Cause(s)*—The licensee reported that the cause of the medical event was that some collateral blood vessels became dominant and blood was shunted through them to the duodenum, allowing movement of the yttrium-90 microspheres. Although the licensee has not seen this relatively uncommon occurrence in the past 3 years, it has been noted in other treatment cases.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee modified its radioembolization therapy procedure to include posttreatment imaging of yttrium-90 distribution. This will allow the licensee to respond appropriately in the event of a recurrence. The licensee's rate of occurrence is approximately 10 times less than is reported in medical literature; therefore, no specific action to prevent a reoccurrence is proposed.

*State*—On November 3, 2010, The ODH performed an onsite investigation of the event. The ODH reviewed and approved the licensee's corrective actions and took no enforcement action.

AS11–13 Medical Event at Rush University Medical Center in Chicago, Illinois

*Date and Place*—November 23, 2010, Chicago, Illinois.

*Nature and Probable Consequences*—The Rush University 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 145 Gy (14,500 rad) to the prostate using 102 iodine-125 seeds. Instead, the seeds were placed 4–5 cm inferior of the treatment plan (wrong treatment site). The patient received an approximate dose of 273.5 Gy (27,350 rad), 112 Gy (11, 200 rad), and 183 Gy (18,300 rad) to the urethra, perineum, and penile bulb (glans), respectively. The patient and referring physician were informed of this event.

During the treatment, the iodine-125 seeds were manually inserted into the prostate needle template via ultrasound imaging. Visualization of the seed placement in the postimplantation scan was problematic for the licensee's staff; however, the staff's initial estimate of seed placement was that the seeds may have been inferior to the ideal placement, but still in an acceptable location. An additional posttreatment scan at the 4-week posttreatment mark indicated that the seeds were placed 4–5 cm inferior to the planned treatment site. The licensee surmised that the geometry of the template against the patient's perineum shifted during the procedure, and pulled away from the patient, perhaps due to leg movement or coughing. This placement resulted in an elevated dose to the patient's urethra, perineum, and penile bulb (glans). The licensee concluded that there were no observed medical effects to the patient, and no long-term significant complications are expected.

*Cause(s)*—The cause of the medical event was the engorgement of the prostate gland and surrounding tissue, which made the visualization and placement of the seeds difficult during the implantation procedure.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee has indicated that these procedures will now be conducted only where fluoroscopic imaging can be performed to provide better ''real time'' imaging of seed placement, in addition to transrectal ultrasound. Needle unloading procedures have been modified, and ultrasound equipment quality assurance tests have been added before each procedure.

*State*—The Illinois Emergency Management Agency (IEMA) conducted an onsite investigation. The IEMA reviewed the event and other similar treatment procedures at the facility and determined that this event was an isolated incident. The IEMA approved the licensee's corrective actions, and issued no citations or enforcement actions at the conclusion of the investigation.

AS11–14 Medical Event at the University of Texas Southwestern Medical Center in Dallas, Texas

*Date and Place*—July 30, 2010, and September 16, 2010 (reported on February 15, 2011), Dallas, Texas.

*Nature and Probable Consequences*—The University of Texas Southwestern Medical Center (the licensee) reported the occurrence of a medical event to two young adult patients prescribed colloidal phosphorus-32 (ranging from 7.4 MBq (0.2 mCi) to 92.5 MBq (2.5 mCi) of activity) for treatment of cranial cysts. The patients were prescribed to receive a total dose of 300 Gy (30,000 rad) and 200 Gy (20,000 rad) respectively, but instead the patients received an approximate dose of 565 Gy (56,500 rad) and 506 Gy (50,600 rad) to the cysts. These dosages were 88 and 153 percent greater than the prescribed dosages. The patients and referring physicians were informed of these events.

On February 15, 2011, the licensee discovered that two young adult patients were administered doses of phosphorus-32 greater than 50 percent of the prescribed doses. The incidents were discovered when the authorized user noticed an area of inflammation surrounding the cysts and along the track of the drainage catheter. The authorized user discussed these findings with the staff medical physicist who reviewed the colloidal phosphorus-32 doses supplied by the nuclear pharmacy. The licensee determined that

for both cases, the labels had the correct total activity, but the incorrect volume and activity per unit volume. Therefore, the doses were incorrectly labeled, and the concentration was approximately 60 percent higher than indicated on the labels. The licensee subsequently calculated the doses to the target and surrounding tissues and does not expect any patient impact or unfavorable outcomes as a result of these events.

*Cause(s)*—The cause of the medical event was that the two colloidal phosphorus-32 prescriptions provided by the vendor's nuclear pharmacy were incorrectly diluted and labeled. In addition, the licensee did not perform a verification assay of the doses before their administration.

Actions Taken To Prevent Recurrence

*Licensee*—To prevent recurrence, the licensee will obtain future doses that have been calibrated to a National Institute of Standards and Technology traceable standard. The licensee also will perform a verification assay at its facility and will assess the dose volume for calculating the specific activity.

*State*—On March 1, 2011, the Texas Department of State Health Services conducted an inspection and reviewed the causes and the licensee's corrective actions. The licensee was cited for a violation for failing to perform a direct measurement of the dosage taken from a bulk quantity for medical purposes.

NRC11–05 Medical Event at the University of Michigan Hospital in Ann Arbor, Michigan

*Date and Place*—March 9, 2011, Ann Arbor, Michigan.

*Nature and Probable Consequences*—The University of Michigan Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer; the treatment consisted of 2.24 GBq (60.5 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 74.4 Gy (7,440 rad) to the left lobe of the liver, but instead, the patient received an approximate dose of 159.4 Gy (15,940 rad). This dosage was in excess of 100 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On March 9, 2011, before the treatment, the licensee's medical physicist calculated the activity needed for the dose to the left lobe of the liver. The medical physicist's calculations used the liver segment volumes for the right lobe and medial segment combined, instead of the much smaller left lobe. As a result of the volume calculation error, the dose to the left lobe of the liver was 159.4 Gy (15,940 rad), which was in excess of 100 percent of the prescribed dose. The licensee concluded that the elevated radiation dose to the patient's liver will not result in permanent medical damage or loss of function. The NRC contracted with a medical consultant who concluded that the administered dose is unlikely to result in any significant adverse effects.

*Cause(s)*—The NRC determined that the root cause of the medical event was a lack of communication between licensee personnel which resulted in an inaccurate written directive and subsequent medical event.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee modified procedures by adding reviews of treatment plans to ensure that written directives properly reflect the treatment plan.

*NRC*—The NRC conducted an inspection on March 15 and 16, 2011, and reviewed the licensee's corrective actions. On January 6, 2012, NRC issued an NOV for failure to possess adequate procedures resulting in the medical event.

AS11–15 Medical Event at Abbott Northwestern Hospital in Minneapolis, Minnesota

*Date and Place*—March 17, 2011, Minneapolis, Minnesota.

*Nature and Probable Consequences*—The Abbott Northwestern Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer; the treatment consisted of 1.11 GBq (29.97 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 30.8 Gy (3,080 rad) to the liver, but instead, the patient received an approximate dose of 46.1 Gy (4,610 rad). This delivered dosage was about 150 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On March 18, 2011, after reviewing the treatment procedure from the previous day, the licensee's radiation oncologist discovered that the dose delivered to the patient's liver was actually 150 percent of the prescribed dose. For further clarification, the radiation oncologist brought this error to the attention of the lead medical physicist responsible for the patient's treatment delivery. Upon investigation, it was deduced that the medical physicist had not read the patient's therapy written directive prescription correctly, resulting in a higher than intended dosage being administered to the patient's liver. The licensee's radiation oncologist and interventional radiologist concluded that this elevated dose would slightly increase the patient's risk of radiation-induced liver disease.

*Cause(s)*—The medical event is believed to have been caused by human error in failing to correctly read the therapy written directive prescription.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee implemented corrective measures, including increasing the font and highlighting in a different color the final dose on the written directive. In addition, the final dose is now transferred automatically rather than manually to the spreadsheet workbook used to draw up the dose. Also, procedures now require a second individual to verify that the correct prescribed activity has been transferred to the worksheet used for drawing up the dose.

*State*—The Minnesota Department of Health (MDH) conducted an investigation on April 5, 2011. During the investigation, MDH met with the radiation safety officer, the medical physicist and both radiation oncologists involved with the incident, and several members of the licensee administrative team. In addition, MDH reviewed the corrective actions implemented by the licensee. The MDH did not issue any violations or penalties associated with the event; however, MDH will evaluate the licensee's corrective actions at its next inspection.

AS11–16 Medical Event at the University of California, Los Angeles in Los Angeles, California

*Date and Place*—April 4, 2011, Los Angeles, California.

*Nature and Probable Consequences*—The University of California, Los Angeles (UCLA) (the licensee) reported the occurrence of a medical event associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a dose of 144 Gy (14,400 rad) to the prostate using 101 iodine-125 seeds. Instead, the iodine-125 seeds were implanted inferior to the target volume (wrong treatment site), resulting in a dose to this tissue of 144 Gy (14,400 rad). The patient and referring physician were informed of this event.

On May 3, 2011, the patient returned to the UCLA Department of Radiation Oncology for a routine postimplant CT scan to verify seed placement and final dosimetry endpoints. The routine postimplant CT scan indicated that of the 101 total seeds implanted, approximately 72 seeds had been placed inferior to the target volume. As a result

of the seed misplacements, approximately 31 $cm^3$ of normal tissue inferior to the prostate received at least 144 Gy (14,400 rad) instead of the prostate tissue receiving that dose. Rectal and bladder doses were not significantly impacted by the seed misplacements and remained within typical doses for prostate implants. The licensee concluded that there was no harm to the patient from doses to the nontargeted tissue.

*Cause(s)*—The licensee reported that the cause of the medical event was movement of the prostate gland during the implantation procedure, coupled with insufficient ultrasound images needed to identify the movement of the prostate gland during the procedure.

Actions Taken To Prevent Recurrence

*Licensee*—The licensee temporarily placed the permanent prostate seed implantation program on hold pending a review of the procedures. Upon completion of the review the licensee changed the implant procedure to require the verification of the base prostate plane and needle placement using both axial and sagittal plane ultrasound views. The licensee also did an internal investigation to determine if any similar incidents of seed misplacements had occurred in the past and reported that postimplant CT had been performed for at least the previous 5 to 6 years without the detection of any significant seed misplacement events.

*State*—The California Radiation Control Program investigated the event and issued violations for failing to have adequate prostate seed implantation procedures, failing to report the medical event within 24 hours of discovery, failing to provide a written report with all of the required information for the medical event within 15 days, and failing to have procedures and to adequately train staff and authorized users for reporting of medical events.

AS11–17 Medical Event at St. Vincent Hospital in Green Bay, Wisconsin

*Date and Place*—May 15, 2011, Green Bay, Wisconsin.

*Nature and Probable Consequences*—The St. Vincent Hospital (the licensee) reported that a medical event occurred associated with HDR brachytherapy treatment for breast cancer; the treatment consisted of 318.2 GBq (8.6 Ci) of iridium-192. The patient was prescribed to receive a total dose of 34 Gy (3,400 rad) over 10 fractionated treatments. Instead, the patient received 8.84 Gy (884 rad) to the tumor site and a dose of 67.5 Gy (6,750 rad) to unintended skin tissue. The patient and referring physician were informed of this event.

On June 6, 2011, the licensee determined that the applicator catheter lengths measured using the check ruler were incorrect during the breast cancer treatment. The licensee ascertained that the incorrect measurement was the result of the wire being caught at the apex of the curved catheter, approximately 4.5 cm from of the end of the catheter. Members of the licensee's staff assumed that this measured length was accurate because they were not aware of the nominal catheter length. The Wisconsin Department of Health Services verified that the nominal catheter length was not provided in the manufacturer's written procedure, and the manufacturer determined that the check wire used by the licensee met all design specifications. The licensee concluded that there were no observed significant adverse effects to the patient, and no long-term significant complications are expected.

*Cause(s)*—The cause of the medical event was human error in the failure to identify that the check wire was not inserted to the end of the catheter's lumen and failure to identify an incorrect measurement length.

Actions Taken To Prevent Recurrence

*Licensee*—Corrective actions include obtaining a new measurement wire that has the same flexible tip as the HDR dummy wire. The treatment protocol was changed to incorporate the manufacturer's expected applicator treatment distances. In addition, the licensee developed a new policy and procedure, which emphasizes the due diligence required by the staff before the first clinical use of new HDR treatment applicators and guide tubes.

*State*—Based on its investigation conducted on June 14, 2011, the Wisconsin Department of Health Services cited the licensee for failure to develop, implement, and maintain written procedures to ensure that each administration is performed according to the provisions of the written directive.

AS11–18 Medical Event at the University of Wisconsin—Madison in Madison, Wisconsin

*Date and Place*—July 7, 2011, Madison, Wisconsin.

*Nature and Probable Consequences*—The University of Wisconsin—Madison (the licensee) reported that a medical event occurred associated with radioembolization brachytherapy treatment for liver cancer; the treatment consisted of 1.05 GBq (28.4 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 120 Gy (12,000 rad) to the left lobe of the liver, but instead, the patient received an approximate dose of 41.8 Gy (4,180 rad) to the right lobe of the liver (wrong treatment site). The patient and referring physician were informed of this event.

On July 7, 2011, the patient was scheduled for treatment for multinodular hepatocellular carcinoma to the left lobe of the liver. The dosimetry for yttrium-90 radioembolization brachytherapy treatment was based on the volume (mass) of the left lobe. The written directive specified the treatment of the left lobe of the liver; however, the right lobe of the liver was treated in error. The licensee concluded that the dose received was not medically significant to the patient.

*Cause(s)*—The cause of the medical event was human error in not correctly following the treatment plan as documented on the written directive. The interventional radiologist forgot that he had changed the initial target of the procedure after the dose had been ordered and did not communicate that change to the rest of the staff.

Actions Taken To Prevent Recurrence

*Licensee*—Corrective actions include a series of checks developed to occur in the interventional radiology room before an administration. Checks include a verbal confirmation between the interventional radiologist and the medical physicist and confirmation of the patient name, target area, dose, and route of administration. This checklist is also compared to the written directive.

*State*—The Wisconsin Department of Health Services conducted a reactive inspection on August 12, 2011, and did not issue any violations to the licensee.

AS11–19 Medical Event at the Swedish American Hospital in Rockford, Illinois

*Date and Place*—September 13, 2011, Rockford, Illinois.

*Nature and Probable Consequences*—The Swedish American Hospital (the licensee) reported a medical event involving brachytherapy seed implant treatment for prostate cancer. The patient was prescribed a dose of 145 Gy (14,500 rad) to the prostate using 71 iodine-125 seeds. Instead, 68 of the iodine-125 seeds were implanted in the large bowel, the small bowel, and the bladder. The licensee calculated that the dose to the prostate was less than 1 Gy (100 rad), but the unintended dose to the large bowel was 10.2 Gy (1,020 rad). The patient and referring physician were informed of this event.

On September 15, 2011, postimplant imaging of the patient revealed that only three seeds were properly located in the prostate (target site), indicating a dose significantly less than the prescribed amount in the written directive. Postimplant imaging also revealed that seven seeds were in the bladder; these seeds were immediately removed. Additional postoperative imaging indicated that a number of seeds had been placed in the bowel wall, bladder wall, and the lumen of the bowel. On October 3, 2011, surgery was performed to remove misplaced seeds. All but four seeds were removed from the patient. With the removal of the seeds that the licensee was able to remove, the licensee concluded that the medical event would not have a significant effect on the patient.

*Cause(s)*—The cause of the medical event was a deviation from protocol by not having a medical physicist present during the procedure and not using fluoroscopy during needle placement.

Actions Taken To Prevent Recurrence

*Licensee*—Corrective actions include emphasizing strict adherence to prostate brachytherapy protocols.

*State*—The IEMA conducted an investigation on September 26, 2011, and verified the root cause of the event as reported by the licensee. The IEMA issued an NOV to the licensee regarding this failure to implement appropriate procedures.

Dated at Rockville, Maryland, this 15th day of June, 2012.

For the Nuclear Regulatory Commission.

**Annette Vietti-Cook,**

*Secretary of the Commission.*

[FR Doc. 2012–15172 Filed 6–20–12; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–67207; File No. SR–CME–2012–21]**

## Self-Regulatory Organizations; Chicago Mercantile Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Amend CME Rule 971 Reporting Requirements for FCM Clearing Members

June 15, 2012.

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 June 7, 2012, the Chicago Mercantile Exchange Inc. (''CME'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I and II below, which items have been prepared primarily by CME. The Commission is publishing this Notice and Order to solicit comments on the proposed rule change from interested persons and to approve the proposed rule change on an accelerated basis.

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

CME proposes amendments to certain reporting requirements for futures commission merchant (''FCM'') clearing members. The enhanced reporting requirements are designed to further safeguard customer funds held at the FCM level. The text of the proposed changes is as follows with additions italicized and deletions in brackets.

* * * * *

Rule 100—Rule 970—No Change

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CME Rule 971. SEGREGATION, SECURED AND SEQUESTERED REQUIREMENTS

A. All clearing members must comply with the requirements set forth in CFTC Regulations 1.20 through 1.30, 1.32, and 30.7, and CME Rules 8F100 through 8F136. This includes, but is not limited to, the following:

1. Maintaining sufficient funds *at all times* in segregation [or set aside in separate or]*, secured 30.7 and* sequestered accounts;

2. Computing, recording and reporting completely and accurately the balances in the:

a. Statement of Segregation Requirements and Funds in Segregation;

b. Statement of Secured Amounts and Funds Held in Separate Accounts; and

c. Statement of Sequestration Requirements and Funds Held in Sequestered Accounts.

3. Obtaining satisfactory segregation, [separate] *secured 30.7* and sequestered account acknowledgement letters and identifying segregated, [separate] *secured 30.7* and sequestered accounts as such; and

4. Preparing complete and materially accurate daily segregation, secured *30.7* and sequestered amount computations in a timely manner.

B. [Exchange staff may prescribe additional segregation, secured and sequestered amount requirements.] *All FCM clearing members must submit a daily segregated, secured 30.7 and sequestered amount statement, as applicable, through Exchange-approved electronic transmissions by 12:00 noon on the following business day.*

C. [All clearing members must provide written notice to the Audit Department of a failure to maintain sufficient funds in segregation or set-aside in separate or sequestered accounts. The Audit Department must receive immediate written notification when a clearing member knows or should have known of such failure.] *All FCM clearing members must submit a report of investments in a manner as prescribed through Exchange-approved electronic transmissions as of the 15th of the month (or the following business day if the 15th is a holiday or weekend) and last business day of the month by the close of business on the following business day. The report of investments shall be prepared and shall identify separately for segregated, secured 30.7 and sequestered funds held:*

*1. The dollar amount of funds held in cash and each permitted investment identified in CFTC Regulation 1.25(a); and*

*2. The identity of each depository holding funds and the dollar amount held at each depository.*

*D. All disbursements not made for the benefit of a customer from a segregated, secured 30.7 or sequestered account which exceed 25% of the FCM clearing members excess segregated, secured 30.7 or sequestered of the respective origin must be pre-approved in writing by the clearing member's Chief Executive Officer or Chief Financial Officer.*

*1. In determining if a disbursement exceeds the 25% level, such disbursement must be:*

*a. Compared to the most recent calculation of excess segregated, secured 30.7 and sequestered amounts; and*

*b. A single disbursement must be reviewed individually and in the aggregated with all other disbursements not made for the benefit of a customer of the respective segregated, secured 30.7 or sequestered origin since the last calculation of excess funds.*

*2. Upon approval of a single disbursement or the disbursement which in the aggregated exceeds the 25% level as defined in Rule 971.D.1., the FCM clearing member must provide immediate notification to the Audit Department through Exchange-approved electronic transmissions. Such notification shall include:*

*a. Confirmation that the FCM clearing member's Chief Executive Officer or Chief Financial Officer pre-approved in writing the disbursement(s);*

*b. The amount(s) and recipient(s) of such disbursement(s); and*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.