facsimile transmission to (301) 415–1101 or by e-mail to *hearingdocket@nrc.gov* and also to the Office of the General Counsel either by means of facsimile transmission to (301) 415–3725 or by e-mail to *OGCMailCenter@nrc.gov.* If a person other than the Mr. Siemaszko requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR § 2.309.

If a hearing is requested by Mr. Siemaszko or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be effective and final 90 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received.

Dated this 21st day of April 2005.

For The Nuclear Regulatory Commission.

Ellis W. Merschoff,

Deputy Executive Director for Reactor Programs, Office of the Executive Director for Operations.

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NUCLEAR REGULATORY COMMISSION

Report to Congress on Abnormal Occurrences Fiscal Year 2004 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 which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104–66) requires that AOs be reported to Congress annually. During fiscal year 2004, 17 events that occurred at facilities licensed or otherwise regulated by the NRC and/or Agreements States were determined to be AOs. The report describes four events at facilities licensed by the NRC. One event involved a uranium hexafluoride release at a fuel cycle facility. Another event, also at a fuel cycle facility, revealed excessive uranium concentrations found in ash deposits in various locations in an incinerator. A third event involved a patient undergoing therapeutic brachytherapy treatment. The fourth event involved an unintentional excessive dose of sodium iodide (I–131) administered to a patient. The report also addresses 13 AOs at facilities licensed by Agreement States. [Agreement States are those States that have entered into formal agreements with the NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA licensed material at facilities located within their borders.] Currently, there are 33 Agreement States. During FY 2004, the NRC received notification of 13 events that occurred at Agreement State-licensed facilities, including 8 therapeutic medical events, 3 diagnostic medical events, 1 event involving an unintentional dose of I–131 to an embryo/fetus, and 1 event involving an extremity overexposure to a radiopharmacy trainee. 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 action taken to prevent recurrence. Each event is also being described in NUREG–0090, Vol. 27, ''Report to Congress on Abnormal Occurrences, Fiscal Year 2004.'' This report will be available electronically at the NRC Web site *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/*.

Nuclear Power Plants

During this period, no events occurred at U.S. nuclear power plants that were significant enough to be reported as AOs.

Fuel Cycle Facilities

(Other Than Nuclear Power Plants)

During this period, two events occurred at U.S. fuel cycle facilities that were significant enough to be reported as AOs.

04–01 Uranium Hexafluoride Release at Honeywell Speciality Chemicals, Inc. in Metropolis, Illinois

Date and Place—December 22, 2003; Honeywell International, Inc., Honeywell Specialty Chemicals, Metropolis, Illinois.

Nature and Probable Consequences—On December 22, 2003, a uranium hexafluoride (UF_6) release occurred from one of the plant's chemical process lines. The release occurred due to improper valve alignment which caused inadvertent pressurization of the system. The licensee did not have a written procedure for a process that was performed infrequently and relied on the operator's memory to perform the required actions. The release lasted approximately 40 minutes. The licensee observed a visible cloud crossing the site boundary and declared a site area emergency, which was terminated approximately 4 hours later. Approximately 25 members of the public were temporarily evacuated from their homes, and approximately 75 persons remained sheltered in their homes for a time. Four members of the public went to the hospital. Three of the four were examined and released, while the fourth was held for observation and released the next day.

This individual showed skin reddening on portions of his face and part of one arm, which indicated a hydrogen fluoride (HF) acid burn. Honeywell's initial estimate of a release of 7 pounds of UF_6 was later refined to be approximately 70 pounds. Honeywell shut the plant down and agreed to discuss corrective actions with the NRC before restarting operations to determine whether the NRC had any objection to restarting specific operations.

Cause(s)—An NRC Augmented Inspection Team (AIT) and Honeywell's Root Cause Investigation Team identified similar root and contributing causes. The Honeywell Root Cause Investigation Team provided its findings to the NRC in a meeting on February 11, 2004.

Key causes were as follows:

- The licensee failed to have a written procedure for an infrequent evolution and, thus, relied on the operator's memory to perform the required actions.
- The licensee's corrective action program had not adequately corrected a previously identified lack of procedures for certain activities, the licensee had not adequately aligned staff to the need for procedures for activities.
- The licensee did not have an alarm to warn operators that the system was becoming pressurized. The licensee did not have procedures or measures to respond to abnormal conditions during operations. The licensee did not have procedures or processes for documenting when equipment was not in proper working order.

In addition, the AIT and Honeywell Root Cause Investigation Team identified problems in implementing the emergency plan once the licensee identified the release, including problems in communication with State and local authorities.

Actions Taken To Prevent Recurrence

Licensee—In addition to the Root Cause Investigation Team, Honeywell chartered a Plant Engineering Team, a ''Triangle of Prevention'' Team, and a Corporate ''Deep Dive'' Team to review the facility and operations. These teams reviewed certain UF_6 safety and environmental improvements, management processes, change management, mechanical integrity, and the emergency plan. As a result of these reviews, Honeywell developed a list of corrective and improvement actions to be completed before restarting operations. On March 4, 2004, Honeywell submitted a list of the actions to be taken for each phase of the restart. Honeywell has also worked with State and local authorities to improve emergency response, and the company conducted an emergency drill with local agencies on March 11, 2004. That drill identified items that needed to be improved, including use of the dedicated phone for communicating with off site authorities. Honeywell plans to improve this communication method. In addition, Honeywell is in the process of implementing other corrective and improvement actions.

NRC—The NRC developed a Restart Readiness Oversight Plan to review Honeywell's actions, including safety and emergency preparedness improvements. The NRC has reviewed actions the licensee planned to prevent recurrence. In addition, the NRC observed an emergency drill of the revised Emergency Plan and procedures.

The NRC held two public meetings in Metropolis, Illinois (on March 18 and April 21, 2004) during the restart phase to inform the public of the licensee's plans and progress and to describe the NRC's oversight activities and results. In addition, the NRC completed inspections of the licensee's corrective actions before the restart of licensed operations. On May 10, 2004, the NRC issued a Notice of Violation for two significant violations identified during the AIT inspection. Specifically, those violations involved (1) reconfiguration of the fluorination system without detailed instructions (which allowed a UF_6 leak to occur), and (2) failure to maintain and execute various response measures in the emergency response plan.

The NRC performed followup inspections specifically focused on Honeywell's implementation of its corrective actions on June 10 and August 13, 2004. The areas inspected included plant operations, chemical safety, emergency preparedness, maintenance and surveillance, management organization and controls, and operator training. The June inspection did not identify any violations, but the August inspection identified two Severity Level IV violations. Those cited violations concerned the conduct of operations that were not adequately described in written operating procedures and an inadequate evaluation of the radiological conditions associated with storage of bed material and filter fines.

On September 30, 2004, the NRC held a public meeting with Honeywell to discuss the company's progress in implementing long-term corrective actions that will ensure sustained performance improvements. Honeywell's long-term efforts were primarily directed at procedures and training, plant material conditions, and emergency preparedness. The NRC also described the additional inspections completed since the restart of licensed operations at the site and the agency's plan to continue increased oversight.

The NRC performed an additional inspection in December 2004, and identified a violation that involved the failure of the licensee's operations personnel to properly perform pre-fill inspections of UF_6 cylinders. This failure resulted in Honeywell's shipment of 14 cylinders with prohibited Hunt valves attached. Based upon the results of this inspection, together with those of the previous inspections, the NRC has determined that the heightened oversight of licensed activities performed at the Honeywell facilities will continue.

This event is open for the purpose of this report.

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04–02 Incinerator Event at Westinghouse Columbia Fuel Fabrication Facility in Columbia, South Carolina

Date and Place—Discovered on March 5, 2004; Westinghouse Columbia Fuel Fabrication Facility; Columbia, South Carolina.

Nature and Probable Consequences—The licensee uses a standard industrial incinerator to reduce uranium-contaminated process waste volume and facilitate uranium recovery from the waste. During a technical review of a proposed procedure change, the licensee determined that its incinerator off-gas system was being operated outside the approved safety basis. Samples of ash deposited at various locations in the incinerator exceeded the assumed uranium concentration for incinerator ash. The licensee immediately stopped incinerator operations and performed a complete incinerator clean-out. The licensee determined that approximately 271 kilograms of ash at a maximum uranium concentration of approximately 30 wt% had accumulated in the incinerator's secondary combustion chamber. The licensee had performed a criticality analysis that concluded no ash would accumulate in the secondary combustion chamber, and the maximum uranium concentration of ash in the incinerator system could not exceed 21.6 wt%. No criticality safety controls were in place to prevent the accumulation of fly-ash containing excessive uranium concentrations.

Cause(s)—The licensee's criticality safety staff failed to recognize that fly-ash could accumulate in the incinerator's secondary combustion chamber, and ash uranium concentrations could exceed 21.6 wt%. Contributing factors were the failure to control incinerator operations that allowed the increased uranium concentration in the fly-ash, and failure to recognize excessive material accumulation or uranium concentration increases.

Actions Taken To Prevent Recurrence

Licensee—The licensee immediately stopped incinerator operations and initiated a project to prevent future material accumulations. The licensee also initiated a program to upgrade criticality safety at the plant, including assigning additional staff to the nuclear criticality safety program, improving ownership of criticality safety by production and engineering staff, improving management and ownership of change, performing a comprehensive review of existing criticality safety analyses, using the integrated safety analysis process to prioritize changes to administrative criticality safety controls, and implementing a comprehensive program throughout the plant to ensure procedure compliance.

NRC—On May 13, 2004, the NRC issued Inspection Report 70–1151/2004–001, which described the event. On July 19, 2004, the NRC issued an Information Notice to fuel cycle licensees concerning the use of less-than-optimal bounding assumptions in criticality safety analyses at fuel cycle facilities. On July 28, 2004, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $24,000 to the licensee for failure to establish and maintain double-contingency protection in the incinerator and failure of management controls to detect the accumulation of a critical mass of fissile material in an unsafe geometry vessel. Although the normal civil penalty assessment process

would have fully mitigated the civil penalty, the NRC exercised enforcement discretion in accordance with Section VII.A.1 of the Enforcement Policy and proposed a base civil penalty to reflect the safety significance of the issue, which resulted in a substantial increase in the likelihood of a nuclear criticality event. On October 21, 2004, the NRC conducted a management meeting with the licensee to discuss the incinerator event and its proposed corrective actions. The NRC will follow the corrective actions through the agency's inspection and oversight programs.

This event is closed for the purpose of this report.

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Other NRC Licensees (Industrial Radiographers, Medical Institutions, etc.)

The NRC determined that the following events which occurred at facilities, licensed or otherwise regulated by the NRC, during this reporting period were significant enough to be reported as AOs:

04–03 Iodine–125 Brachytherapy Seed Medical Event at Albert Einstein HealthCare Network in Philadelphia, Pennsylvania

Date and Place—October 16, 2003 (identified on November 20, 2003); Albert Einstein HealthCare Network in Philadelphia, Pennsylvania.

Nature and Probable Consequences—A patient received a permanent brachytherapy implant using iodine–125 (I–125) seeds as treatment for prostate carcinoma on October 16, 2003. The authorized user prescribed a dose of 145 Gy (14,500 rads) to the prostate gland. The implant was performed under ultrasound guidance, and 89 sources were implanted as prescribed in the written directive. On November 17, 2003, the patient returned for a routine postoperative computerized tomography (CT) scan. On November 20, 2003, a review of the scan revealed that many of the seeds were not located in the prostate as intended, but were in adjacent tissue where they were ineffective during treatment. As a result, the prostate gland received an inadequate dose of 18.6 Gy (1,860 rads), while the adjacent tissue received a dose of approximately 115 Gy (11,500 rads). An NRC medical consultant determined that the probable consequences to the patient would be comparable to the effects of external beam radiation treatment for prostate cancer and would not cause further damage to the patient. The patient and the patient's referring physician were notified of the event.

Cause(s)—The licensee determined that this medical event was caused by human error, the most likely being the misidentification of the prostate gland on the intra-operative ultrasound. Other possible causes include shifting of the needle grid in the patient on the operating room table or the suction of the seeds into the needle tract after the removal of the individual needles from the patient.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions for future prostate brachytherapy treatments include new requirements that an outside radiation oncologist with expertise in prostate brachytherapy will monitor authorized users, and an experienced prostate brachytherapist will observe authorized users as they perform prostate implant procedures. In addition, the licensee implemented revised procedures, including performing a pre-operative CT scan; reviewing pre-planned ultrasound studies prior to, during, and after the procedure; and reviewing postoperative pelvic x-rays within 1 day of the procedure. Furthermore, the Radiation Safety Committee will review all forms, documents, education, and oversight associated with the permanent prostate implant program, and will make recommendations or amendments, as necessary, to reflect programmatic changes.

NRC—The NRC staff conducted a special safety inspection on December 5, 2003, and did not identify any violations associated with the licensee's actions. The NRC also reviewed the licensee's current prostate implant program, and concluded that 12 other I–125 prostate implants had been completed without incident.

This event is closed for the purpose of this report.

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04–04 Diagnostic Medical Event at William Beaumont Hospital in Royal Oak, Michigan

Date and Place—June 8, 2004; William Beaumont Hospital; Royal Oak, Michigan.

Nature and Probable Consequences—The licensee reported that a patient was prescribed a dose of 0.37 megabecquerels (MBq) [10 microcuries (μCi)] of I–131 for a thyroid uptake procedure, but instead received 33.86 MBq (915 μCi) of I–131. The pipette used to prepare I–131 therapy dosages earlier in the day was inadvertently used to draw the 0.37 MBq (10 μCi) I–131 uptake dosage. The technician properly disposed of the I–131 uptake dosage after identifying the error.

The technician then obtained the ''uptake'' pipette and prepared a second dosage from the I–131 bulk uptake solution. However, the ''uptake'' pipette had inadvertently been switched with the ''therapy'' pipette used earlier. This may have occurred because both the thyroid ''uptake'' pipette and the ''therapy'' pipette had illegible labels. As a result, the second dosage contained 0.074 MBq (2 μCi) of I–131 remaining from the earlier therapy administrations and the newly drawn I–131 prepared for the thyroid uptake. The total activity for the second dosage measured 33.86 MBq (915 μCi). The technician focused on drawing the calculated volume required to obtain the prescribed activity, rather than the radioactive activity measured in the dose calibrator and interpreted the ''0.915 millicuries (mCi)'' displayed on the dose calibrator as ''9.15 μCi.'' The technician electronically transferred the dosage measurement from the dose calibrator to a dosage label. A second technician administered the dosage to the patient. Assuming a 55% uptake, the absorbed dose to the patient's thyroid was 26.75 Gy (2,675 rads) with an effective dose equivalent of 0.81 Gy (81 rads). The patient and referring physician were notified of the medical event on June 9, 2004. The licensee indicated that the additional dosage administered to the patient would not result in any increased risk or biological effect to the patient.

Cause(s)—This event was caused by human error. The nuclear medicine technologist who drew the dose misinterpreted the reading on the dose calibrator, and the technician who administered the dose did not verify the dose before administration.

Actions Taken To Prevent Recurrence

Licensee—The licensee implemented a requirement to use a new pipette each time an I–131 uptake dose is prepared, reprogrammed the computer to accept uptake dose activity rather than volume and stopped the computer from printing a dose label when the activity is not within the established range. The licensee also trained the radiopharmacy staff not to override the computer's failsafe mechanisms, and retrained the nuclear medicine technologist in the process for dose verification prior to administration.

NRC—The NRC staff conducted a special safety inspection on June 10, 2004. Then, on September 14, 2004, the NRC issued a Notice of Violation for a significant violation involving the administration of a dosage of liquid I–131 to a patient for a thyroid uptake study that was approximately 90 times

larger than the 10-μCi dosage prescribed by the authorized user physician.

This event is closed for the purpose of this report.

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Agreement State Licensees

The NRC determined that the following events, which occurred at Agreement State licensed facilities during this reporting period, were significant enough for reporting as AOs:

AS 04–01 I–125 Brachytherapy Seed Medical Event at Central Arkansas Radiation Therapy Institute in Conway, Arkansas

Date and Place—December 4, 2003; Central Arkansas Radiation Therapy Institute; Conway, Arkansas.

Nature and Probable Consequences—The licensee reported that a patient received a radiation dose to an unintended area during an I–125 prostate-seed implant procedure. The patient was prescribed treatment with 122 I–125 seeds, with each seed containing an activity of 13.3 MBq (0.36 mCi). During the patient's post-implant CT scan on December 18, 2003, the licensee discovered that the seeds had been implanted 2 centimeters (cm) too low and missed treating the upper portion of the prostate gland. As a result, 68 cm^3 of adjacent tissue received the prescribed dose of 144 Gy (14,400 rads). The licensee reported that the adjacent tissue should not be affected adversely by the dose delivered by the seeds. The licensee administered additional treatment to deliver the intended dose to the upper 2 cm of the prostate gland. The licensee notified the patient and the patient's referring physician of the event.

Cause(s)—This event was attributed to human error in that the treatment site was not verified.

Actions Taken To Prevent Recurrence

Licensee—The licensee wrote a new procedure to implement the use of fluoroscopic guidance to ensure the correct placement of seeds.

State Agency—The State has reviewed and accepted the licensee's corrective actions.

This event is closed for the purpose of this report

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AS 04–02 Dose to Fetus at Hillcrest Hospital of Mayfield Heights, Ohio

Date and Place—November 20, 2003, Hillcrest Hospital; Mayfield Heights, Ohio.

Nature and Probable Consequences—The Ohio Bureau of Radiation Protection reported that a 19-year-old female patient was administered 5.18 gigabequerels (GBq) (140 mCi) of I–131 as prescribed for thyroid carcinoma. At the time, the patient was unaware that she was pregnant and she completed the required forms indicating that she was not pregnant. However, on December 5, 8, and 11, 2003, quantitative tests confirmed that the patient was pregnant. The licensee provided the results to the patient's endocrinologist, who recommended performing a fetal dose calculation. The licensee was notified and its consultant informed the endocrinologist that the fetus would have received a whole body dose of 0.19 Gy (19.8 rads). The endocrinologist sent the results to the Center for Human Genetics at the University Hospital in Cleveland, Ohio, where an assessment determined that the pregnancy could safely continue.

Cause(s)—This event was caused by human error. At the time of the administration, the patient was unaware of her pregnancy status and completed forms indicating that she was not pregnant.

Actions Taken To Prevent Recurrence

Licensee—The licensee has implemented pregnancy testing for patients of child bearing age, who receive radiation therapy.

State Agency—The Ohio Bureau of Radiation Protection was notified of this event on January 16, 2004, and performed a special inspection on January 22, 2004. The State found the licensee's corrective actions adequate to prevent recurrence.

This event is closed for the purpose of this report.

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AS 04–03 High Dose Rate Afterloader Medical Event at New Orleans Cancer Institute at Memorial Medical Center, Louisiana

Date and Place—March 31, 2004; New Orleans Cancer Institute; New Orleans, Louisiana.

Nature and Probable Consequences—A cancer patient undergoing therapeutic radiation treatment for prostate cancer received 18 Gy (1,800 rads) to the wrong treatment site. This error occurred using a high dose rate (HDR) afterloader device with a radioactive source containing 270.7 GBq (7.32 Ci) of Ir–192. The event occurred after the dosimetrist made an error while inputting data into the afterloader's dosimetry software program. Although the dosimetrist appropriately clicked the ''catheter tip'' selection, the dosimetrist did not highlight and choose ''catheter tip.'' Therefore, the computer cursor stayed on the ''connector end'' selection. This resulted in a 2-cm positioning error, which caused the source to stop short of the target so that the total prescribed dose was not delivered. The patient was informed of the event, and the remaining dose was delivered by external beam therapy. According to the Radiation Oncologist, no detrimental effects are expected. The patient was self-referred for the therapeutic treatment.

Cause(s)—This event was attributed to operator error.

Actions Taken To Prevent Recurrence

Actions taken to prevent recurrence include implementing procedures to add a visual check and documentation that the treatment plan was administered with the source position calculated from the tip end of the catheter or needle. This procedure will be added to the pre-treatment checklist, which is performed and signed by the radiation oncologist, physicist, and dosimetrist. The checklist will be performed prior to initial treatment and at treatment plan changes, and will be part of the patients' permanent records. Also, the licensee contacted the device's manufacturer regarding the confusion associated with the default orientation in the software program, and requested an adjustment to the program. The manufacturer stated that this could not be done at this time, but is discussing the issue. The manufacturer offered additional training to the licensee's employees, and the licensee is sending its employees to the training.

State Agency—The State accepted the licensee's implementation of new procedures and its corrective actions as appropriate.

This event is closed for the purpose of this report.

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AS 04–04 Diagnostic Medical Event at Northeast Alabama Regional Medical Center, Alabama

Date and Place—August 10, 2004; Northeast Alabama Regional Medical Center; Montgomery, Alabama.

Nature and Probable Consequences—A patient received 111 MBq (3,000 μCi) of I–131 instead of the prescribed dose of 0.93 MBq (25 μCi). The licensee discovered the event on August 12, 2004, when the patient returned for the whole body scan 48 hours later. The referring physician had requested a diagnostic I–131 scan to assess a thyroid nodule, which requires 0.93 MBq (25 μCi). The technologist misunderstood the order by assuming that the referring physician wanted a whole body scan to assess thyroid cancer, and administered 111 MBq (3,000 μCi) of I–131 without

requesting clarification or approval from the authorized users.

Two authorized users determined that the patient could become hypothyroid. Therefore, patient followup assessments included thyroid profiles and thyroid uptakes to determine thyroid function. The patient and the referring physician were informed of the event.

Cause(s)—This event was attributed to human error. The technologist misunderstood the treatment ordered by the referring physician and failed to verify the written directive.

Actions Taken To Prevent Recurrence

Licensee—The licensee implemented corrective measures to ensure that authorized users approve all procedures involving the administration of radiopharmaceuticals and re-instructed nuclear medicine personnel.

State Agency—The State conducted an inspection.

This event is closed for the purpose of this report.

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AS 04–05 Occupational Exposure at Palmetto Health and Baptist Hospital in Columbia, South Carolina

Date and Place—March 17, 2004; Palmetto Health and Baptist Hospital; Columbia, South Carolina.

Nature and Probable Consequences—The licensee reported that a pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent to the hand of 7,420 mSv (742 rem), a deep dose equivalent to the hand of 70 mSv (7.02 rem), and a thyroid dose of 0.9 mSv (0.09 rem). The exposures occurred when a spill took place while compounding I–131 from a vial. The pharmacist trainee cleaned up the area, decontaminated his skin, and reported the spill to the imaging manager the following day. The imaging manager conducted a second survey of the area, which showed that no contamination remained from the spill. The pharmacist trainee completed a spill report but did not reveal his contamination in the report. The pharmacist trainee left for vacation and 11 days later, after his return, informed the Radiation Safety Officer (RSO) that his forearm had been contaminated during the I–131 spill. Immediate actions were taken to determine whether any contamination still remained on his arm. Elevated levels were discovered on his right forearm and left fingertips. The appropriate hospital/nuclear medicine personnel were notified. The pharmacist trainee was suspended from any and all duties involving radioactive material.

Cause(s)—This event occurred as a result of human error and failure to follow established procedures. An initial crimp failure on the vial may also have contributed to the spill.

Actions Taken To Prevent Recurrence

Licensee—The licensee retrained all staff in spill procedures, emphasizing proper notification of supervisors. Additionally, at the prompting of the licensee, the vial supplier reevaluated the process of ensuring that each crimp is acceptable for shipment, although the supplier believed it was more likely an isolated incident.

State Agency—The State agency conducted inspections and cited the licensee for violations of regulations for controlling radiation.

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AS 04–06 Gamma Stereotactic Radiosurgery (Gamma Knife) Medical Event at Radiosurgical Center of Memphis in Memphis, Tennessee

Date and Place—January 24, 2003; Radiosurgical Center of Memphis; Memphis, Tennessee. This event was not determined to be an AO until the preparation of the FY2004 report.

Nature and Probable Consequences—The licensee reported that a patient received 27 Gy (2,700 rads) to a brain metastasis instead of the intended 18 Gy (1,800 rads) during gamma knife treatment. The physicist did not determine that an error had occurred until the treatment was complete. The RSO determined that one of the four brain metastases received greater than the prescribed dose. The other three brain metastases received the prescribed dose. The tumor that received the incorrect dose was at the periphery of the brain next to the skull in a non-critical area so that much of the extra dose was delivered to the space between the brain and the skull. The cause of the incident was that a 14-millimeter (mm) (.55-inch) collimator helmet was used instead of the prescribed 8-mm (.31 inch) collimator helmet. The personnel setting up the treatment neglected to change the helmet. The tumor that received the unintended dose was located at the periphery of the brain, adjacent to the skull. Because most of the unintended dose was delivered to a non-critical space, between the brain and skull, the additional radiation exposure should have no significant effect on the patient.

The referring physician was notified of the event and informed the patient's family of the unintended dose.

Cause(s)—The cause was human error, in that the event resulted from use of the wrong collimator helmet.

Actions Taken To Prevent Recurrence

Licensee—The licensee established a new procedure to require the physician, physicist, and nurse to sign off on the treatment time, helmet size, and position before each shot. Also, new labels identifying the size of the helmet were attached to each of the four helmets. These labels can be seen by personnel via the TV monitor located at the control panel outside the treatment room. The physician will verify the correct size before the control panel button is pushed to start the treatment.

State Agency—The State reviewed and approved the licensee's new procedures.

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AS 04–07 Strontium-90 Eye Applicator Brachytherapy Medical Event at St. Francis Hospital in Memphis, Tennessee

Date and Place—March 25, 2004; St. Francis Hospital; Memphis, Tennessee.

Nature and Probable Consequences—A 79-year-old patient was prescribed radiation treatment for pterygium (an eye abnormality). The patient was to receive 20 Gy (2,000 rads), but instead received 70 Gy (7,059 rads). The prescribed dose was to be administered via a Sr-90 radioactive source with an activity of 3.7 GBq (100 mCi) for a duration of 42.5 seconds. However, the manual timer was incapable of being set for fractions of a second and interpreted the entry to be 4 minutes and 25 seconds. During the treatment, the physician questioned the treatment time and terminated the treatment after 2 minutes and 30 seconds. The Radiation Oncologist concluded that the maximum possible dose delivered to the sclera was well below the sclera tolerance dose and that the optic nerve and retina did not receive any meaningful dose. The patient and the referring physician were notified of the event.

Cause(s)—The wrong treatment time was programmed for the patient's eye treatment.

Actions Taken To Prevent Recurrence

Licensee—The licensee updated its procedures, which require use of an additional person to operate a second timer during brachytherapy eye treatment.

State Agency—The Tennessee Department of Radiological Health conducted an onsite inspection on March 29, 2004. The State investigated, reviewed, and approved the licensee's new procedures.

This event is considered closed for the purpose of this report.

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AS 04–08 Therapeutic Medical Event at Southern Regional Medical Center in Riverdale, Georgia

Date and Place—July 1, 2004; Southern Regional Medical Center; Riverdale, Georgia.

Nature and Probable Consequences—The licensee informed the Georgia Department of Natural Resources (GDNR) that a patient received 3.7 GBq (100 mCi) of I–131 instead of the prescribed dose of 0.64 GBq (17.3 mCi). Three patients were scheduled for I–131 treatments on the same day. An inpatient was scheduled to receive 3.7 GBq (100 mCi), and two outpatients were scheduled to receive less than 1.2 GBq (33 mCi). One of the outpatients was mistakenly injected with the 3.7 GBq (100 mCi) dose intended for the inpatient and was also allowed to leave the facility without receiving proper instructions. The licensee did not discover the error until after the patient had left the facility with her children. The authorized user who signed the written directive was at the facility when the dose was administered. The temporary RSO was at South Fulton Hospital, but was notified of the event. The patient and referring physician were immediately notified of the event by the licensee. The GDNR received a report from the licensee's medical physicist consultant estimating the dose to the patient's children was 0.5 mSv (0.05 rem), with a maximum possible dose of 1.0 mSv (0.1 rem). The radiation should not have any effects on the patient's children or other individuals. The medical significance to the patient is the possibility of developing hypothyroidism which would require thyroid medication.

Cause(s)—This event was attributed to human error. The wrong patient was administered a therapeutic dose of I–131 that was prescribed for someone else.

Actions Taken To Prevent Recurrence

Licensee—The licensee discussed the incident with all technicians who prepare and administer I–131, revised nuclear medicine protocols pertaining to the therapeutic use of I–131 and patient instructions, and revised procedures to incorporate better practices to prevent this type of error from recurring.

State Agency—The State agency reviewed and approved the corrective actions that the licensee implemented to prevent recurrence.

This event is considered closed for the purpose of this report.

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AS 04–09 Intravascular Brachytherapy Medical Event at Ireland Cancer Center in Middleburg Heights, Ohio.

Date and Place—December 22, 2003; Ireland Cancer Center; Middleburg Heights, Ohio.

Nature and Probable Consequences—The licensee reported that a patient received a radiation dose to an unintended site 3 cm proximal to the prescribed treatment site during an intravascular brachytherapy (IVB) treatment procedure. The dose delivered to the unintended site was approximately 18.40 Gy (1,840 rads). The event involved an IVB device that used a 3.5-mm catheter and a source train that contained Sr-90 with an activity of 2.0 GBq (53.8 mCi). The source train traveled to a location approximately 3 cm proximal to the intended treatment site. It was determined that there was a kink in the delivery catheter, which kept the source train from traveling to the correct site. The kink was not substantial enough to affect the flow of sterile water used to send and retrieve the source train. The kink was discovered the following day during medical physics quality checks. The referring physician and patient were notified of the event. According to the licensee, no adverse effects are expected.

Cause(s)—The cause of the event was determined to be a kink in the delivery catheter, which kept the source train from traveling to the correct site.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions incorporated by the licensee included additional films taken during procedures to verify the placement of the catheter. When there is any doubt of the placement of the catheter, the treatment will be aborted. The treatment team will then evaluate whether to attempt treatment with a different catheter.

State Agency—The Ohio Department of Health conducted an investigation, reviewed the licensee's corrective actions, and found them adequate to prevent recurrence.

This event is considered closed for the purpose of this report.

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AS 04–10 Intravascular Brachytherapy Medical Event at Swedish Medical Center in Seattle, Washington

Date and Place—November 18, 2003; Swedish Medical Center; Seattle, Washington.

Nature and Probable Consequences—A patient undergoing an intravascular brachytherapy (IVB) treatment for coronary restenosis received 13.78 Gy (1,378 rads) to an unintended site (healthy tissue). The licensee reported that the source train was partially inserted into a small artery, and the routing did not follow a direct path. When the difficulty occurred, the source train had been partially inserted 65 mm proximal to the intended site. The source train contained a total activity of 2.91 GBq (78.56 mCi). A 143-second exposure time elapsed before the cardiologist withdrew the source train, even though the licensee's procedure requires sources to be immediately withdrawn once a problem occurs. The delay occurred as the cardiologist first worked to fully insert the source train and then discussed correcting the problem with the oncologist. The catheter was examined, and there were no kinks or bends. It was determined that there were no failures of the IVB device. It was suspected that the pressure from the artery and the tortuous route to the site caused a contraction of a portion of the catheter and resulted in the seeds becoming stuck at a particular location. The cardiologist was suspended from licensed activities until the details of the event were fully understood. According to the licensee, no adverse health effects are expected. The patient and the patient's referring physician were notified of the event.

Cause or Causes—It is suspected that the pressure from the small artery and the tortuous route to the site caused a contraction of a portion of the source train and resulted in the seeds becoming stuck at a particular location.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions included reemphasizing the importance of adhering to established procedures and protocols before administering radiopharmaceuticals, and ensuring that all staff completed refresher training.

State Agency—The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

This event is closed for the purpose of this report.

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AS 04–11 Diagnostic Medical Event at Swedish Medical Center in Seattle, Washington

Date and Place—September, 24, 2004; Swedish Medical Center; Seattle, Washington.

Nature and Probable Consequences—The licensee reported that a patient received 190.9 MBq (5.16 mCi) of I–131, instead of the prescribed 74 MBq (2 mCi) for a post thyroid treatment follow-up scan. The prescribing physician

realized that the error occurred on September 27, 2004, when the patient underwent the scan. A viable follow-up scan was performed even though the error occurred. The referring physician notified the patient of the error on September 27, 2004. The nuclear medicine physician indicated there would be no negative health effects from this administration.

Cause or Causes—The licensee stated that human error led to procedural checks not being performed prior to the administration.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions included re-emphasis on the importance of adhering to established procedures and protocols prior to the administration of radiopharmaceuticals and the completion of staff refresher training.

State Agency—The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

This event is considered closed for the purpose of this report.

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AS 04–12 Therapeutic Medical Event at University of California at Los Angeles Harbor Medical Center in Torrance, California

Date and Place—June 7, 2002; Los Angeles County Harbor University of California at Los Angeles (UCLA) Medical Center; Torrance, California. This event was not identified as an AO until the preparation of the FY 2004 report.

Nature and Probable Consequences—A patient receiving treatment for thyroid ablation was administered a dose of 4.74 GBq (128 mCi) of I–131 instead of the prescribed dose of 1.18 GBq (32 mCi) of I–131.

On June 7, 2002, five patients were scheduled to be treated with I–131. Five vials containing I–131 arrived from the radiopharmacy and were properly labeled with the patients' names. The nuclear medicine technologist incorrectly thought that the name on the 4.74 GBq (128mCi) vial did not match any of the patient's names scheduled for treatment that day. Assuming that this vial was incorrectly labeled, the 4.74 GBq (128 mCi) dosage was administered to the patient for whom the technologist thought the dose was intended. However, the technologist failed to verify whether any of the remaining four dosages were labeled for that patient. In fact, a vial was correctly labeled as prepared for that patient.

The authorized user was present during the administration to supervise the administration of the radiopharmaceutical, and to verify that the correct radiopharmaceutical and dosage were administered. The authorized user did not perform an independent verification, but instead assumed that the nuclear medicine technologist had verified that the dosage was correct. The error was discovered about 5 hours later, when the patient scheduled to receive the 4.74 GBq (128 mCi) dosage arrived at the medical center for treatment. The patient and the referring physician were notified. The authorized user went to the home of the patient who received the inadvertent administration and verified that appropriate radiation safety precautions were in place. The patient's treatment plans were modified to accommodate the larger dosage. The authorized user stated that the dosage was intended to ablate the thyroid and render the patient hypothyroid, and that was accomplished with the larger dose. He further stated the patient is doing well, with no complications.

Cause(s)—This medical event was caused by human error which resulted in the licensee's failure to follow proper policies and procedures and verify the prescribed dosage for a specific patient.

Actions Taken To Prevent Recurrence

Licensee—The licensee re-instructed all nuclear medicine personnel on the importance of following the division's policies and procedures and the use of a third party to check the prescription dose and patient identification before administration. Additionally, the RSO will review all I–131 therapy documents and administrations.

State Agency—The State cited the licensee for failure to provide written notification to the referring physician and the patient within 15 days after the occurrence of the medical event. The State has reviewed and approved the licensee's corrective actions.

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AS 04–13 Diagnostic Medical Event at University Hospital in Cincinnati, Ohio

Date and Place—March 10, 2004; University Hospital; Cincinnati, Ohio.

Nature and Probable Consequences—The licensee reported that a patient was given 74 MBq (2,000–Ci) of I–131 for a thyroid cancer work-up instead of the prescribed dose of 7.4 MBq (200–Ci) of I–123 for a thyroid uptake scan. The patient scheduled to receive the I–123 dose responded affirmatively to being the patient that was to receive the I–131 dose. The technologist did not follow procedures regarding proper identification of the patient, which requires two separate methods for verifying patient identification. A follow-up scan revealed the patient does have hypothyroidism, and as a result, the 74 MBq (2,000–Ci) of I–131 would have been prescribed based on the scan results. The referring physician and patient were notified. No adverse health effects are expected.

Cause or Causes—The technologist failed to follow established procedures.

Actions Taken to Prevent Recurrence

Licensee—The licensee disciplined the technologist in accordance with hospital policy and reiterated to all technologists the need to thoroughly check patient identification using two approved methods. Additionally, the Radiation Safety Committee modified the Quality Management Program to require a photo as one method of verifying patient identification.

State Agency—The Ohio Department of Health conducted an investigation of the event on May 11, 2004, and reviewed the licensee's corrective actions. The State found the licensee's corrective actions adequate to prevent a recurrence of the event.

This event is closed for the purpose of this report.

Dated at Rockville, Maryland this 18th day of April 2005.

For the Nuclear Regulatory Commission

Annette L. Vietti-Cook,

Secretary of the Commission.

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NUCLEAR REGULATORY COMMISSION

Draft Report for Comment: ''Consideration of Geochemical Issues in Groundwater Restoration at Uranium In-Situ Leach Mining Facilities,'' NUREG/CR–6870

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability and request for comments.

Background: Some mining processes use fluids to dissolve (or leach) a mineral without the need to remove physically the ore containing the mineral from an ore deposit in the ground. In general, these ''in-situ'' leach mining operations at uranium mines are considerably more environmentally benign than traditional mining and milling of uranium ore. Nonetheless, the use of leaching fluids to mine uranium may contaminate the groundwater aquifer in and around the region from which the uranium is extracted. The U.S. Nuclear Regulatory Commission (NRC) requires licensees to restore the