

**MATTERS TO BE CONSIDERED:****Week of April 30, 2001**

There are no meetings scheduled for the Week of April 30, 2001.

**Week of May 7, 2001—Tentative**

*Thursday, May 10, 2001*

10:25 a.m.—Affirmation Session (Public Meeting) (If needed).

10:30 a.m.—Briefing on Office of Nuclear Regulatory Research (RES) Programs and Performance (Public Meeting) (Contact: James Johnson, 301-415-6802).

*Friday, May 11, 2001*

10:30 a.m.—Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: John Larkins, 301-415-7360).

**Week of May 14, 2001—Tentative**

There are no meetings scheduled for the Week of May 14, 2001.

**Week of May 21, 2001—Tentative**

There are no meetings scheduled for the Week of May 21, 2001.

**Week of May 28, 2001—Tentative**

*Wednesday, May 30, 2001*

10:25 a.m.—Affirmation Session (Public Meeting) (If needed).

**Week of June 4, 2001—Tentative**

*Tuesday, June 5, 2001*

9:25 a.m.—Affirmation Session (Public Meeting) (If needed).

2 p.m.—Discussion of Management issues (Closed-Ex. 2).

*Wednesday, June 6, 2001*

10:30 a.m.—All Employees Meeting (Public Meeting).

1:30 p.m.—All Employees Meeting (Public Meeting).

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415-1292. Contact person for more information: David Louis Gamberoni (301) 415-1651.

**ADDITIONAL INFORMATION:** By a vote of 5-0 on April 23, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Affirmation of Final Rule to Amend 10 CFR Part 2, Subpart J, in Regard to the Licensing Support Network" be held on April 24, and on less than one week's notice to the public.

The NRC Commission Meeting Schedule can be found on the Internet at: <http://www.nrc.gov/SECY/smj/schedule.htm>

This notice is distributed by mail to several hundred subscribers; if you no

longer wish to receive it, or would like to be added to the distribution, please contact the office of the Secretary, Washington, DC 20555 (301-415-1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to [dkw@nrc.gov](mailto:dkw@nrc.gov).

Dated: April 26, 2001.

**David Louis Gamberoni,**

*Technical Coordinator, Office of the Secretary.*

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**BILLING CODE 7590-01-M**

**NUCLEAR REGULATORY COMMISSION****Report to Congress on Abnormal Occurrences Fiscal Year 2000; Dissemination of Information**

Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines is 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 2000, nine events that occurred at facilities licensed or otherwise regulated by the NRC and/or the Agreement States were determined to be AOs. These events are discussed below. 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. 23, "Report to Congress on Abnormal Occurrences, Fiscal Year 2000." This report will be available electronically at the NRC Web site <<http://www.nrc.gov/NRC/NUREGS/indexnum.html>> at the NRC Homepage.

**Nuclear Power Plants**

The following event that occurred at U.S. nuclear power plants during fiscal year 2000 was determined to be significant enough to be reported as an AO to Congress.

00-1 Steam Generator Tube Failure at Indian Point Unit 2 in Buchanan, New York

*Date and Place*—February 15, 2000; Indian Point Unit 2, a commercial nuclear power plant operated by

Consolidated Edison Company, located about 24 miles north of New York City.

*Nature and Probable Consequences*—On February 15, 2000, at 7:17 p.m., the Indian Point Unit 2 nuclear plant experienced a steam generator tube failure which required the declaration of an "Alert" (the second lowest of four emergency classifications in the NRC-required emergency response plan) at 7:29 p.m., and a manual reactor trip at 7:30 p.m. The steam generator is a heat exchanger which allows heat to pass from the reactor (primary system) to the turbine generator (secondary system). It also provides the boundary between the radioactive primary system and the non-radioactive secondary system. At Indian Point Unit 2 there are four steam generators and each steam generator has approximately 3300 tubes. On February 15, the failure of one of these tubes allowed reactor water to leak into the secondary system. By 8:31 p.m. the operators had taken steps to isolate the steam generator which contained the leaking tube. After the steam generator was isolated, the operators began to cool down the plant. At 9:02 p.m. they were forced to suspend the cooldown process when they realized they had inadvertently established an excessive cooldown rate. This excessive cooldown rate caused a rapid reduction in reactor coolant system (pressurizer) level. To restore the level the licensee pumped boric acid water into the reactor coolant system using the safety injection system. After the level was restored the operators resumed the cooldown and reached cold shutdown at 4:57 p.m. on February 16, 2000. The licensee exited the "Alert" emergency classification at 6:50 p.m. that day.

The steam generator tube failure resulted in an initial primary-to-secondary leak of reactor coolant of approximately 146 gallons per minute, and required an "Alert" declaration. This event involved some procedural and equipment issues that challenged operators, complicated the event response, and delayed achieving the cold shutdown condition. It caused significant public and media interest, and required increased NRC attention. The event resulted in a minor radiological release to the environment that was well within regulatory limits. No radioactivity was measured offsite above normal background levels, and the event did not impact public health and safety.

Following the event, the NRC performed an inspection and determined that Consolidated Edison Company had not performed an adequate examination of the steam generator tubes during its 1997 outage.

As a result, degraded tubes were allowed to remain in service during plant operation, which ultimately led to a steam generator tube failure.

**Cause or Causes**—The event was caused by primary water stress corrosion cracking (PWSCC) flaws in steam generator tubes. There were deficiencies in the overall direction and execution of the 1997 steam generator in-service examinations at Indian Point Unit 2. Specifically, the licensee did not identify the presence of PWSCC flaws in steam generator tubes and remove these tubes from service, despite opportunities to do so. As a result, tubes with PWSCC were left in service following the 1997 steam generator inspection until one of these tubes failed on February 15, 2000, when the reactor was at 100 percent power.

#### *Actions Taken To Prevent Recurrence*

**Licensee**—The licensee performed the necessary actions to protect the health and safety of the public. Before the event, the licensee was in the process of implementing a station improvement program. This event demonstrated the need for continuous management attention to planned improvements to ensure they are timely and effective. Subsequently the licensee made the decision to replace all four steam generators prior to returning to power. The industry completed a lessons-learned report based on the Indian Point Unit 2 steam generator tube failure event and provided it to the NRC on October 26, 2000.

**NRC**—The NRC reviewed the causes, safety implications, and licensee actions following the event. Information Notice 2000-09, "Steam Generator Tube Failure at Indian Point Unit 2," was issued on June 28, 2000, to alert other licensees to this event. A Notice of Violation was issued to Indian Point 2 on November 20, 2000. A lessons-learned report on the steam generator tube failure at Indian Point Unit 2 was completed on October 23, 2000. In this report, the NRC evaluated the staff's technical and regulatory processes related to assuring steam generator tube integrity and identified and recommended areas for improvement applicable to the NRC and the industry. Subsequently, the NRC established a Steam Generator Action Plan detailing activities to be addressed by the NRC and the industry to improve management of steam generator performance.

This event is closed for the purpose of the AO report to Congress.

#### **Fuel Cycle Facilities (Other Than Nuclear Power Plants)**

None of the events that occurred at the fuel cycle facilities during fiscal year 2000, was determined to be significant enough to be reported as an AO to Congress.

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

The following three events occurred at facilities licensed or otherwise regulated by the NRC during fiscal year 2000 and were determined to be significant enough to be reported as AOs to Congress.

00-2 Overexposures at Mallinckrodt, Inc., in Maryland Heights, Missouri

**Date and Place**—From 1995 through 2000; Mallinckrodt, Inc.; Maryland Heights, Missouri.

**Nature and Probable Consequences**—On March 31, 2000, a contract employee who was providing services for Mallinckrodt, Inc., was attempting to correct flow problems with a 703,000 megabecquerel (19 curie) molybdenum-99/technetium-99m generator. The employee performed the operation in a glove box. The employee's initial attempts to correct the generator problem were not successful. The employee then removed the generator column containing the radioactive material from its shield and determined that the inlet line was not connected and the outlet line was bent at an angle. Holding the unshielded column in his right hand, the employee corrected the problems with the inlet and outlet lines. This process took between 10 and 20 seconds to complete. Dose rates at the location of the column held by the employee were calculated to be approximately 510 mSv (51 rem) per second. As a result the employee's thumb and index finger of the right hand received a dose ranging from 5,100 mSv (510 rem) to 11,200 mSv (1,120 rem) shallow-dose equivalent. The NRC annual dose limit to the skin or any extremity is 500 mSv (50 rem) shallow-dose equivalent. The employee believed that the gloves he wore provided him adequate protection from radiation.

On April 5, 2000, Mallinckrodt determined that the radiation monitor worn on the employee's right hand recorded a dose of 57 mSv (5.7 rem) shallow-dose equivalent in excess of its administrative weekly limit which was 20 mSv (2 rem). Mallinckrodt's investigation of the exposure determined that the employee had directly handled the generator column and reported the event to the NRC on

April 13, 2000. The employee was examined by a physician, who identified no immediate health effects. Due to the inability of either the NRC or the licensee to precisely estimate the likely exposure to the employee's finger and thumb, long-term health effects could not be predicted.

During its investigation of the March 31, 2000, event, Mallinckrodt identified other employee overexposures that occurred in the preceding 5 years during the performance of two routine operations. As a result of the first routine operation, 11 employees involved in the hand-labeling of vials containing millicurie quantities of indium-111 (In-111) (a State-regulated, non-NRC licensed material) received extremity doses ranging from 500 mSv (50 rem) to 3,200 mSv (320 rem) shallow-dose equivalent. In addition to these doses from In-111, the 11 employees had also received doses from NRC-regulated material, typically less than 5 percent of their total extremity doses.

The second operation involved the handling of unshielded and partially shielded vials and syringes containing radioactive material (State- and NRC-regulated material) in a sterility testing laboratory. As a result of this operation Mallinckrodt identified four employees who received extremity doses ranging from 680 mSv (68 rem) to 960 mSv (96 rem) shallow-dose equivalent.

**Cause or Causes**—The causes of the March 31, 2000, event were insufficient training to ensure that the employee understood the difference between radioactive contamination and radiation and inadequate oversight of the laboratory. The written, approved procedure on the employee's assigned duties did not allow the removal of the generator column during manufacturing. However, an ad hoc procedure had been developed by the staff of the laboratory that was not known to, or approved by, the management outside the laboratory. The ad hoc procedure allowed the removal of the generator column from the shield using remote handling tools. On March 31, 2000, the employee was using the ad hoc procedure but the tools that were used to remove the generator column from the shield had fallen to the bottom of the glove box and were out of the employee's reach. The employee decided on his own to remove the column and to perform repairs without using tools.

Regarding the other operations that resulted in significant doses, Mallinckrodt personnel believed, erroneously, that the doses recorded by the personnel monitoring devices worn by its employees reflected the actual

exposures received. However, the actual doses were, in some instances, 100 times greater than those recorded by the monitors. This was due to the distance between the monitors, which are normally worn like a ring at the base of the finger, and the fingertips, where the exposures were received.

#### *Actions Taken To Prevent Recurrence*

**Licensee**—The licensee staff was instructed in the proper handling of unshielded containers of radioactive material. The licensee increased its radiation safety and supervisory oversight in the generator manufacturing laboratory. In addition, the licensee initiated and implemented managerial changes to its operations and agreed to: (1) Retain an independent organization to assess the radiation safety program and the radiation safety aspects of its radioactive material manufacturing processes; (2) provide assurance that workers have received training and understand procedures and practices to maintain radiation exposures as low as is reasonably achievable (ALARA); (3) develop a plan to review operations for the last five years to determine if additional workers have received exposures in excess of regulatory limits; and (4) request an amendment to incorporate a corrective action program into its license. NRC confirmed the licensee's agreement in a Confirmatory Order Modifying license issued on June 22, 2000.

**NRC**—The NRC conducted an Augmented Inspection Team (AIT) inspection on May 4 through May 26, 2000, and a follow up inspection on July 17 through August 4, 2000. As a result of the AIT inspection, NRC issued the June 22, 2000, Confirmatory Order Modifying License to Mallinckrodt. On December 21, 2000, NRC issued a Notice of Violation and Proposed Imposition of a \$125,000 Civil Penalty.

This event is closed for the purpose of the AO report to Congress.

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**00-3 Brachytherapy Misadministration at Sibley Memorial Hospital in Washington, District of Columbia**

*Date and Place*—September 15–20, 2000; Sibley Memorial Hospital; Washington, District of Columbia.

*Nature and Probable Consequences*—Two patients were prescribed doses of 70 Gy (7,000 rad) each for eye treatment. The first patient received a dose of 108.7 Gy (10,870 rad) and the second patient received a dose of 114.70 Gy (11,470 rad).

The two patients were prescribed iodine-125 (I-125) eye plaques for

treatment of ocular melanomas. These treatments were performed in an attempt to preserve the patients' eyes, which otherwise would have been surgically removed. The licensee's treatment planning system uses air-kerma, and the supplier of the I-125 seeds uses millicurie units. The licensee made an error converting air-kerma to millicurie units. Consequently, orders were placed for a higher source strength of I-125 seeds, which were subsequently administered to the patients, resulting in the overdoses.

The error was identified by the licensee during a review of the patients' charts on September 22, 2000, after the physicist noted that the dosimetrist was ordering I-125 seeds for an upcoming study with higher than expected source strength.

The patients were informed of the misadministrations. Before the start of the treatments, the patients were informed of the substantial risk of vision loss, the possibility of cataract formation, and a 10 to 15 percent possibility that removal of the eye might be required due to tumor progression or eye pain.

*Cause or Causes*—The principal cause of the misadministrations was a human error in converting source strength of the I-125 seeds from air-kerma to millicurie units. A secondary cause was the failure of the authorized user and medical physicist to recheck the conversion factor equations before the treatment was completed (a requirement of the licensee's Quality Management Plan).

#### *Actions Taken To Prevent Recurrence*

**Licensee**—The licensee suspended all procedures involving the eye plaques until corrective actions were developed and the staff was trained in the corrective actions. Written procedures were established to ensure the accuracy of the treatment calculations. The licensee has submitted to the NRC its planned corrective actions to prevent potential errors in the future.

**NRC**—An inspection was conducted by the NRC's Region I office on September 28 and 29, 2000, to examine the circumstances of the misadministration and the licensee's corrective and preventive actions. In accordance with the NRC's Medical Event Assessment Program, the NRC has retained a medical consultant to assess the misadministrations and their potential consequences. Enforcement action is pending.

This event is closed for the purpose of the AO report to Congress.

#### **Agreement State Licensees**

The following six events occurred at facilities of Agreement State licensees during fiscal year 2000 and were determined to be significant enough to be reported as AOs to Congress.

**AS 00-1 Gamma Stereotactic Radiosurgery Misadministration at Healthsouth Medical Center in Birmingham, Alabama**

*Date and Place*—April 12, 2000; Healthsouth Medical Center; Birmingham, Alabama.

*Nature and Probable Consequences*—Patient A was prescribed a dose of 80 Gy (8,000 rad) to the left trigeminal nerve using a gamma stereotactic radiosurgery (GSR) device. However, because of an error, a dose of about 0.2 Gy (20 rad) was delivered to the intended treatment site and a dose of 80 Gy (8,000 rad) was delivered to a wrong treatment site.

On the same day that patient A was scheduled for a GSR treatment, patient B was also admitted for a similar treatment using the same device. During the approval process of the treatment plan, the dose delivery sheet of patient B was inadvertently switched with that of patient A. As a result, patient A was treated with the radiosurgery parameters intended for patient B, and a dose of 80 Gy (8,000 rad) was delivered at the wrong treatment site within the patient's skull. The misadministration was discovered immediately following the delivery of the dose by the patient's radiation oncologist. The identification of this misadministration prevented a related misadministration for patient B. The licensee notified the State agency of this misadministration on April 12, 2000. The patient returned to the Medical Center on April 20, 2000, and was treated as prescribed.

The licensee stated that the misadministration resulted in no observable acute effects to the patient. The patient was notified verbally within 24 hours by the referring physician and the neurosurgeon and will be closely monitored by the neurosurgeon.

*Cause or Causes*—This misadministration was caused by mixing patient treatment protocol documentation during approval of the treatment plans for the two different patients that were prescribed similar treatments.

#### *Actions Taken To Prevent Recurrence*

**Licensee**—The licensee took immediate action to prevent the mixing of patient treatment protocol documentation. As a result, each page of the treatment protocol contains a unique

name and time stamp, which the radiation oncologist or medical physicist will in the future check before delivering the radiosurgery treatment.

*State Agency*—The Alabama Department of Public Health, Office of Radiation Control was satisfied with the licensee's corrective actions. The licensee's corrective measures will be reviewed during the agency's next routine inspection of the licensee's activities.

This event is closed for the purpose of the AO report to Congress.

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AS 00-2 Gamma Stereotactic Radiosurgery Misadministration at University of California in San Francisco, California

*Date and Place*—September 11, 1998; University of California; San Francisco, California. The California Department of Health Services, Radiologic Health Branch was notified of the misadministration on September 17, 1998. The NRC staff was informed of this event in July 2000. The State of California indicated that the delay in reporting this event to the NRC resulted from a computer error.

*Nature and Probable Consequences*—A patient was prescribed a radiation therapy treatment of two metastatic lesions of the brain using a gamma stereotactic radiosurgery (GSR) device. One of the brain lesions was prescribed a dose of 16 Gy (1,600 rad). However, because of an error, the wrong site of the brain received more than 10 Gy (1,000 rad).

The patient was treated for two metastatic brain lesions, one in the left thalamus and the other in the right parietal regions of the brain. A treatment plan was developed for the lesion in the left thalamus to deliver a single dose of 16 Gy (1600 rad), at the 60% isodose line. However, one of the seven parameter settings of the GSR, the "left Y" coordinate, was erroneously set at 111 mm (4.37 in.) instead of 101 mm (3.98 in.) resulting in a 5 mm (0.20 in.) translocation of the treatment volume. This error resulted in an under-dose of a portion of the intended treatment volume and an unintended dose of more than 10 Gy (1,000 rad) to brain tissue outside of the prescribed treatment volume. The misadministration was discovered when the licensee performed a quality control verification of the GSR parameters after the radiation treatment.

The licensee reported that the patient experienced no acute side effects from this misadministration. The physician who was involved in this treatment notified the patient of this misadministration. The physician

explained the necessity of another treatment because of the under-dose to a portion of the tumor site. An additional treatment was added to the treatment plan to complete the prescribed dose to the intended treatment volume of the left thalamus, and the treatment was completed. The patient died as a direct result of the metastatic condition on March 3, 1999.

*Cause or Causes*—The misadministration was caused by a human error. One member of the treatment team set a wrong coordinate and another member of the treatment team failed to independently verify the coordinate setting.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—The initial corrective actions by the licensee included decreasing distractions to the treatment team by limiting telephone calls in the treatment control area and restricting conversations in the treatment room to conversations required for the treatment of the patient. The licensee was requested by the State to contact other GSR facilities to review their methods of operation. The licensee found that another GSR facility had performed a study comparing the frequency of incorrect coordinate settings by licensees who did one independent verification and licensees who did two. The licensee used this study as a guide and has adopted the procedure of performing two independent checks of the coordinate settings before each treatment and retaining the follow-up check of the coordinate settings after each treatment to determine if an error was made.

*State Agency*—The findings of the onsite investigation by the State staff agreed with the findings of the licensee's quality assurance review. The State also shared the finding of the study performed by the licensee with other Agreement States and with the NRC because of the study's generic implications. The State was satisfied with the licensee's corrective actions and believes they should be adequate to prevent recurrence. No enforcement actions were taken by the State for this misadministration.

This event is closed for the purpose of the AO report to Congress.

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AS 00-3 Gamma Stereotactic Radiosurgery Misadministration at Healthsouth Doctor's Hospital in Coral Gables, Florida

*Date and Place*—January 25, 2000; Healthsouth Doctor's Hospital; Coral Gables, Florida.

*Nature and Probable Consequences*—A patient was prescribed a gamma stereotactic radiosurgery (GSR) treatment for 80 brain lesions. Each brain lesion site was prescribed 12 Gy (1,200 rad). However, a lesion site was treated twice because of an error.

The patient's treatments were based on computer-generated magnetic resonance imaging (MRI) slices taken in the Z direction. Prior to each treatment, the lesion site coordinates were printed out as part of the written directive and they were checked manually and initialed by the authorized user and the medical physicist. For the fourth treatment, the licensee intended to deliver 12 Gy (1,200 rad) to lesion site 47. However, prior to the treatment the wrong MRI slice was displayed in the computer showing lesion site 16 (Z=70.7 mm [2.78 in.]) instead of lesion site 47 (Z= 65.0 mm [2.56 in.]). Thus, the treatment plan was calculated at lesion site 16, which had already been treated. The written directive was prepared and signed by the authorized user and the radiation safety officer (RSO) indicating a dose of 12 Gy (1,200 rad) to Z=70.7 mm (2.78 in.). The treatment was administered as indicated in the directive. As a result, lesion site 16 was treated twice. The RSO discovered the error on January 28, 2000, during a routine quality assurance review of the treatment plan. The licensee indicated that the retreatment of site 16 did not result in harmful effects for the patient. The patient was rescheduled for treatment of lesion site 47 and treatment of additional untreated sites.

The misadministration was reported to the Florida Bureau of Radiation Control, the authorized user, and the patient on January 28, 2000.

*Cause or Causes*—The licensee determined that this misadministration was caused by human error.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—No action was taken by the licensee. The licensee has not identified any quality management procedures that need to be changed to prevent this type of human error. In addition, the licensee believes that this type of error was detected because of its aggressive quality assurance program.

*State Agency*—The Bureau of Radiation Control performed an onsite investigation on February 2, 2000. The investigation found no apparent violations of the licensee's license or the regulations. During the investigation the licensee indicated that it has performed in excess of 2,000 GSR procedures and a quality assurance review of each procedure. Of the 2,000 procedures the

licensee has estimated that over 600 procedures involved the treatment of 20 or more lesion sites and that this was the only time a lesion site was treated twice.

This event is closed for the purpose of the AO report to Congress.

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AS 00-4 Gamma Stereotactic Radiosurgery Misadministration at University of Maryland Medical Systems in Baltimore, Maryland

*Date and Place*—April 20, 2000; University of Maryland Medical Systems (UMMS); Baltimore, Maryland.

*Nature and Probable Consequences*—A patient was prescribed a radiation therapy treatment for pituitary adenoma using a gamma stereotactic radiosurgery (GSR) device. The licensee's therapy treatment team planned to deliver a maximum dose of 18 Gy (1,800 rad) to the 50% isodose line given in six administrations. However, because of the incorrect settings of the Y and Z coordinates, a dose of 12.5 Gy (1,250 rad) was administered to the wrong treatment site.

The licensee's therapy treatment team consisted of a neurosurgeon, an oncologist, and a medical physicist. The treatment plan was developed, reviewed, and signed by each member of the treatment team prior to the administration of the first dose. When the medical physicist briefly left the GSR facility, the neurosurgeon and the oncologist inadvertently reversed the Y and the Z coordinates while adjusting the position of the patient's stereotactic frame (moving the patient's head to the incorrect position). When the medical physicist returned, each member of the treatment team incorrectly verified the position of the patient's frame assembly. All team members signed the quality assurance checklist to indicate that they conducted this check and that the patient's frame was positioned in accordance with the written directive. As a result, the patient's base of the frontal lobe received the unintended dose. The medical physicist identified the incorrect settings of the Y and Z coordinates while preparing to adjust the frame assembly for the second administration. Upon discovery of the misadministration, the treatment team revised the treatment plan to accommodate for the error and to complete the therapy procedure. The State agency was notified of this misadministration on April 21, 2000, and performed an onsite investigation on April 26-28, 2000.

The neurosurgeon notified the patient, provided an estimate of the unintended dose delivered, and

explained that no adverse health effects were expected to result from this event.

*Cause or Causes*—This misadministration was determined to be a sequence of human errors made by the neurosurgeon, oncologist, and medical physicist during patient positioning. However, while the root cause of the event appears to be human errors during the setting of the patient positioning parameters, other factors may have contributed to the event. For example, to position the patient, the treatment team used an internal procedure which was not documented in writing. This procedure was not sent to the licensee's Radiation Safety Committee or the State Agency for approval. The radiation safety officer (RSO) was a contract employee of the UMMS. Furthermore, he had not received any specialized training, e.g., equivalent to the authorized user training. Interaction between the RSO and the authorized users was rare. Finally, the RSO failed to complete and document the annual reviews of the GSR radiation protection program content and implementation for the previous 3 years (1997 through 2000).

#### *Actions Taken To Prevent Recurrence*

*Licensee*—The licensee held a management conference with key members of management, radiation safety, radiation oncology, neurosurgery, patient care services, and clinical effectiveness. As a result of this meeting, the licensee implemented a written protocol regarding patient positioning.

*State Agency*—The onsite investigation by the State determined that the licensee failed to implement approved written procedures regarding treatment planning, patient positioning, and administration of doses. Furthermore, the licensee failed to complete and document the annual reviews of the GSR radiation protection program content and implementation for the previous 3 years. A Department Letter/Notice of Violation was issued on June 21, 2000. An enforcement action is pending.

This event is closed for the purpose of the AO report to Congress.

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AS 00-5 Teletherapy Misadministration at Western Baptist Hospital in Paducah, Kentucky

*Date and Place*—October 16, 1996, to November 1, 1996; Western Baptist Hospital; Paducah, Kentucky. This misadministration was discovered by the hospital on January 8, 1997. The State was informed of the misadministration on January 8, 1997

and was reported to NRC on March 5, 1997. However, it was identified as an AO during discussions of the event at an Integrated Materials Performance Evaluation Program review of the State of Kentucky in July 2000.

*Nature and Probable Consequences*—A patient was prescribed a radiation therapy treatment using cobalt-60 teletherapy equipment. The patient was prescribed a dose of 39 Gy (3900 rad). However, the dose was administered to the wrong treatment site because of an error.

The patient was treated for bone pain associated with renal cell carcinoma with metastases to the right iliac bone. The prescribed treatment was 5 treatments per week for a total of 13 treatments. The prescribed dose to the right iliac bone was 39 Gy (3900 rad). When the patient returned for evaluation of the right iliac bone pain, the physician determined that the dose of 39 Gy (3900 rad) was administered to the left iliac bone.

The licensee stated that the misadministration had no effect on the patient's life-span and did not result in any permanent impairment or dysfunction.

*Cause or Causes*—The causes of this misadministration were that (1) markers were not used on the patient's x-ray film to distinguish the supine/prone positions; (2) a second x-ray film was incorrectly labeled as to left/right; (3) the physician did not perform a visual inspection to determine that the correct area had been marked on the patient; and (4) the prescribing physician and simulator therapists failed to correctly orient left/right on fluoroscopy.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—The licensee established a requirement to label the x-ray films to distinguish left/right and supine/prone positions. One of the radiation physicists will review the treatment plans of patients that are not responding clinically as expected. The physicists have been retrained to check all information in the patient's chart regarding calculations and setup. The physicians and therapists have been reminded of the importance of accurately determining patient orientation.

*State Agency*—The State agency reviewed the written directive and no problems were noted. A telephone conference was held with the radiation safety officer, the attending physician, and the Director of Safety Management. The inspection frequency for the facility was increased. An inspection in March 1998 found no violations.

This event is closed for the purpose of the AO report to Congress.

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AS 00-6 Brachytherapy Misadministration at Aultman Hospital in Canton, Ohio

*Date and Place*—August 22, 2000 through October 30, 2000; Aultman Hospital; Canton, Ohio.

*Nature and Probable Consequences*—As a result of a common error, four patients that were prescribed manual brachytherapy gynecological procedures were administered doses higher than those prescribed.

The first patient was prescribed a total dose of 92.9 Gy (9,290 rad). This dose included brachytherapy treatments of 20 Gy (2,000 rad) and 22.5 Gy (2,250 rad) using Ir-192 sources and a dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator. On September 18, 2000, the patient was administered a brachytherapy dose of 33.3 Gy (3,330 rad) Ir-192 instead of the prescribed dose of 20 Gy (2,000 rad). On October 9, 2000, the same patient was administered a brachytherapy dose of 35 Gy (3,500 rad) Ir-192 instead of the prescribed dose of 22.5 Gy (2,250 rad) Ir-192. The patient was also administered the prescribed dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator.

The second patient was prescribed a total dose of 90.7 Gy (9,070 rad). This dose included brachytherapy treatments of 19.8 Gy (1,980 rad) using Ir-192 sources and of 20.5 Gy (2,050 rad) using a combination of Ir-192 and radium-226 (Ra-226) sources and a dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator. On August 22, 2000, the patient was administered a brachytherapy dose of 35.2 Gy (3,520 rad) Ir-192 instead of the prescribed dose of 19.8 Gy (1,980 rad) Ir-192. On September 5, 2000, the same patient was administered the prescribed dose of 20.5 Gy (2,050 rad) using a combination of Ir-192 and Ra-226 implant sources. The patient was also administered the prescribed dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator.

The third patient was prescribed a total dose of 63.9 Gy (6,390 rad). This dose included a brachytherapy treatment of 18.9 Gy (1,890 rad) using Ir-192 sources and a dose of 45 Gy (4,500 rad) from an external beam linear accelerator. On October 30, 2000, the patient was administered a brachytherapy dose of 32.4 Gy (3,240 rad) Ir-192 instead of the prescribed dose of 18.9 Gy (1,890 rad) Ir-192. The patient was also administered the prescribed dose of 45 Gy (4,500 rad)

from an external beam linear accelerator.

The fourth patient was prescribed a total dose of 79.3 Gy (7,925 rad). This dose included brachytherapy treatments of 20.3 Gy (2,025 rad) and 14 Gy (1,400 rad) using Ir-192 sources and a dose of 45 Gy (4,500 rad) from an external beam linear accelerator. On October 23, 2000, the patient was administered a brachytherapy dose of 31.5 Gy (3,150 rad) Ir-192 instead of the prescribed dose of 20.3 Gy (2,025 rad) Ir-192. On November 6, 2000, the same patient was administered the prescribed brachytherapy dose of 14 Gy (1,400 rad) Ir-192. The patient was also administered the prescribed dose of 45 Gy (4,500 rad) from an external beam linear accelerator.

The misadministrations were discovered on November 3, 2000, and November 13, 2000, during an internal audit of the licensee's Quality Management Program (QMP) by the Radiation Safety Officer (RSO) and the Radiation Protection Staff. A telephone report by the licensee's RSO was made to the Ohio Department of Health, Bureau of Radiation Protection, on November 4, 2000, and November 13, 2000.

The first, second, and fourth patients were notified of the misadministrations. The notification of the third patient is pending because the patient was hospitalized for an unrelated infection. The licensee stated that the clinical treatment of these patients has not been affected by the misadministrations.

*Cause or Causes*—The licensee indicated that this event was primarily caused by an operator error in the data entry of the source strength in the treatment planning computer. The facility obtained a new computer in August 2000, and the operator made a mistake and entered the source strengths in milligram-radium-equivalent instead of millicurie. Also, the quality assurance of the treatment planning was inadequate, and the second checks of treatment plans, to which the licensee committed in its QMP were inadequate.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—As soon as the licensee's management determined that a reportable event had occurred, the licensee took action to provide additional training to the staff involved in brachytherapy procedures. The licensee submitted a written report to the Ohio Department of Health, Bureau of Radiation Protection, within 15 days of discovering the misadministrations.

*State Agency*—The Ohio Department of Health, Bureau of Radiation

Protection, performed an onsite investigation on November 21 and 22, 2000, to review the procedures and the findings of the licensee's quality management review and to confirm that the licensee's corrective action proposal is adequate to prevent recurrence. Enforcement actions or penalties, if any, will be determined at a later date.

This event is closed for the purpose of the AO report to Congress.

\* \* \* \* \*

Dated at Rockville, Maryland this 25th day of April, 2001.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

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## NUCLEAR REGULATORY COMMISSION

### Plan for Updating and Consolidating the Decommissioning Policy and Guidance of the Nuclear Regulatory Commission's Office Nuclear Material Safety and Safeguards, and Notice of Public Meeting

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Publication of plan and notice of public meeting.

**SUMMARY:** The Office of Nuclear Material Safety and Safeguards (NMSS) intends to consolidate and update the policy and guidance for NMSS's decommissioning program. This endeavor is in response to the NMSS performance goals, in the NRC's Strategic Plan, of: (1) Making NRC activities and decisions more effective, efficient, and realistic; and (2) reducing unnecessary regulatory burden on stakeholders.

**DATES:** Comments on this plan should be submitted by June 15, 2001. The comments will be considered by NRC in the process of updating and consolidating the policy and guidance for NMSS's decommissioning program.

**ADDRESSES:** Submit written comments to: Jack D. Parrott, Project Scientist, Office of Nuclear Material Safety and Safeguards, Mail Stop T-7F27, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand-deliver comments to: 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 11555 Rockville Pike, Room O-1F21, Rockville, MD 20852. The NRC Public Document Room is open from 7:45 a.m.