DRAFT

REPORT TO CONGRESS

ON

ABNORMAL OCCURRENCES

FISCAL YEAR 2000

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Office of Nuclear Regulatory Research
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ATTACHMENT 1

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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) identifies 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 (Public Law 104-66) requires that AOs be reported to Congress annually. This report includes those events that the NRC determined were AOs during Fiscal Year 2000.

The report discusses three AOs at facilities licensed or otherwise regulated by the NRC. One event involved a steam generator tube failure at a nuclear power plant, the second event resulted in overexposures of occupational workers, and the third event involved a brachytherapy misadministration. The report also discusses six AOs at facilities licensed by Agreement States. Agreement States are those States that have entered into a formal agreement with NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 32 Agreement States. Four of the Agreement State AOs involved gamma stereotactic radiosurgery misadministrations, one event involved a brachytherapy misadministration, and one involved a teletherapy misadministration. In addition, Appendix C of the report, "Other Events of Interest," includes two non-power reactor events and one materials event.

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PREFACE

INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines 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 (Public Law 104-66) requires that AOs be reported to Congress annually. This report discusses those events that the NRC determined were AOs during Fiscal Year 2000.

The NRC defined AOs for the purpose of this report using the criteria in Appendix A. The criteria were initially promulgated in the NRC policy statement that was published in the *Federal Register* on February 24, 1977 (42 FR 10950). This policy statement was published before medical licensees were required to report medical misadministrations to the NRC, and few of the examples in the policy statement were applicable to these misadministrations. Therefore, in 1984, the NRC adopted additional guidance for reporting medical misadministrations as AOs. In 1996, the NRC revised the AO criteria, including criteria for medical misadministrations, and published them in the *Federal Register* on December 19, 1996 (61 FR 67072). In 1997, the NRC again revised these criteria to include AO criteria for gaseous diffusion plants and published them in the *Federal Register* on April 17, 1997 (62 FR 18820).

The NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described herein meet the AO criteria for being reported as AOs. Information reported for each AO includes (1) the date and place, (2) nature and probable consequences, (3) cause or causes, and (4) actions taken to prevent recurrence.

Appendix A to this report contains the criteria for selecting AOs and the guidelines for selecting "Other Events of Interest." Appendix B presents updates on previously reported AOs. Appendix C presents information on events that are not reportable to Congress as AOs but are reportable as "Other Events of Interest" based on a guideline provided by the Commission and listed in Appendix A to this report.

Historically, the body of the AO report and Appendix C include events that are required to be reported to the NRC or an Agreement State and those events that NRC licensees and Agreement States voluntarily report to the NRC.

To disseminate information widely to the public, a *Federal Register* notice is issued which includes AOs that occurred at facilities licensed or otherwise regulated by the NRC or an Agreement State. Information on activities licensed by Agreement States is also publicly available from the appropriate Agreement State. The report to Congress is available electronically at the NRC Web site <http://www.nrc.gov/NRC/NUREGS/indexnum.html> at the NRC Homepage.

THE REGULATORY SYSTEM

The system of licensing and regulation by which the NRC carries out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations* (10 CFR). Public participation is an element of the regulatory process. To accomplish its objectives, the NRC regularly conducts licensing proceedings, inspection and enforcement

activities, operating experience evaluations, and confirmatory research, and maintains programs for establishing standards and issuing technical reviews and studies.

The NRC adheres to the philosophy that the health and safety of the public are best ensured by establishing multiple levels of protection. These levels can be achieved and maintained through regulations specifying requirements that will ensure the safe use of radioactive materials. The regulations contain design and quality assurance criteria appropriate for the various activities regulated by the NRC. An inspection and enforcement program assists in ensuring compliance with the regulations. The NRC is seeking to make the regulatory system more risk-informed and performance-based, where appropriate.

REPORTABLE OCCURRENCES

Operating experience is an essential element in the regulatory process for ensuring that licensed activities are conducted safely. Licensees are required to report certain incidents or events to the NRC. Such reporting helps to identify deficiencies and to ensure that corrective actions are taken to prevent recurrence.

The NRC and the industry review operating experience to identify safety concerns. Information from operational experience can be disseminated and fed back to licensing activities, regulations, and operations. Operational data is maintained in computer-based data files for more effective collection, storage, retrieval, and evaluation.

Except for records exempt from public disclosure by statute or regulation, the NRC routinely disseminates information concerning reportable occurrences at facilities licensed or otherwise regulated by the NRC to the industry, the public, and other interested groups as these events occur. Dissemination includes special notifications (to licensees and other affected or interested groups) and public announcements. In addition, information on events is available electronically. Congress is routinely informed of significant events occurring in facilities licensed or otherwise regulated by the NRC.

AGREEMENT STATES

Section 274 of the Atomic Energy Act, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes, and the States assume, regulatory authority over byproduct, source, and special nuclear materials (in quantities not capable of sustaining a chain reaction). Agreement States must maintain programs that are adequate to protect public health and safety and are compatible with the Commission's program for such material. Currently, there are 32 Agreement States.

In early 1977, the Commission determined that events that meet the criteria for AOs occurring at Agreement State licensed facilities should be included in the annual report to Congress. Therefore, AOs reported by the Agreement States to the NRC are included in the AO report and in the *Federal Register* notice issued to disseminate the information to the public. Agreement States report event information to the NRC in accordance with compatibility criteria established by the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the *Federal Register* on September 3, 1997 (62 FR 46517). Procedures have been developed and implemented for evaluating material events to determine those that should be reported as AOs. The AO criteria found in Appendix A are applied uniformly to materials events at facilities regulated by the NRC and the Agreement States.

FOREIGN INFORMATION

The NRC exchanges information with various foreign governments that regulate nuclear facilities. This foreign information is reviewed and considered in the NRC's assessment of operating experience and in its research and regulatory activities. Although foreign information may occasionally be referred to in the AO reports to Congress, only domestic AOs are reported.

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC provides updates to previously reported AOs if significant new information about an AO becomes available. Similarly, previously reported "Other Events of Interest" are updated if significant new information becomes available.

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ABNORMAL OCCURRENCES
IN FISCAL YEAR 2000

NUCLEAR POWER PLANTS

Using the criteria and guidelines in Appendix A to this report, one event that occurred at U.S. nuclear power plants during this reporting period was determined to be significant enough to be reported as an AO.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion II. A. 2. "For Commercial Nuclear Power Plant Licensees") to this report states, in part, that an event will be considered an AO if it involves a serious degradation of the primary coolant pressure boundary.

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 borated 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 off-site above normal background levels, and the event did not impact the public health and safety.

Following the event the NRC performed an inspection and determined that Consolidated Edison Corporation had not performed an adequate examination of the steam generator tubes during their 1997 outage. As a result, degraded tubes were allowed to remain in service during plant operation and 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 and correct the presence of PWSCC flaws in steam generator tubes, 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% power.

Actions Taken to Prevent Recurrence

Licensee — The licensee performed the necessary actions to protect the health and safety of the public. Prior to 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/or the industry. Subsequently, the NRC established a Steam Generator Action Plan detailing activities to be addressed by the NRC and industry to improve management of steam generator performance.

This event is closed for the purpose of this report.

FUEL CYCLE FACILITIES
(Other Than Nuclear Power Plants)

Using the criteria in Appendix A to this report, none of the events that occurred at fuel cycle facilities during this reporting period were determined to be significant enough to be reported as an AO.

OTHER NRC LICENSEES

(Industrial Radiographers, Medical Institutions, etc.)

Using the criteria in Appendix A to this report, the following events that occurred at facilities licensed or otherwise regulated by the NRC during this reporting period were determined to be significant enough to be reported as AOs:

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.1, "For Medical Licensees") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more will be considered for reporting as an AO.

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.

With regard to 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 their 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; (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 their 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 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 this report.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

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. Prior to 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 this report.

AGREEMENT STATE LICENSEES

Using the criteria in Appendix A to this report, the following events, which occurred at facilities of Agreement State licensees during this reporting period, were determined to be significant enough for reporting as AOs:

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. This information is also available from the Agreement State regulatory program office. Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

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 inside the patient's skull, which was the wrong treatment site. The misadministration was discovered immediately following the delivery of the dose by the patient's radiation oncologist. 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 this report.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. This information is also available from the Agreement State regulatory program office. Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

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 was due to 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 (GRS) 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 GRS, 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 GRS 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 of 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 GRS facilities to review their methods of operation. The licensee found that another GRS 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 followup check of the coordinate settings after each treatment to determine if an error was made.

State Agency — The findings of the on-site 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 this report.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. This information is also available from the Agreement State regulatory program office. Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

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 (GRS) 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 GRS 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 this report.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. This information is also available from the Agreement State regulatory program office. Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

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 (GRS) 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 GRS 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 GRS 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 GRS 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 this report.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. This information is also available from the Agreement State regulatory program office. Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

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 in order 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 this report.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. This information is also available from the Agreement State regulatory program office. Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

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 this report.

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APPENDIX A

ABNORMAL OCCURRENCE CRITERIA AND GUIDELINES FOR OTHER EVENTS OF INTEREST

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) identifies 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. This type of incident or event would have a moderate or more severe impact on public health or safety and could include, but need not be limited to, the following:

(1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;

(2) Major degradation of essential safety-related equipment; or

(3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

The following criteria for determining an AO and the guidelines for "Other Events of Interest" were stated in an NRC policy statement published in the *Federal Register* on December 19, 1996 (61 FR 67072). The policy statement was revised to include criteria for gaseous diffusion plants and was published in the *Federal Register* on April 17, 1997 (62 FR 18820).

Note that in addition to the criteria for fuel cycle facilities (Section III of the AO criteria) that are applicable to licensees and certificate holders, such as the gaseous diffusion plants, other criteria that reference "licensees," "licensed facility," or "licensed material" also may be applied to events at facilities of certificate holders.

The guidelines for including events in Appendix C "Other Events of Interest" of this report were provided by the Commission in the Staff Requirements Memorandum on SECY-98-175, dated September 4, 1998, and are listed at the end of this Appendix.

<u>Abnormal Occurrence Criteria</u>

Criteria by types of events used to determine which events will be considered for reporting as AOs are as follows:

I. For All Licensees.

A. Human Exposure to Radiation from Licensed Material.

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads, of 2500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and

committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement.

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with §20.1301 using §§20.1302 (b) (1) or 20.1302 (b) (2) (ii).

2. Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material; (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47; or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.[1]

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A_2 or 0.01 times the A_1 values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in

[1] Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.

2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.

3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.

4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

D. Other Events (i.e., Those Concerning Design, Analysis, Construction, Testing, Operation, Use, or Disposal of Licensed Facilities or Regulated Materials)

1. An accidental criticality [10 CFR 70.52(a)].

2. A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

3. A serious deficiency in management or procedural controls in major areas.

4. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.

II. For Commercial Nuclear Power Plant Licensees.

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) [§ 50.36(c)].

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy.

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

III. For Fuel Cycle Facilities

A. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.

B. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.

C. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological, or chemical process hazard.

IV. For Medical Licensees.

A medical misadministration that:

A. Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, *or* (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and

B. Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive *or* (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical,[2] or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

Guidelines for "Other Events of Interest"

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an Appendix to the AO report as "Other Events of Interest." Guidelines for events to be included in the AO report for this purpose may include, but not necessarily be limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of

[2] "The wrong radiopharmaceutical" as used in the AO criterion for medical misadministrations refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

APPENDIX B

UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, no previously reported abnormal occurrences were updated.

APPENDIX C

OTHER EVENTS OF INTEREST

This Appendix discusses "Other Events of Interest," that do not meet the abnormal occurrence (AO) criteria but have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

NON-POWER REACTORS

1. Unplanned High Radiation Field at the University of Missouri Research Reactor at Columbia, Missouri

This event has resulted in significant public interest and caused the NRC to increase its oversight of the licensee's activities. This event did not meet the AO reporting criteria since it did not involve a major reduction in the degree of protection of public health or safety.

The University of Missouri-Columbia operates a 10-megawatt non-power reactor. On April 6, 2000, the licensee removed a portion of the biological shield, adjacent to an in-pool fuel storage area, to perform inspections of the reactor pool liner. On April 12, 2000, an unscheduled shut down occurred that resulted in reactor refueling. During this refueling process, a fuel element was placed, by mistake, in the storage area near where the shielding had previously been removed. This resulted in unplanned high radiation levels in the basement floor level of the reactor containment, which triggered a radiation alarm. The licensee moved the fuel element to a different location in the storage area which did not alleviate the situation, and then moved the fuel back to the reactor which ended the event. The elevated radiation field, with a calculated maximum dose rate at the opening in the shielding of 4.0 Sv per hour (400 rem per hour) existed for about 3 minutes.

Subsequent review by the NRC determined that radiation overexposures had not occurred and that the event did not affect members of the public. However, the NRC concluded that the licensee did not properly evaluate the impact of removing the shielding prior to removal of the shielding. The NRC's review of this event also raised concerns in reactor operations, radiation protection, fuel handling, procedures, and emergency preparedness.

The NRC issued a Notice of Violation on October 5, 2000. The licensee has instituted numerous corrective actions which the NRC will review during future inspections.

This event is closed for the purpose of this report.

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2. Removal of Control Rod with Improper Core Configuration at the University of Missouri Research Reactor at Columbia, Missouri

This event has resulted in significant public interest and caused the NRC to increase its oversight of the licensee's activities. This event did not meet the AO reporting criteria since it did not involve a major reduction in the degree of protection of public health or safety.

The University of Missouri-Columbia operates a 10-megawatt non-power reactor. On June 12, 2000, as part of normal maintenance activities, the licensee removed one of four control rods from the reactor without meeting the requirement to first unload two of eight fuel elements from the reactor core. When the licensee recognized this error, it removed two fuel elements, which ended the event.

Subsequent review by the NRC determined that the reactor met the minimum requirements for shut down at all times during the event and the event had no impact on the health and safety of the licensee staff or the public. However, the NRC determined that the licensee did not follow procedures that required the two fuel elements to be removed from the core. Also, with eight fuel elements in the reactor core and the control rod removed, the reactor was in a configuration that was in violation of the licensee's technical specifications. The NRC also had concerns in the areas of organizational function, shift turnover and communication, operator cognizance of facility conditions, and procedural implementation.

The NRC issued a Notice of Violation on October 5, 2000. The licensee has instituted numerous corrective actions which the NRC will review during future inspections.

This event is closed for the purpose of this report.

NRC AND AGREEMENT STATE MATERIALS LICENSEES

During FY 2000, 633 materials events were reported to the NRC. Of these events 230 resulted in licensed material entering the public domain in an uncontrolled manner: 35 of the 230 events were reported by NRC licensees and 195 of the 230 events were reported by Agreement State licensees. In some cases, the material caused radioactive contamination or radiation exposures.

The licensed material that entered the public domain in an uncontrolled manner was mainly discovered when the radiation monitor alarms in landfills and scrap yards activated after detecting radioactivity coming from wastes and/or recycled metal shipments. Once the radiation monitor alarms were triggered, the radioactive material in these shipments was identified and disposed of properly.

The 230 events of loss of control of material involved both medical and industrial uses. Examples are (1) radioactive sources in medical treatments or research and development, (2) gauges that can be used in industries such as construction and civil engineering to measure the moisture density in soils, or to monitor a production process to ensure quality control, (3) chemical agent monitors/chemical agent detectors used by the military to detect the presence of chemical warfare agents, (4) tritium contained in exit signs or used in illuminating mortar-sighting mechanisms by the military, and (5) radiography cameras used in industrial settings for checking welds, castings, assembled machinery (e.g., jet engines), and ceramics.

It is not unusual that a lost source cannot be located. At some point a decision must be made that it is no longer practical to continue the search for the lost source. However, there are safeguards in place that may eventually lead to the identification, recovery and disposal of the source. These safeguards include that (1) the source is typically contained in a well-marked container, (2) the source has identification markers, (3) many public landfills have radiation detectors, (4) scrap metal recycling industry maintains radiation detectors at recycling facilities, a report file of the lost/stolen event, and possibly a criminal investigation file. In cases where

the source is never found, there are no health and safety concerns if the source remains in its original device.

The frequency of events involving the loss of control of materials and the growing public interest and concern have caused the NRC to pay more attention to this issue. The NRC and Agreement States have issued generic communications to inform licensees about these events and their consequences in order to prevent future incidents. In some cases, enforcement actions have been taken, and regulatory changes intended to increase licensees' accountability for generally-licensed devices have been developed.

For illustration purposes, the following example involving loss of control of material, which occurred in FY 2000, is provided.

Loss of a Radiography Camera Owned by Welding Testing X-Ray, Inc., Canyon Lake, Texas

This event resulted in significant media interest.

The State of Texas representatives indicated that Welding Testing X-Ray, Inc., a licensee of the Sate of Louisiana, was authorized to conduct radiography in the State of Texas under reciprocity. On August 13, 2000, a licensee employee placed the radiography camera on the bumper of his truck temporarily before leaving his residence for the work site. The licensee employee left his residence with the camera remaining on the bumper. Apparently, the camera fell out of the truck soon after the truck took off for the work site. The sheriff's department found the radiography camera by the fire department near Canyon Lake, Texas, and notified the licensee. When the employee arrived at the job site the licensee's supervisor informed the employee that the licensee had received notification from the sheriff's department that they had found a radiography camera belonging to the licensee near Canyon Lake. The licensee notified the State of Louisiana and the State of Texas.

The sheriff's department also notified NRC's Region IV the same day. The radiography camera contained 4.41 terabecquerel (119 curie) of iridium-192. The Region IV staff contacted the State of Texas and was informed that an inspector had been dispatched to the site and had taken possession of the radiography device. The State of Texas returned the radiography camera to Welding Testing X-Ray, Inc.

The licensee has established appropriate procedures to prevent future incidents.

This event is closed for the purpose of this report.

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