UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
SECRETARY

April 3, 2001

COMMISSION VOTING RECORD

DECISION ITEM: SECY-01-0030

TITLE: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 2000

The Commission (with Chairman Meserve and Commissioners Diaz, McGaffigan, and Merrifield agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 3, 2001. Commissioner Dicus disapproved the paper.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-01-0030

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	3/19/01
COMR. DICUS		X			X	3/15/01
COMR. DIAZ	X				X	3/15/01
COMR. McGAFFIGAN	X					3/7/01
COMR. MERRIFIELD	X				X	3/12/01

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners Diaz, McGaffigan, and Merrifield approved the staff's recommendation and some provided additional comments. Commissioner Dicus disapproved the paper until various questions could be clarified. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on April 3, 2001.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

SUBJECT: SECY-01-0030 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 2000

Approved X/w comments and edits **Disapproved** _____ **Abstain** _____

Not Participating _____ **Request Discussion** _____

COMMENTS:

See attached comments

SIGNATURE

March 19, 2001
DATE

Entered on "STARS" Yes X **No** ____

COMMENTS OF CHAIRMAN MESERVE ON SECY-01-0030

I approve the issuance of the FY 2000 Abnormal Occurrences report, subject to the modifications identified by Commissioner Dicus in her vote. I also offer a number of minor edits to the report, reflected in the attached markup of the draft report.

In reviewing the Abnormal Occurrences report, I note that all of the non-reactor-related events classified as AOs occurred in the area of medical uses of radioactive materials, either in the production of radiopharmaceuticals or in the administration of medical therapy. Moreover, all of the events involved failures of what can be classified broadly as quality assurance (QA). This suggests that there may be a generic problem with QA programs associated with the manufacture and medical uses of radioisotopes. Accordingly, I suggest that the Advisory Committee on the Medical Uses of Isotopes (ACMUI) examine the issue of QA in this area, and provide recommendations, as appropriate, as to whether additional NRC regulatory oversight is required.

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~~ which ultimately led to a steam generator tube failure.

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.

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~~ 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 (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

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

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-01-0030 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 2000**

Approved _____ Disapproved X Abstain _____

Not Participating _____

COMMENTS: See attached comments.

Greta Joy Dicus
SIGNATURE

March 15, 2001
DATE

Entered on "STARS" Yes X No ____

COMMISSIONER DICUS' COMMENTS ON SECY-01-0030:

gvd
3-15-01

I disapprove of the issuance of the current draft of the REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 2000. Various statements in the report raise questions or require clarification that should be addressed by NRC staff before the report is issued to Congress. These statements are identified below.

Abstract, Second Paragraph, Second and Third Sentences:

The following additions are recommended to assist any congressman who would choose only to read the abstract:

"...the second event resulted in overexposures of occupational workers at a radiopharmaceutical manufacturing plant, and the third event involved a medical brachytherapy misadministration. The report also discusses six medical AOs...."

Event 00-1, Nature and Probable Consequences, Second Paragraph

Add the underlined phrase to the last sentence:

"No radioactivity was measured off-site above normal background levels, and the event did not impact the public health and safety or the environment."

Event AS 00-1, Nature and Probable Consequences, Second Paragraph, Third Sentence

The sentence states that the patient was treated with a dose that "was delivered inside the patient's skull, which was the wrong treatment site."

Since GSR treatments are always intended to be inside the patient's skull, perhaps the intent was to state that the dose was delivered at the wrong treatment site within the patient's skull.

Also, the report should clarify that intervention prevented a related misadministration for patient B, if this was the case.

Event AS 00-3, Actions to Prevent Recurrence

The report states that no action was taken by the licensee and that the State found no violations. In summary, no actions were taken to prevent recurrence. The inference is that since this type of event is expected to rarely occur, no corrective action is justified.

It would seem that any event reported as an AO should include corrective actions to prevent recurrence; otherwise, this kind of event can reasonably be expected to reappear in this report in the future.

APPENDIX C, OTHER EVENTS OF INTEREST, Page 20

The description of the first event, the unplanned high radiation field at the University of Missouri Research Reactor, states that the event resulted in unplanned high radiation

gvd
3-15-07

levels in the basement floor level of the reactor containment, which triggered a radiation alarm, and that the calculated maximum dose rate at the opening in the shielding was 400 rem/hr for about 3 minutes. That is, if it were possible for anyone to be at that location, they would have received a 20 rem dose. Later the report states that radiation overexposures had not occurred and that the event did not affect members of the public.

Although the report clarifies that members of the public were not affected, questions arise regarding possible exposures to workers at the reactor:

Were there any workers in the basement floor level at the time of the event?

Did any of them receive radiation exposures, given the high levels reported? (It is clear from the report that no overexposures occurred; thus, if there were exposures they were less than 5 rems.)

NRC AND AGREEMENT STATE MATERIALS LICENSEES, Page 21

The first paragraph of this section states that there were 230 events resulting "in licensed material entering the public domain in an uncontrolled manner...." The report further states, "In some cases, the material caused radioactive contamination or radiation exposures." The report should be amplified to better describe the risk perspective on these events.

In the second sentence of the third paragraph, add the word "used." "Examples are (1) radioactive sources used in medical treatments...."

Loss of a Radioactive Camera Owned by Welding Testing X-Ray, Inc., Page 22

"State" is spelled incorrectly in the second line of the event description.

One sentence states, "The sheriff's department found the radiography camera by the fire department near Canyon Lake, Texas." This sentence is not clear. Region IV staff recalls that either fire department personnel or sheriff's personnel found the camera and reported it to the licensee.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-01-0030 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 2000**

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

I believe a final "scrub" of the report would be useful.

SIGNATURE

March 15, 01

DATE

Entered on "STARS" Yes X No ____

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-01-0030 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 2000**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

SIGNATURE

March 7 2001

DATE

Entered on "STARS" Yes X No ____

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-01-0030 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FOR FISCAL YEAR 2000**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

Approved subject to minor technical edits.

SIGNATURE

3/12/01
DATE

Entered on "STARS" Yes ✓ No ____

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.

GSR

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.

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.