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Report to Congress on Abnormal Occurrences

April - June 1995

U.S. Nuclear Regulatory Commission

Office for Analysis and Evaluation of Operational Data



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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission determines to be significant from the standpoint of public health or safety and requires a quarterly report of such occurrences to be made to Congress. This report provides a description of those incidents and events that have been determined to be AOs during the period of April 1 through June 30, 1995.

This report addresses five AOs at NRC-licensed facilities. One involved a reactor coolant system blowdown at a pressurized water reactor (PWR) nuclear power plant, one involved a previously

unidentified path for the potential release of radioactivity at a PWR nuclear power plant, two involved medical brachytherapy misadministrations, and one involved a medical therapeutic radiopharmaceutical misadministration. Four AOs submitted by the Agreement States are included. One involved a medical teletherapy misadministration, two involved medical brachytherapy misadministrations, and one involved the overexposure of personnel at a medical center. The report also contains an update of one AO previously reported by an NRC licensee, and two AOs previously reported by the Agreement States. No "Other Events of Interest" items are being reported.

CONTENTS

	<i>Page</i>
Abstract	iii
Preface	vii
Introduction	vii
The Regulatory System	vii
Reportable Occurrences	viii
Agreement States	viii
Foreign Information	viii
Reopening of Closed Abnormal Occurrences	viii
Report to Congress on Abnormal Occurrences, April-June 1995	1
Nuclear Power Plants	1
95-2 Reactor Coolant System Blowdown at Wolf Creek Nuclear Generating Station	1
95-3 Previously Unidentified Path for the Potential Release of Radioactivity at Millstone Nuclear Power Station Unit 2	2
Fuel Cycle Facilities (Other than Nuclear Power Plants)	3
Other NRC Licensees (Industrial Radiographers, Medical Institutions, Industrial Users, etc.)	3
95-4 Medical Brachytherapy Misadministration at the University of Virginia, in Charlottesville, Virginia	4
95-5 Medical Therapeutic Radiopharmaceutical Misadministration of Iodine-131 at Massachusetts General Hospital in Boston, Massachusetts	4
95-6 Multiple Medical Brachytherapy Misadministrations at Madigan Army Medical Center in Fort Lewis, Washington	5
Agreement State Licensees	6
AS 95-1 Medical Teletherapy Misadministration at an "Unspecified Licensee" in New York, New York	6
AS 95-2 Medical Brachytherapy Misadministration by Mobile Technology, Inc., at Irvine Medical Center in Irvine, California	7
AS 95-3 Overexposure of Personnel at Gwinnett Medical Center in Lawrenceville, Georgia	7
AS 95-4 Medical Brachytherapy Misadministration at Southwest Texas Methodist Hospital in San Antonio, Texas	8

	<i>Page</i>
Appendix A - Abnormal Occurrence Criteria	11
Appendix B - Update of Previously Reported Abnormal Occurrences	15
Other NRC Licensees	15
92-18 Loss of Iridium-192 Source and Medical Therapy Misadministration at Oncology Services Corporation in Indiana, Pennsylvania	15
Agreement State Licensees	16
AS 88-5 Medical Teletherapy Misadministration at Sacred Heart Hospital in Cumberland, Maryland	16
AS 88-6 Multiple Medical Teletherapy Misadministrations at Sacred Heart Hospital in Cumberland, Maryland	16
Appendix C - Other Events of Interest	17

PREFACE

Introduction

The Nuclear Regulatory Commission (NRC) reports to Congress each quarter, under provisions of Section 208 of the Energy Reorganization Act of 1974, any abnormal occurrences (AOs) involving facilities and activities regulated by NRC. An AO is defined in Section 208 as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety.

NRC identifies an AO for the purpose of this report using the criteria in Appendix A. The criteria were initially promulgated in an NRC policy statement that was published in the *Federal Register* on February 24, 1977 (Vol. 42, No. 37, pages 10950-10952).

This policy statement was published before medical licensees were required to report misadministrations to NRC and few of the examples in the policy statement were applicable to medical misadministrations. Therefore, in 1984, NRC adopted additional guidance for AO reporting of medical misadministrations. These guidelines augment the NRC policy statement examples and are summarized in Table A-1 in Appendix A.

On January 27, 1992, new medical misadministration requirements became effective. As directed by the Commission, the staff is currently developing a new policy statement for reporting incidents and events to Congress. The policy statement will be published for public comment in the *Federal Register* prior to final Commission approval for use in developing future AO reports.

In order to provide wide dissemination of information to the public, a *Federal Register* notice is issued on NRC licensee AOs. Copies of the notice are distributed to the NRC Public Document Room and all Local Public Document Rooms. At a minimum, each notice must contain the date and place of the occurrence and a

description of its nature and probable consequences.

NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described in this report meet the criteria for reporting as AOs. This report covers the period from April 1 through June 30, 1995. Information reported on each AO includes date and place, nature and probable consequences, cause or causes, and actions taken to prevent recurrence.

Appendix B contains updated information on previously reported AOs.

Appendix C contains information on incidents that can be perceived as significant but do not involve a major reduction in the level of protection provided for public health and safety. These events are not reportable as AOs but are provided as "Other Events of Interest."

The Regulatory System

The system of licensing and regulation by which NRC carries out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations*. This includes public participation as an element. To accomplish its objectives, NRC regularly conducts licensing proceedings, inspection and enforcement activities, evaluation of operating experience, and confirmatory research, while maintaining programs for establishing standards and issuing technical reviews and studies.

In licensing and regulating nuclear power plants and the uses of byproduct nuclear materials, NRC follows 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 nuclear materials. The regulations include design and quality assurance criteria appropriate for the various activities licensed by NRC. An inspection and enforcement program helps ensure compliance with the regulations.

Reportable Occurrences

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

For nuclear power plants, dedicated groups have been formed, both by NRC and the nuclear power industry, for the detailed review of operating experience to help identify safety concerns early; to improve dissemination of such information; and to feedback the experience into licensing, regulations, and operations. In addition, NRC and the nuclear power industry have ongoing efforts to improve the operational data systems, which include not only the type and quality of reports required to be submitted, but also the methods used to analyze data. In order to more effectively collect, collate, store, retrieve, and evaluate operational data, the information is maintained in computer-based data files.

Three primary sources of operational data are Licensee Event Reports (LERs) submitted pursuant to 10 CFR 50.73, immediate notifications submitted pursuant to 10 CFR 50.72, and medical misadministration reports submitted pursuant to 10 CFR 35.33.

Except for records exempt from public disclosure by statute and/or regulation, information concerning reportable occurrences at facilities licensed or otherwise regulated by NRC is routinely disseminated by NRC to the nuclear 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 reportable events is routinely sent to the NRC's Local Public Document Rooms throughout the United States and to the NRC Public Document Room in Washington, D.C. Congress is routinely kept informed of reportable events occurring in licensed facilities.

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 State programs must be comparable to and compatible with the Commission's program for such material.

Presently, information on reportable occurrences for Agreement State licensed activities is publicly available at the State level. For the purpose of developing a nationwide database, Agreement States are encouraged to provide information to NRC on reportable events.

In early 1977, the Commission determined that AOs happening at Agreement State licensed facilities should be included in the quarterly reports to Congress. The AO criteria included in Appendix A are applied uniformly to incidents and events that occur at NRC and Agreement State licensed facilities. Procedures have been developed and implemented, and AOs reported by the Agreement States to NRC are included in the quarterly reports to Congress.

Foreign Information

NRC participates in an exchange of information with various foreign governments that have nuclear facilities. This foreign information is reviewed and considered in the NRC's assessment of operating experience and in its research and regulatory activities. Reference to foreign information may occasionally be made in these quarterly AO reports to Congress; however, only domestic AOs are reported.

Reopening of Closed Abnormal Occurrences

NRC reopens previously closed AOs if significant new information becomes available. Similarly, previously reported "Other Events of Interest" are updated if significant new information becomes available.

REPORT TO CONGRESS ON ABNORMAL OCCURRENCES APRIL-JUNE 1995

NUCLEAR POWER PLANTS

NRC has reviewed all incident and event reports received from licensees for operating nuclear power plants in the United States (U.S.) through the second quarter of 1995. Using the criteria and guidelines in Appendix A of this report, the following occurrences were determined to be significant enough to be reported as AOs.

95-2 Reactor Coolant System Blowdown at Wolf Creek Nuclear Generating Station

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see General Criteria No. 3) of this report notes that major deficiencies in design, construction, use of, or management controls for licensed facilities or material can be considered an AO.

Date and Place—September 17, 1994; Wolf Creek Nuclear Generating Station, a Westinghouse-designed pressurized water reactor nuclear power plant, operated by Wolf Creek Nuclear Operating Corporation and located about 5.63 kilometers (3.5 miles) northeast of Burlington, Kansas.

Nature and Probable Consequences—An inadvertent blowdown of approximately 34,868 liters (9200 gallons) of reactor coolant through the residual heat removal (RHR) system to the refueling water storage tank (RWST) occurred because of incompatible, concurrent RHR valve manipulations. At the time of the event, the reactor had been shutdown for 28 hours and was on RHR cooling (2413 kPa gauge and 149 C [350 psi gauge and 300 F]). The event was successfully terminated in 1 minute by operator intervention. There was only minimal interruption to heat removal processes, and no core damage or fission product release occurred. However, if the blowdown continued, the licensee estimated that RHR cooling could have failed in about 3.5 minutes, the RWST header could have filled with steam in about 6 minutes, and uncovering of the core could have begun in about 30 minutes.

All of the emergency core cooling system (ECCS) pumps take their suction from the RWST header line. If the ECCS pumps were started to mitigate the blowdown after the RWST header filled with steam, a common-mode failure of all ECCS pumps could have occurred as a result of steam binding. The ECCS pumps could also have failed as a result of pressure pulses caused by cold RWST water collapsing the steam in the RWST and RWST header. If they failed, successful mitigation of such an event would depend on the control room operators' cognitive abilities to establish core heat removal via the steam generators.

If core damage did occur, then a possibility for a significant offsite release existed because the blowdown path in place at the time bypassed the reactor containment.

Cause or Causes—This event was attributed to the following three causes:

- (1) **Unrecognized design vulnerability**—An RHR-RWST connecting line was designed to provide operational convenience for refilling the RWST after a refueling outage, but not for safety purposes. The inappropriate use of this line while on RHR cooling could result in a rapid blowdown event and a subsequent common-mode failure of all ECCS pumps.
- (2) **Inappropriate use of the RHR-RWST connecting line**—The licensee inappropriately used the RHR-RWST connecting line to increase the boron concentration of the RHR train. (Other boration paths existed that would not have resulted in an inadvertent blowdown.)
- (3) **Inadequate work control**—The licensee was deficient in the control of maintenance and operational evolutions by allowing incompatible activities to occur simultaneously. The control room crew had ample warning of the potential adverse effects of these activities just prior to the

event, but failed to limit the concurrent manipulation of selected RHR valves.

The licensee also had previous warnings of blowdown events from its experience at Wolf Creek and from the following NRC Information Notices: 90-55, "Recent Operating Experience on Loss of Reactor Coolant Inventory While in a Shutdown Condition"; and 91-42, "Plant Outage Events Involving Poor Coordination Between Operations and Maintenance Personnel During Valve Testing and Manipulations." The licensee's response to these warnings was that its administrative controls adequately addressed the concerns.

Actions Taken to Prevent Recurrence

Licensee—The licensee implemented the following actions: (1) chain locked the isolation valve in the RHR-RWST connecting line, and made the plant manager and operations manager solely responsible for access to this valve; (2) removed the use of the RHR-RWST connecting line from the RHR boration procedures; and (3) approached the Westinghouse Owners Group to address the issue generically.

NRC—NRC issued Information Notice No. 95-03, "Loss of Reactor Coolant Inventory and Potential Loss of Emergency Mitigation Functions While in a Shutdown Condition," to inform all reactor licensees of the circumstances and potential consequences associated with the Wolf Creek event.

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

95-3 Previously Unidentified Path for the Potential Release of Radioactivity at Millstone Nuclear Power Station Unit 2

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see For Commercial Nuclear Power Plants, Criterion No. 3) of this report notes that a loss of plant capability to perform essential safety functions, such that a potential release of radioactivity in excess of 10

CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system), can be considered an AO.

Date and Place—December 6, 1994; Millstone Nuclear Power Station Unit 2, a Combustion Engineering-designed pressurized water reactor nuclear power plant, operated by Northeast Nuclear Energy Company and located about 5.15 kilometers (3.2 miles) west-southwest of New London County, Connecticut.

Nature and Probable Consequences—While the plant was in a refueling outage, a systems engineer employed by the licensee identified a condition that established a potential unfiltered release path to the atmosphere that could have resulted in offsite doses in excess of 10 CFR Part 100 guidelines in the event of a postulated loss-of-coolant accident (LOCA). The licensee immediately declared the enclosure building inoperable and promptly reported the condition to NRC.

The Millstone Unit 2 design includes an Enclosure Building around the reactor Containment Building to collect all leakage out of the containment during a postulated LOCA. The Enclosure Building Ventilation System contains a charcoal bed filtration unit to remove radioactive iodine prior to discharging the Enclosure Building air out of the 114.4-meter (375-foot) high Unit-1 stack. The condition identified on December 6, 1994, was that the ventilation system associated with the Hydrogen Analyzer cabinet and waste gas sample hood fan, located within the East Electrical Penetration Room of the Enclosure Building, would not isolate in the event of a LOCA. During a postulated accident, this ventilation system, which does not contain a charcoal filter unit, would draw Enclosure Building air (contaminated with any containment leakage) from the East Penetration Room and discharge it through the 45.8-meter (150-foot) high Unit 2 vent. The lack of a charcoal filter and the lower release point would significantly increase the potential of a thyroid dose in excess of the 10 CFR Part 100 guideline at the exclusion area boundary.

The Technical Specifications for Millstone Unit 2 require that the Enclosure Building integrity be maintained to ensure that the Enclosure Building Ventilation System limits the site boundary doses to within 10 CFR Part 100 guidelines following a

postulated design basis accident. NRC performed a design basis dose calculation which took into account the lack of charcoal filtration and the lower elevation release path which would result from the noted design deficiency. This calculation indicated that an exclusion area boundary dose to the thyroid greater than the 10 CFR Part 100 guideline of 3000 millisievert (mSv) (300 rem) would occur. It also indicated that the whole body dose would not exceed the 250 mSv (25 rem) 10 CFR Part 100 guideline. The NRC calculation was very conservative in that it assumed that all of the designed allowable containment leakage, following the design basis accident, would be through the penetrations in the East Electrical Penetration Room and released from the Enclosure Building through the Hydrogen Analyzer Ventilation system.

Cause or Causes—The cause of this condition was an original design deficiency of the hydrogen analyzer cabinet exhaust system.

Actions Taken to Prevent Recurrence

Licensee—The licensee modified the design to route the exhaust path from the hydrogen analyzer cabinet into the enclosure building ventilation system, thereby going through the appropriate filtration, in order to reduce any post-LOCA radioactive release to below 10 CFR Part 100 guidelines. The waste gas sample sink was relocated from the enclosure building to the auxiliary building. This design modification was implemented prior to the start up of Millstone Unit 2.

NRC—On February 16, 1995, NRC exercised enforcement discretion and did not issue a violation. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) then set out at 10 CFR Part 2, Appendix C, this design deficiency would normally be categorized as a Severity Level III violation and enforcement action would normally be considered because it involved a violation of the Technical Specifications and could have resulted in 10 CFR Part 100 guidelines being exceeded in the event of a LOCA. However, the exercise of discretion for the apparent Severity Level III violation was determined to be warranted in this instance because: (1) the condition was identified by the licensee's staff as a result of a questioning attitude by a system engineer and was promptly reported to the NRC; (2) the condition, which existed since initial startup, was difficult to discover and such identification was not likely by routine inspection, surveillance and quality assurance activities; (3) comprehensive corrective actions were taken within a reasonable time period that involved an adequate root cause determination and a review for failures caused by similar root causes; and (4) the condition was caused by an old performance failure that is not reasonably linked to present performance."

This event was determined to be plant specific due to the unique design of the ventilation system.

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

**FUEL CYCLE FACILITIES
(Other than Nuclear Power Plants)**

NRC has reviewed all incident and event reports received from licensees for the milling, processing, and fabrication of nuclear fuel in the U.S. through the second quarter of 1995. Using the criteria and guidelines in Appendix A of this report, none of

the occurrences reviewed for this reporting period were determined to be significant enough to be reported as an AO.

**OTHER NRC LICENSEES
(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)**

There are approximately 22,000 active material licenses for the use of byproduct materials in industrial, medical, and academic applications in the U.S. Twenty-nine States, known as

Agreement States, have entered into agreements with NRC to assume regulatory authority for approximately 15,000 of these licensees within their States. NRC is responsible for regulating

approximately 7000 licensees located in the remaining 21 States, the District of Columbia, and all U.S. territories. NRC has reviewed all incident and event reports received from NRC licensees through the second quarter of 1995. Using the criteria and guidelines in Appendix A of this report, the following occurrences were determined to be significant enough to be reported as AOs.

95-4 Medical Brachytherapy Misadministration at the University of Virginia, in Charlottesville, Virginia

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

Date and Place—March 14, 1995; University of Virginia Medical Center; Charlottesville, Virginia.

Nature and Probable Consequences—A patient was prescribed a manual brachytherapy procedure using cesium-137 (Cs-137) sources loaded in an applicator, for a total gynecological treatment dose of 3000 centigray (cGy) (3000 rad).

During insertion of the applicator into the patient, one of the sources fell onto the patient's bed and was unnoticed by the licensee staff involved in performing the procedure. A nurse found the source in the bed on March 15 and removed it. The source was reloaded into the applicator and the physician revised the prescribed dose to 2500 cGy (2500 rad). The licensee estimated that the source remained at approximately 10 centimeters (4 inches) from the patient's foot for 18 hours and delivered a dose of about 13 cGy (13 rad) to the foot.

The licensee notified the referring physician and the patient of the misadministration. An NRC medical consultant was obtained who concluded that the patient was receiving appropriate follow-up care. In addition, the licensee and the medical consultant concluded that the patient will not experience any adverse health effects as a result of the misadministration.

Cause or Causes—The licensee's staff involved in the brachytherapy procedure were not familiar with handling of the applicator that contained the

Cs-137 sources. Also, because of anatomic characteristics of the patient, the physician had difficulty inserting the source carrier into the applicator. The design of the afterloading device allows the source to slide out of the carrier if any unusual manipulation of source carrier is required. The difficulty experienced by the physician in inserting the source in the applicator and the design of the source carrier resulted in the source falling out of the carrier during the insertion process.

Actions Taken to Prevent Recurrence

Licensee—The licensee provided training for its staff, involved in brachytherapy procedures, concerning the precautions which must be taken when handling an applicator such as the one used in the subject procedure. Also, emphasis was placed on the need to be more attentive during the source insertion process in order to account for all prescribed sources.

NRC—NRC conducted a special inspection on March 23-24, 1995, to review the circumstances surrounding the misadministration. The inspection report was issued on May 2, 1995. Enforcement action will be taken as appropriate.

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

95-5 Medical Therapeutic Radiopharmaceutical Misadministration of Iodine-131 at Massachusetts General Hospital in Boston, Massachusetts

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5 [a] in Table A-1) of this report notes that administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent and the actual dose is greater than 1.5 times the prescribed dose can be considered an AO.

Date and Place—May 9, 1995; Massachusetts General Hospital; Boston, Massachusetts.

Nature and Probable Consequences—A patient was prescribed a 296 megabecquerel (MBq) (8

millicurie [mCi]) dosage of iodine-131 (I-131) for hyperthyroidism; however, a dosage of 1106.3 MBq (29.9 mCi) was administered.

Representatives of the hospital informed the referring physician and the patient of the misadministration. An NRC medical consultant was obtained to evaluate the event and stated that the higher dosage given to the patient will result in a more likely achievement of the intended therapeutic goal to eliminate the patient's hyperthyroidism. Additionally, the consultant determined that it is unlikely that the patient is at significant risk of experiencing long-term consequences from receiving the higher dosage beyond the risk associated with the prescribed dosage. Therefore, the impact on the patient's health is expected to be negligible with no expected long-term disability. (The intent of the prescribed dose was to ablate the portion of the thyroid remaining after surgery and then support the patient with thyroid supplement the rest of her life. This did not change with the administered dose.)

Cause or Causes—The licensee stated that this event occurred because of a human error. The technologist involved in this procedure inadvertently switched the labeled lids on the vial shields containing the I-131 dosages prescribed for different patients. Additionally, the technician failed to check for the correct dosage on the vial label, and the wrong dose was administered to the intended patient.

Actions Taken to Prevent Recurrence

Licensee—The licensee instituted a procedure for checking the vial label before giving a dose. In addition, the licensee is obtaining a second dose calibrator which will be used in the out-patient dosing room of the Thyroid Clinic. Each dose will be re-assayed immediately before the I-131 is administered to the patient, rather than relying on the assay which was performed in the Thyroid Lab before the dose was transported to the outpatient dosing room.

NRC—NRC performed an inspection on May 12, 1995, to learn about the event and determined that it constituted a misadministration as defined in 10 CFR 35.2. NRC determined that this was an isolated violation of the licensee's Quality Management Program and issued a Notice of

Violation at the Severity Level IV on June 26, 1995.

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

95-6 Multiple Medical Brachytherapy Misadministrations at Madigan Army Medical Center in Fort Lewis, Washington

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5[d] in Table A-1) of this report notes that administering a therapeutic dose from a sealed source such that the treatment dose differs from the prescribed dose by more than 10 percent and the event (regardless of health effects) affects two or more patients at the same facility can be considered an AO.

Date and Place—February 1994 through May 1995; Madigan Army Medical Center (MAMC); Fort Lewis, Washington.

Nature and Probable Consequences—Four patients were prescribed brachytherapy procedures, using iridium-192 seeds of different source strengths, and received doses other than those prescribed because of the same computer input error. (The same computer input error could cause either underdoses or overdoses because the algorithm used was dose dependent.) Details of the misadministrations are as follows:

Patient A: The patient was prescribed a dose of 2800 centigray (cGy) (2800 rad) for a gynecological brachytherapy treatment, but received a dose of about 1680 cGy (1680 rad) instead.

Patient B: Event 1 - The patient was prescribed a dose of 1600 cGy (1600 rad) for lung treatment, but received a dose of about 2128 cGy (2128 rad) instead.

Event 2 - On another day, the same patient was prescribed a dose of 1500 cGy (1500 rad) for lung treatment, but

received a dose of about 2350 cGy (2350 rad) instead.

Patient C: The patient was prescribed a dose of 3000 cGy (3000 rad) for gynecological treatment, but received a dose of about 5142 cGy (5142 rad) instead.

Patient D: The patient was prescribed a dose of 1500 cGy (1500 rad) for a biliary tract treatment, but received a dose of about 2050 cGy (2050 rad) instead.

The licensee does not expect the patients to experience any adverse health effects as a result of the misadministrations.

Cause or Causes—Based upon NRC's initial review of the misadministrations, it appears that the probable causes of the treatment errors were failures to: (1) independently review or check the data input to the computerized treatment planning system, and (2) perform an independent

check of dose rate calculations generated by the treatment planning system.

Actions Taken to Prevent Recurrence

Licensee—The physics staff at MAMC promptly corrected the data entered into the computer treatment planning computer, recalculated the doses received by the patients, and took steps to ensure that appropriate data will be used for future treatment plans.

NRC—NRC initiated an inspection on June 6, 1995, to review the circumstances associated with the misadministrations and to review the licensee's corrective actions. (As of the date of this report, the inspection is ongoing.) An NRC medical consultant will review each case in order to provide an independent assessment of the potential consequences of the overdoses.

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

AGREEMENT STATE LICENSEES

The 29 Agreement States have approximately 15,000 active material licenses for the use of byproduct materials in industrial, medical, and academic applications. Procedures have been developed for Agreement States to screen incidents and events using the same criteria and guidelines as NRC, and to report those occurrences that have been determined to be significant enough to be considered as AOs. Using the criteria and guidelines in Appendix A of this report, the following occurrences were determined to be significant enough to be reported as AOs.

AS 95-1 Medical Teletherapy Misadministration at an "Unspecified Licensee" in New York, New York

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

Date and Place—May 23-26, 1993; "Unspecified Licensee"; New York, New York. (New York State law prohibits disclosure of the licensee's name.)

Nature and Probable Consequences—A patient was prescribed a total dose to the right superclavicular area and spine of 2400 centigray (cGy) (2400 rad) using cobalt-60 teletherapy equipment. During simulation, the technologist erroneously placed the preparatory tattoo marking the treatment area on the wrong side of the patient. The patient consequently received a dose of 900 cGy (900 rad) to the left superclavicular area which was the wrong treatment site. The patient was then resimulated and the treatment to the correct site was administered as prescribed.

The licensee informed the referring physician of the misadministration, and the referring physician chose not to inform the patient. The licensee also stated that no adverse health effects resulted from the misadministration.

Cause or Causes—The misadministration occurred because the licensee staff marked the

wrong treatment area on the patient during a simulation in preparation for treatment.

Actions Taken to Prevent Recurrence

Licensee—The licensee issued a notice to all of its personnel concerning the importance of accurate marking of treatment areas. Also, residents, physicists, technologists, and attending staff were reminded that the treatment remarks in patient charts should accurately reflect the original prescription. In-service training was held concerning the issues, and the applicable procedures covering treatment prescriptions and field markings were revised.

State Agency—Acting under authority granted by the State Agency, the New York City Bureau of Radiological Health investigated the misadministration and submitted its investigative reports to NRC. The reports contained information about the licensee's actions to prevent recurrence.

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

AS 95-2 Medical Brachytherapy Misadministration by Mobile Technology, Inc., at Irvine Medical Center in Irvine, California

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

Date and Place—March 14, 1995; Irvine Medical Center; Irvine, California.

Nature and Probable Consequences—A patient was prescribed a brachytherapy treatment to the left lung using a high dose rate (HDR) remote afterloading unit. However, because of an error the patient received 800 centigray (800 rad) to the right lung.

The patient and the referring physician were informed of the misadministration. The patient's physician stated that based on a five-year survival rate the chance of clinically noticeable complications would be extremely low, and no

significant change in lung function could be measured with the dose given to the right lung. A dose of this type may eventually cause a drying out of the lung mucosal cells in that region, resulting in a "dry cough."

Cause or Causes—A chest x-ray showing that the HDR remote afterloading unit's positioning catheter was erroneously placed in the right lung was not reviewed by either the pulmonologist or the radiation oncologist.

Actions Taken to Prevent Recurrence

Licensee—The licensee took the following actions to prevent recurrence: (1) real-time fluoroscopy will be used at the time of the bronchoscopy; (2) a guide wire will be utilized within all bronchial catheters at the time of the bronchoscopy; (3) a chest x-ray will be obtained and reviewed by the participating physicians immediately following the bronchoscopy and catheter insertion, and prior to patient transport to the brachytherapy unit; and (4) confirmation of the intended treatment site will be obtained from the patient consent form and through verbal communication with the pulmonologist, radiation oncologist, patient, and unit staff members.

State Agency—The State Agency requested that the licensee take the above corrective actions.

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

AS 95-3 Overexposure of Personnel at Gwinnett Medical Center in Lawrenceville, Georgia

Appendix A (see For All Licensees, Criterion No. 1) of this report notes that exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation can be considered an AO.

Date and Place—April 6, 1995; Gwinnett Medical Center; Lawrenceville, Georgia.

Nature and Probable Consequences—Licensee personnel involved in a brachytherapy treatment using iridium-192 seeds received exposures above minimum as a result of handling what they assumed was a dummy source. The personnel included physicists, physicians, technologists and

nursing staff. One of the physicists was pregnant (estimated at 11 weeks), but did not receive any significant overexposure. The most significant case was an overexposure to Physicist A who received 8.83 millisievert (mSv) (883 millirem [mrem]) effective dose equivalent and 12,560 mSv (1256 rem) to the hands. Exposures for other involved individuals were as follows:

Physicist B: 1.15 mSv (115 mrem) effective dose equivalent and 433 mSv (43.3 rem) to the hands

Physician A: 1.08 mSv (108 mrem) effective dose equivalent and 54 mSv (5.4 rem) to the hands

Physician B: 0.31 mSv (31 mrem) effective dose equivalent and 108 mSv (10.8 rem) to the hands

Technologist: 1.55 mSv (155 mrem) effective dose equivalent

It should be noted that physicist A has not shown any signs of erythema.

Cause or Causes—The licensee stated that the overexposures occurred because: (1) the hospital procedures were not followed when ordering the radioactive material; (2) the personnel handling the iridium-192 seeds assumed that they were dummy sources; (3) the physicist who primarily handled the sources did not have proper training and experience, or adequate supervision during the performance of the treatment; (4) a survey meter was not used while opening the shipping container; (5) film badges were not worn or were worn improperly; (6) there was confusion among the physicists as to whether a dummy source was ordered; (7) there were problems in identifying the dummy source from the radioactive seeds, and (8) the source was left unshielded after being returned to the shipping container.

Actions Taken to Prevent Recurrence

Licensee—The licensee addressed the issues involving the incident, and either has or will implement corrective actions to prevent recurrence. Exposure dose calculations have been made by a certified health physicist. The personnel training and accreditation program has been modified. Physicist A and Physicist B have

received inservice training and were advised not to handle any radioactive material until May 1996.

State Agency—The Department of Natural Resources of the State of Georgia investigated the incident. The corrective and preventative actions submitted by the licensee will be reviewed during the next inspection by the Department. Enforcement action will be taken as appropriate.

The event is considered closed for the purpose for this report.

AS 95-4 Medical Brachytherapy Misadministration at Southwest Texas Methodist Hospital in San Antonio, Texas

Appendix A (see Event Type 5[d] in Table A-1) of this report notes that administering a therapeutic dose from a sealed source such that the treatment dose differs from the prescribed dose by more than 10 percent and the event (regardless of health effects) affects two or more patients at the same facility can be considered an AO.

Date and Place—July 28, 1994; Southwest Texas Methodist Hospital; San Antonio, Texas.

Nature and Possible Consequences—Two patients were prescribed brachytherapy procedures using manual loading for prostate treatment. One was prescribed to receive a dose of 160 gray (Gy) (16,000 rad) of iodine-125 and the other was prescribed a dose of 115 Gy (11,500 rad) of palladium-103. However, because of an error the implant sources of the two patients were switched.

The patients and their referring physician were notified of the misadministration. The licensee staff indicated that the two doses were biologically equivalent and stated that the only effects expected are those that would result if the prescribed doses were administered to the correct patients.

Cause or Causes—The licensee was unable to determine how the misidentification occurred.

Actions Taken to Prevent a Recurrence

Licensee—The Radiation Safety Committee immediately implemented new procedures for

ordering, receiving, loading, sterilizing, and implanting prostate implants.

State Agency—The State agency investigated the incident and reviewed the new procedures for prostate implants. No violations were cited.

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

APPENDIX A

ABNORMAL OCCURRENCE CRITERIA¹

The following criteria used to determine an abnormal occurrence (AO) were set forth in an NRC policy statement published in the *Federal Register* on February 24, 1977, (Vol. 42, No. 37, pages 10950-10952).

An event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. Such an event would involve a moderate or more severe impact on the public health or safety and could include but need not be limited to:

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 licensed facilities or material.

Examples of the types of events that are evaluated in detail using these criteria are:

For All Licensees

1. Exposure of the whole body of any individual to 25 rem or more of radiation; exposure of the skin of the whole body of any individual to 150 rem or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation [10 CFR 20.403(a)(1)], or equivalent exposures from internal sources.
2. An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year [10 CFR 20.105(a)].
3. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 500 times the regulatory limit of Appendix B, Table II, 10 CFR Part 20 [CFR 20.403(b)(2)].
4. Radiation or contamination levels in excess of design values on packages, or loss of confinement of radioactive material such as (a) a radiation dose rate of 1000 mrem per hour three feet from the surface of a package containing the radioactive material, or (b) release of radioactive material from a package in amounts greater than the regulatory limit.
5. Any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas.
6. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
7. 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.
8. 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.
9. An accidental criticality [10 CFR 70.52(a)].
10. A major deficiency in design, construction, or operation having safety implications requiring immediate remedial action.
11. Serious deficiency in management or procedural controls in major areas.
12. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create major safety concern.

¹On January 1, 1994, changes to Title 10 of the *Code of Federal Regulations* Part 20 were promulgated. At the Commission's directive, the staff is currently developing a policy statement revising criteria for various types of AOs. The changes pertinent to the 10 CFR 20 revision will also be included in that draft policy statement. Upon Commission's approval, the appropriate changes to this Appendix will be published.

For Commercial Nuclear Power Plants

1. Exceeding a safety limit of license Technical Specifications [10 CFR 50.36(c)].
2. Major degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.
3. Loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).
4. Discovery of a major condition not specifically considered in the Safety Analysis Report (SAR) or Technical Specifications that requires immediate remedial action.
5. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

For Fuel Cycle Licensees

1. A safety limit of license Technical Specifications is exceeded and a plant shutdown is required [10 CFR 50.36(c)].
2. A major condition not specifically considered in the safety analysis report or Technical Specifications that requires immediate remedial action.
3. An event that seriously compromised the ability of a confinement system to perform its designated function.

Medical Misadministrations

As discussed in the Preface to this report, the NRC policy statement on AOs was published before licensees were required to report medical misadministrations to the NRC. Therefore, during 1984, NRC developed guidelines for selecting such events for AO reporting. These guidelines, which are summarized in Table A-1, augment the NRC policy statement.

As noted in the Preface, revised guidelines are currently being developed because new medical misadministration definitions became effective on January 27, 1992.

Table A-1 NRC Guidelines for Selecting Medical Misadministration Events for Abnormal Occurrence (AO) Reporting

Event Type	AO Reporting Threshold	
	Diagnostic Exposure	Therapeutic Exposure
(1) Administering a radiopharmaceutical or radiation from a sealed source other than the one intended.	<p>If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed if:</p> <p>(a) the actual dose to the wrong body part is greater than five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part, or</p> <p>(b) there are clinical indications of any adverse health effects to the wrong body part.</p> <p>If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if:</p> <p>(a) the actual dose is greater than five times that intended to the above described body parts, or,</p> <p>(b) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used.</p>	<p>If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed for any such event.</p> <p>If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if:</p> <p>(a) the actual dose is greater than 1.5 times that intended to the above described body parts, or,</p> <p>(b) the actual dose is less than 0.5 times that intended to the above described body parts, or,</p> <p>(c) the above described bodyparts show signs of adverse health effects greater than expected had the proper administration been used, or</p> <p>(d) the event (regardless of any health effects) affects two or more patients at the same facility.</p>
(2) Administering a radiopharmaceutical or radiation to the wrong patient, or	<p>An AO report should be proposed if:</p> <p>(a) the actual dose to the wrong patient exceeds five times the prescribed dose for the intended patient, or</p> <p>(b) the event results in any adverse health effects.</p>	<p>An AO report should be proposed for any such event.</p>
(3) Administering a radiopharmaceutical or radiation by a	<p>Same guidelines as for Event Type 1.</p>	<p>Same guidelines as for Event Type 1.</p>

Table A-1 (Continued)

Event Type	AO Reporting Threshold	
	Diagnostic Exposure	Therapeutic Exposure
route of administration other than that intended by the prescribing physician.		
(4) Administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent.	An AO report should be proposed if: <ul style="list-style-type: none"> (a) the actual dose is greater than five times the prescribed dose, or, (b) the event results in adverse health effects worse than expected for the normal range of exposures prescribed for the diagnostic procedure. 	Not applicable.
(5) Administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or administering a therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose from the final prescribed total treatment dose by more than 10 percent.	Not applicable.	An AO report should be proposed if: <ul style="list-style-type: none"> (a) the actual dose is greater than 1.5 times the prescribed dose, or, (b) the actual dose is less than 0.5 times the prescribed dose, or (c) the event results in adverse health effects worse than would be expected for the normal range of exposures prescribed for the therapeutic procedure, or, (d) the event (regardless of any health effects) affects two or more patients at the same facility.
(6) Recurring or series of events (regardless of the number of patients or facilities involved).	For either diagnostic or therapeutic exposures, an AO report should be proposed for recurring events or a series of events (in which each individual misadministration is not of major importance) that create a significant public health or safety concern.	
(7) Generic events.	For either diagnostic or therapeutic exposures, an AO report should be proposed for misadministrations with generic implications that create a significant public health or safety concern.	

APPENDIX B

UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During April through June 1995, NRC licensees, Agreement States, Agreement State licensees, and other involved parties, such as reactor vendors and architect-engineering firms, continued with the implementation of actions necessary to prevent recurrence of previously reported abnormal occurrences (AOs). The AOs discussed

below contain a summary of information presented in previous reports and any subsequent updated information provided during the reporting period. Those updated events which still require additional information will be discussed in future reports.

OTHER NRC LICENSEES

92-18 Loss of Iridium-192 Source and Medical Therapy Misadministration at Oncology Services Corporation in Indiana, Pennsylvania

This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 15, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1992," under the title "Loss of Iridium-192 Source and Medical Therapy Misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania."

The AO criteria used were:

- (1) Event Type 5, in Table A-1—A therapeutic dose that is greater than 1.5 times the prescribed dose; and
- (2) For All Licensees, Criterion No. 2—An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year.

On November 16, 1992, Oncology Services Corporation lost a 159,000 gigabecquerel (4.3 curie) sealed iridium-192 source from a high dose rate (HDR) remote afterloader brachytherapy unit at its Indiana Regional Cancer Center in Indiana, Pennsylvania. The source had: (1) broken off of the HDR unit while in service; (2) subsequently killed a patient with a 1,600,000 centigray (1,600,000 rad) absorbed dose, after remaining on the patient's body for almost 4 days; and (3) caused 94 other people to receive radiation ranging from 400 microsievert to 220 millisievert

(40 millirem to 22 rem). The source was eventually mixed by accident with medical biohazard waste and was subsequently found and recovered at the site of a company that had been contracted to dispose of biological waste material.

The AO report is updated as follows:

The licensee submitted information in letters dated August 31, 1994 and October 4, 1994 in response to the NRC's Notice of Violation and Proposed Imposition of Civil Penalties dated May 31, 1994. After consideration of the licensee's responses, NRC concluded that an adequate basis was not provided for withdrawal of any of the violations or for mitigation of the civil penalties. An Order Imposing Civil Penalties - \$280,000 (Order) was issued on April 24, 1995. The licensee had 30 days after the Order was issued to pay the civil penalties. The licensee also had 30 days after the Order was issued to request a hearing on the Order, and it did so via a letter dated May 18, 1995.

Concurrent with the enforcement process, the licensee requested the termination of its license on December 13, 1993, with the license to be replaced by individual licenses issued to the facilities named as locations of use on the Oncology Services Corporation (OSC) license. The OSC license was terminated on August 24, 1994, concurrent with new licenses being issued to five of the six facilities which were previously listed as locations of use on the OSC license.

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

AGREEMENT STATE LICENSEES

AS 88-5 Medical Teletherapy Misadministration at Sacred Heart Hospital in Cumberland, Maryland

This AO was originally reported in NUREG-0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1988."

The AO criterion used was a moderate or more severe impact on public health or safety, as stated in the second paragraph of the General Criteria.

On September 2, 1988, an 81-year-old patient received a therapeutic dose of 1400 centigray (1400 rad) to a part of the body not scheduled to receive radiation. The event was reported as an AO because it involved a moderate or more severe impact on public health or safety.

The AO report is updated as follows:

NRC is continuing to work with the State of Maryland to obtain more information regarding this incident.

This event will be updated when additional information becomes available.

AS 88-6 Multiple Medical Teletherapy Misadministrations at Sacred Heart Hospital in Cumberland, Maryland

This AO was originally reported in NUREG-0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1988."

The AO criterion used was a moderate or more severe impact on public health or safety, as stated in the second paragraph of the General Criteria.

Over a 13-month period 33 patients undergoing brain cancer treatments had received therapeutic radiation exposures from a cobalt-60 teletherapy machine that exceeded the prescribed dose by at least 10 percent in each case. The event was reported as an AO because it involved a moderate or more severe impact on public health or safety.

The AO report is updated as follows:

NRC is continuing to work with the State of Maryland to obtain more information regarding these incidents.

This event will be updated when additional information becomes available.

APPENDIX C

OTHER EVENTS OF INTEREST

"Other Events of Interest" are reported because they can be perceived as being significant but have been determined not to involve a major reduction in the level of protection provided for public health or safety; therefore they are not reportable as abnormal occurrences.

During the period from April 1 through June 30, 1995, no "Other Events of Interest" items were reported.

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11. ABSTRACT (200 words or less)

Section 208 of the Energy Reorganization Act of 1974 identifies abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission determines to be significant from the standpoint of public health or safety requires a quarterly report of such occurrences to be made to Congress. This report provides a description of those incidents and events that have been determined to be AOs during the period of April 1 through June 30, 1995.

This report addresses five AOs at NRC-licensed facilities. One involved a reactor coolant system blowdown at a pressurized water reactor (PWR) nuclear power plant, one involved a previously unidentified path for the potential release of radioactivity at a PWR nuclear power plant, two involved medical brachytherapy misadministrations, and one involved a medical therapeutic radiopharmaceutical misadministration. Four AOs submitted by the Agreement States are included. One involved a medical teletherapy misadministration, two involved medical brachytherapy misadministrations, and one involved the overexposure of personnel at a medical center. The report also contains an update of one AO previously reported by an NRC licensee and two AOs previously reported by the Agreement States. No "Other Events of Interest" items are being reported.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

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