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Report to Congress on Abnormal Occurrences

Fiscal Year 1999

U.S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually. This report includes those events that NRC determined were AOs during Fiscal Year 1999.

The report addresses four AOs at facilities licensed or otherwise regulated by NRC. One event involved a fire that breached containment and required shutdown of a portion of the cascade at a gaseous diffusion plant. Two medical events involved the administration of radioactive material to pregnant women and one event involved a sodium iodide misadministration. The report also addresses nine AOs at facilities licensed by Agreement States. Agreement States are those States that have entered into a formal agreement with NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 31 Agreement States. One of the Agreement State AOs involved the administration of radioactive material to a pregnant woman, two involved overexposures of an occupational worker and a member of the public at industrial radiography operations, two involved gamma stereotactic radiosurgery misadministrations, three involved therapeutic radiopharmaceutical misadministrations, and one involved sodium iodide misadministration. In addition, Appendix C of the report, "Other Events of Interest," includes two events and one issue with two examples.

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PREFACE

INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines is significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually. This report discusses those events that NRC determined were AOs during Fiscal Year 1999.

NRC defined AOs 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 (42 FR 10950). This policy statement was published before medical licensees were required to report medical misadministrations to NRC, and few of the examples in the policy statement were applicable to these misadministrations. Therefore, in 1984, NRC adopted additional guidance for reporting medical misadministrations as AOs.

In 1996, NRC revised the AO criteria, including criteria for medical misadministrations, and published them in the *Federal Register* on December 19, 1996 (61 FR 67072). In 1997, NRC again revised these criteria to include AO criteria for gaseous diffusion plants and published them in the *Federal Register* on April 17, 1997 (62 FR 18820). The events included in this report were determined to be AOs based on the 1997 AO criteria.

To disseminate information widely to the public, a *Federal Register* notice is issued on events reported by facilities licensed or otherwise regulated by NRC or an Agreement State that have been determined to be AOs. At a minimum, each notice must contain the date on which and place where the AO occurred and must describe its nature and probable consequences. Information on activities licensed by Agreement States is also publicly available from the appropriate Agreement State. The notice and the report to Congress are available electronically at the NRC Public Electronic Reading Room link <http://www.nrc.gov/NRC/ADAMS/index.html> at the NRC Homepage.

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

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

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* (10 CFR). Public participation is an element of the regulatory process. To accomplish its objectives, NRC regularly conducts licensing proceedings, inspection and enforcement activities, operating experience evaluation, and confirmatory research, while maintaining programs for establishing standards and issuing technical reviews and studies.

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

REPORTABLE OCCURRENCES

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

NRC and the industry review operating experience to help identify safety concerns early in order to improve dissemination of such information and to feed back the experience into licensing, regulations, and operations. The information about operational data is maintained in computer-based data files for more effective collection, storage, retrieval, and evaluation.

Except for records exempt from public disclosure by statute or regulation, NRC routinely disseminates information concerning reportable occurrences at facilities licensed or otherwise regulated by NRC to the industry, the public, and other interested groups as these events occur.

Dissemination includes special notifications (to licensees and other affected or interested groups) and public announcements. In addition, information on reportable events is available electronically. Congress is routinely informed of reportable events occurring in facilities licensed or otherwise regulated by NRC.

AGREEMENT STATES

Section 274 of the Atomic Energy Act, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes, and the States assume, regulatory authority over byproduct, source, and special nuclear materials (in quantities not capable of sustaining a chain reaction). Agreement States must maintain programs that are adequate to protect public health and safety and compatible with the Commission's program for such material. Currently, there are 31 Agreement States.

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

FOREIGN INFORMATION

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

REOPENING OF CLOSED ABNORMAL OCCURRENCES

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

ABNORMAL OCCURRENCES IN FISCAL YEAR 1999

NUCLEAR POWER PLANTS

Using the criteria and guidelines in Appendix A to this report, none of the events that occurred at U.S. nuclear power plants during this reporting period was determined to be significant enough to be reported as an abnormal occurrence (AO) in this reporting period.

FUEL CYCLE FACILITIES
(Other Than Nuclear Power Plants)

Using the criteria in Appendix A to this report, one event that occurred at a fuel cycle facility during this fiscal year was determined to be significant enough to be reported as an AO in this reporting period:

99-1 Fire Breaches Containment and Requires Shutdown of a Portion of the Cascade at the Portsmouth Gaseous Diffusion Plant in Piketon, Ohio

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criteria III.A and III.C, "For Fuel Cycle Facilities") to this report states, in part, that an event will be considered an AO if it represents a shutdown of a portion of the plant resulting from a significant event or a significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a radiological or chemical process hazard.

Date and Place — December 9, 1998; Portsmouth Gaseous Diffusion Plant, a uranium enrichment plant, operated by Lockheed Martin Utility Services for the United States Enrichment Corporation, located about 3.2 kilometers (2 miles) east of Piketon, Ohio.

Nature and Probable Consequences — On December 9, 1998, the certificate holder's operations staff observed a series of abnormal conditions associated with the side purge cascade, Cell 25-7-2. The staff's immediate response to the abnormal conditions was not successful in restoring normal operations and an exothermic reaction was either started or propagated within the cascade. The exothermic reaction continued until sufficient heat was generated to cause a failure of the Cell 25-7-2 cooling system, initiating a second exothermic reaction. Subsequent heat and pressure increases within the side purge cascade resulted in (1) the creation of holes within the process gas cascade boundary of Cell 25-7-2, (2) an automatic shutdown of the side purge cascade caused by the motor load overcurrent protection system which provides "Defense in Depth," (3) the activation of a portion of the Building X-326 automatic fire suppression sprinkler system, (4) an emergency response and approximately 2 hours of firefighting activities by the onsite fire department, and (5) challenges to the continued operation of the remainder of the process gas cascade.

There were no measurable radiological consequences or chemical consequences to the plant staff or the general public from the release of radioactivity during this event. The holes created

in the side purge cascade equipment and piping created a credible pathway for water to accumulate in unsafe geometry sections of the cascade. This led to the need to revise the criticality safety basis for this portion of the side purge cascade.

Cause or Causes — The extensive fire damage experienced by Cell 25-7-2 equipment has made it difficult to determine the root cause. Much of the equipment has been damaged to such an extent that evidence needed to determine the root cause was destroyed. The investigation by the certificate holder identified two possible initiating events: a physical failure of the compressor impeller or a chemical deposit caused by wet air leakage into the equipment. In either event, mechanical friction within the process gas cascade equipment generated a sufficient amount of sustained heat to begin an exothermic reaction between the aluminum compressor components and the process gas (uranium hexafluoride). On the basis of a review of some of the Cell 25-7-2 components removed since the fire, the exothermic reaction was believed to have been initiated in the Stage 2 compressor and propagated through the cell equipment to the Stage 4 compressor. In the Stage 4 compressor, the reaction was thought to have been intensified by the input gases, received from the remainder of the cascade, resulting in increasing internal process gas cascade temperatures until there was a failure in the freon coolant system boundary. Elevated pressure, caused by the introduction of freon from the coolant system and a second exothermic reaction between the hot metal and freon, was thought to be the final event that occurred before the holes were burned in the process gas cascade boundary.

Actions Taken To Prevent Recurrence

Certificate Holder — Initial compensatory and corrective measures implemented by the plant staff as a result of the fire included: (1) administrative controls to preclude a restart of the side purge cascade and some other plant operations pending the completion of a root cause evaluation for the fire, (2) immediate manual vibration monitoring of other centrifugal compressors to search for other unstable equipment, (3) covering of openings created in the process gas piping and equipment of Cell 25-7-2 as a result of the fire, (4) development of a revised nuclear criticality safety basis for Cell 25-7-2, (5) interim training of cascade operators and managers on the lessons learned about operations from the event, and (6) interim training of firefighters and management on the safety risks of and the proper fire fighting techniques for a fire concurrent with holes in process gas cascade equipment. The long-term corrective actions include the following "Defense in Depth" features and administrative actions: (1) adding process gas temperature monitoring to detect high temperature reactions in a timely manner, (2) adding alarm and automatic shutdown systems on the side purge compressors for compressor high-process gas temperature to protect against the propagation of high temperature accidents by detecting hot spots in a timely manner, (3) improving the process for evaluating and responding to cascade component vibrations to improve the identification of precursors to a hot metal reaction, and (4) completing procedures for improving operator response to other precursors to hot metal reactions. These corrective actions will be instituted prior to re-introducing process gas into the side purge cascade.

NRC — An augmented inspection team was sent to the site on December 9, 1998. The team documented its findings in an inspection report issued on February 19, 1999. A follow-up inspection was conducted in March 1999 to evaluate the effectiveness of the certificate holder's corrective actions. Although the follow-up inspection team found the certificate

holder's corrective actions adequate, several procedural and reporting violations were identified during the follow-up inspections. One violation was that the event met the criteria for an "Alert" declaration and that the certificate holder failed to identify and declare the Alert. Since many credible accidents postulated for the Portsmouth Gaseous Diffusion Plant can occur suddenly and last a short duration, it is important for the certificate holder to make proper and timely emergency declarations that would lead to timely notifications to the appropriate regulatory agencies. Therefore, even though, in this case, there were no significant radiological releases to the environment, the NRC staff considered the certificate holder's failure to declare an Alert, which is the lowest level emergency category, a serious violation (Level III) that carried a $55,000 civil penalty. The certificate holder acknowledged the violation and paid the civil penalty.

This event is closed for the purpose of this report.

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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 NRC during this reporting period were determined to be significant enough to be reported as abnormal occurrences (AOs):

99-2 Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at St. Joseph Health Center in Kansas City, Missouri

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.3, "For All Licensees") to this report states, in part, that any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician will be considered an AO.

Date and Place — October 6, 1998; St. Joseph Health Center; Kansas City, Missouri.

Nature and Probable Consequences — After a patient was administered a 5.75 gigabecquerel (155.2 millicurie) dosage of iodine-131 (I-131) for ablation of residual thyroid tissue and for the treatment of metastatic thyroid cancer, the patient was determined to be pregnant.

Preceding the administration of the I-131 therapy dosage, the licensee's nuclear medicine technologist and the authorized user, following internal policies and procedures to determine the pregnancy status of a patient, repeatedly questioned the patient regarding the possibility of a pregnancy and whether she was breast-feeding. The patient stated that she was not breast-feeding and there was no possibility of pregnancy. Approximately 3½ hours after the I-131 administration, the licensee received the positive results of a pregnancy test previously ordered by the patient's referring physician. The licensee had not been aware that the referring physician had ordered the pregnancy test.

Upon notification of the pregnancy, the licensee told the patient she was pregnant and attempted to minimize the potential exposure to the fetus by having the patient increase fluid

intake in order to flush the free iodine from her system. The licensee also notified the patient's referring physician of the event. Ultrasound performed following identification of the pregnancy confirmed that the patient had been approximately 13½ weeks pregnant with twins at the time of the procedure.

The licensee does not expect the patient to experience any ill effects. The dose equivalent to each fetus was estimated to be about 0.38 sievert (Sv) (38 rem) and the dose equivalent to each fetal thyroid was estimated to be in excess of 2,000 Sv (200,000 rem). The licensee expected that such a dose would result in the following likely effects to the fetuses (1) thyroid ablation, (2) a 30 percent increase in the likelihood of microcephaly (small head size), (3) a 20 to 50 percent increase in the probability of childhood cancer, and (4) an increased probability for mental retardation. On the basis of this information, the patient elected to terminate the pregnancy.

Cause or Causes — This medical event appears to have been caused by the licensee's reliance on the patient's statements preceding the administration of I-131 that she was not pregnant. The patient's referring physician had ordered a pregnancy test for the patient preceding the administration of I-131; however, neither the patient nor the referring physician had informed the licensee. The referring physician believed that the pregnancy test was standard practice preceding all radiopharmaceutical therapy treatments.

Actions Taken To Prevent Recurrence

Licensee — The licensee modified its internal procedures for the administration of therapeutic radiopharmaceuticals, including diagnostic quantities of I-131 in excess of 7.4 megabecquerel (MBq) (200 microcurie [μCi]). All such procedures will include a statement that female patients between the ages of 10 and 55 years, without exception, prescribed to receive I-131 dosages equal to or greater than 7.4 MBq (200 μCi) shall obtain a "beta serum pregnancy test" within 24 hours preceding administration.

NRC — The NRC staff reviewed the licensee's revised procedures and determined that they were adequate to address the cause of this medical event and to preclude similar events. Because the licensee made a reasonable effort to obtain a confirmation from the patient that she was not pregnant before the I-131 administration, no NRC requirements were violated.

The corrective actions taken by the licensee were voluntary and were not required by NRC regulations.

This event is closed for the purpose of this report.

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99-3 Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at Camden-Clark Memorial Hospital in Parkersburg, West Virginia

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.3, "For All Licensees") to this report states, in

part, that any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician will be considered an AO.

Date and Place — September 1, 1998; Camden-Clark Memorial Hospital; Parkersburg, West Virginia. The investigation on this event was completed in Fiscal Year 1999.

Nature and Probable Consequences — A patient was administered 340 megabecquerel (MBq) (9.2 millicurie [mCi]) of sodium iodide-131 (I-131) in accordance with licensee procedures for the treatment of hyperthyroidism. However, after the procedure was performed, the licensee learned that the patient was pregnant.

On July 15, 1998, the patient was scheduled for a thyroid uptake and scan involving the administration of 7.62 MBq (0.206 mCi) of iodine-123 (I-123). Before performing the procedure, the licensee's nuclear medicine technologist asked the patient if she was pregnant. The patient indicated that she was not pregnant and the technologist administered the dosage of I-123. On August 4, 1998, the patient was examined by one of the licensee's authorized users. As part of the examination, the patient was asked about her pregnancy status and she again stated that she was not pregnant. The licensee confirmed with the patient's referring physician a negative pregnancy test, performed on May 5, 1998. The authorized user determined that the patient was a good candidate for I-131 therapy based on the results of the thyroid scan and other tests and prepared a written directive for the administration of 333 MBq (9 mCi) of I-131. The authorized user informed the patient about the effects of I-131 to the fetus if it is administered to a pregnant patient. The patient signed a form acknowledging the risks associated with the procedure, as explained by the authorized user, and stated that she would not become pregnant for 1 year after the I-131 procedure.

The patient returned to the licensee's facility on September 1, 1998, and was administered 340 MBq (9.2 mCi) of I-131 in accordance with the written directive and other licensee procedures regarding the administration of radiopharmaceuticals. On October 5, 1998, the patient informed the licensee about recent information she received indicating that she was about 5 months pregnant. Subsequently, it was determined that the patient had been 14 weeks pregnant at the time of the administration.

The licensee personnel contacted a pediatric endocrinologist for assistance in calculating the thyroid and the whole-body doses to the fetus. Using the information supplied by the licensee, the dose equivalent to the fetus was estimated to be about 0.023 sievert (Sv) (2.3 rem) and the dose equivalent to the fetal thyroid to be about 88 Sv (8,800 rem). The fetus received intra-amniotic thyroid hormone therapy from high-risk pregnancy specialists at a major university hospital.

On October 8, 1998, the licensee notified the patient's referring physician of the event and potential consequences. On October 20, 1998, the licensee notified the NRC of the event. The NRC staff engaged a medical consultant to evaluate the incident. The consultant concluded that (1) the hypothyroidism developed in the fetal thyroid is expected to be permanent, (2) there is no increase in the risk of thyroid carcinoma, (3) a radiation-induced severe mental retardation is unlikely, and (4) the risk of leukemia and other childhood cancers is slightly higher than normal. At the time of the evaluation of this event the patient had decided to continue the pregnancy.

Cause or Causes — The cause of the event was the licensee's assumption that the patient was not pregnant at the time the radiopharmaceutical was administered based on the verbal and written statements made by the patient to the licensee staff.

Actions Taken To Prevent Recurrence

Licensee — The licensee is considering professional standards such as the 1996 American College of Radiology's "Standard for the Performance of Therapy with Unsealed Radioactive Sources," which specifies acceptable methods for ruling out pregnancy preceding the administration of therapeutic doses of radiopharmaceuticals. These include a pregnancy test obtained within 48 hours preceding administration of the radiopharmaceutical; or documented hysterectomy or tubal ligation; or post-menopausal condition.

NRC — An inspection was conducted to review the circumstances of the event. Because the licensee made a reasonable effort to obtain a confirmation from the patient that she was not pregnant before the I-131 administration, no NRC requirements were violated.

The corrective actions taken by the licensee were voluntary and were not required by NRC regulations.

This event is closed for the purpose of this report.

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99-4 Sodium Iodide Radiopharmaceutical Misadministration at Holy Redeemer Hospital and Medical Center in Meadowbrook, Pennsylvania

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

Date and Place — September 14, 1999; Holy Redeemer Hospital and Medical Center; Meadowbrook, Pennsylvania.

Nature and Probable Consequences — A patient's referring physician intended for the patient to receive a thyroid uptake and scan. The licensee routinely performed this procedure using iodine-123 (I-123). However, because of an error, the patient was administered iodine-131 (I-131).

The authorized user intended to administer 11.1 megabecquerel (MBq) (0.300 millicurie [mCi]) of I-123 to a patient for the evaluation of hyperthyroidism. However, no one prepared a written directive to indicate the type of thyroid procedure to administer. The patient was mistakenly listed on the licensee's schedule for a whole-body imaging as part of an evaluation for thyroid cancer therapy. The licensee routinely performs this type of procedure using I-131. Therefore,

the licensee's technologist administered a 196.1 MBq (5.3 mCi) dosage of I-131 without obtaining a written directive. As a result of this error, the licensee's medical physicist determined that the patient's thyroid received an unintended dose of about 41.9 gray (4,190 rad) based on a 65 percent uptake.

The NRC's consultant stated that the impact of the misadministration on the status of the patient's health should be negligible, with no expected long-term disability. The licensee believes that no harm was done to the patient because the patient's condition required additional thyroid treatment using I-131. The patient was notified of the misadministration on September 16, 1999, and a written report was prepared. The patient's referring physician was also notified.

Cause or Causes — The technologist performed a thyroid procedure using I-131 without a written directive from an authorized user. The licensee's authorized user was not involved in the process of administration of I-131 to clarify what type of thyroid evaluation was needed for the patient.

Actions Taken to Prevent Recurrence

Licensee — The licensee counseled the technologist on the importance of implementing the NRC regulations.

NRC — The NRC staff conducted a special safety inspection on September 17, 1999, and is evaluating enforcement options.

This event is closed for the purpose of this report.

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AGREEMENT STATE LICENSEES

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

AS 99-1 Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at Via Christi Regional Medical Center in Wichita, Kansas

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.3, "For All Licensees") to this report states, in part, that any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician will be considered an AO.

Date and Place — May 7, 1999; Via Christi Regional Medical Center; Wichita, Kansas.

Nature and Possible Consequences — A pregnant patient was administered a 436.6 megabecquerel (MBq) (11.8 millicurie [mCi]) dosage of I-131 for a thyroid treatment.

Before the treatment, the technologist and the authorized user interviewed the patient regarding her pregnancy status and the patient certified that she was not pregnant and signed a consent form for the treatment. The patient then was administered the dosage of 436.6 MBq (11.8 mCi) of I-131. Approximately one week after the I-131 administration during a routine gynecological exam the patient learned that she was between 18 and 20 weeks pregnant.

A telephone report was made to the State of Kansas Radiation Control Program on May 12, 1999, and the State staff conducted an on-site investigation on May 13, 1999. They contacted the Department of Energy's Radiation Emergency Assistance Center/Training Site (REACTS) in Oak Ridge, Tennessee for assistance. REACTS provided initial medical guidance and dosimetry calculations and agreed to act as consultant to the attending physician.

The dose equivalent to the fetus was estimated to be about 0.03 sievert (Sv) (3 rem) and the dose equivalent to the fetal thyroid was about 253 Sv (25,300 rem). The fetal thyroid dose was considered to be ablative. The authorized user notified the patient and her husband about the fetal exposure and the possible consequences. The patient continued her pregnancy to full term.

Causes or Causes — The cause of the event was the licensee's assumption that the patient was not pregnant at the time the radiopharmaceutical was administered based on the verbal and written statements made by the patient to the licensee staff.

Actions Taken To Prevent Recurrence

Licensee — The licensee's radiation safety officer conducted an investigation and determined that the licensee's procedures and policies had been followed and that a reasonable effort had been made to determine the pregnancy status of the patient preceding the administration of I-131. The licensee indicated a revision of its policy to require that all females of child-bearing age be tested for pregnancy preceding administration of therapeutic doses of radioactive material.

State Agency — The State staff conducted an investigation and agreed with the licensee's findings and believes that the licensee's proposal is adequate to prevent recurrence.

The corrective actions taken by the licensee were voluntary and were not required by the State Agency.

This event is closed for the purpose of this report.

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AS 99-2 Industrial Radiography Occupational Overexposure at Global X-ray and Testing Corporation in Aransas Pass, Texas

The following information pertaining to this event is also being reported concurrently in the *Federal Register.* Appendix A (See Criterion I.A.1, "For All 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 total effective dose equivalent (TEDE) of 250 millisievert (mSv)

(25 rem) or more or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more will be considered an AO.

Date and Place — December 31, 1998; Global X-ray and Testing Corporation; Aransas Pass, Texas.

Nature and Probable Consequences — A radiography trainee failed to retract a 4.6 terabecquerel (123 curie) source of iridium-192 into the shielded position after taking a radiograph (exposure). As a result, the trainee received an estimated TEDE of about 100 mSv (10 rem) and an extremity annual shallow-dose equivalent of about 30,000 to 50,000 mSv (3,000 to 5,000 rem).

On December 31, 1998, a radiographer and a radiography trainee were working at a job site. At about 6:00 p.m., the radiography trainee thought that the radiography work was completed and removed a tool belt with a dosimeter and an alarming ratemeter and placed it in the truck. However, the radiographer asked the trainee for assistance to obtain additional radiographs. The trainee tried to take an additional radiograph but the source would not crank and the trainee realized that the source was not retracted into the shielded position after the previous exposure. During this process, the trainee stood at the end of the guide tube for approximately 4 minutes at a distance of about 61 centimeters (2 feet) and touched the end of the guide tube where the source was located three or four times for about 2 or 3 seconds each time.

On January 10, 1999, signs of a radiation injury, including redness, dry skin, and slight swelling accompanied by aching pain, appeared in the index finger of the trainee's right hand. On January 27, 1999, the finger developed a callous. On follow-up of the symptoms, it was indicated that the trainee received an extremity annual shallow-dose equivalent of about 30,000 to 50,000 mSv (3,000 rem to 5,000 rem).

Cause or Causes — The company's president told the office manager that the radiographer could act as a trainer because the paperwork requesting to name the individual radiographer as a trainer had been mailed to the State's Bureau of Radiation Control. Therefore, the radiographer was sent with the trainee to the job site. However, the radiation safety officer later told the office manager and the president of the company that Global X-ray and Testing Corporation had not yet received a license amendment naming the radiographer as a trainer.

The radiographer had been a trainer for several other radiography companies and was familiar with the requirements for a trainer working with a trainee. However, the radiographer was new with the company, was not familiar with this trainee, and was not aware that the trainee was not a radiographer. Therefore, the trainee was not appropriately supervised.

The trainee thought that the work for the day was completed and took the belt off and put it in the truck. The dosimeter and alarming rate meter were on the tool belt and were not used during the additional exposures. An operating survey meter was available, but the trainee did not use it during the radiographs.

Actions Taken To Prevent Recurrence

Licensee — The licensee met with all the radiography personnel to discuss the incident and make a presentation on radiation safety. Trainees were told to verify they were assigned to work with a trainer before leaving for a job site and radiographers were told to verify whether or not they were assigned to work with trainees. A memorandum stating these requirements was added to the licensee's safety training program. The office manager was given a written reprimand, which stated that another violation of any radiation regulation or safety policy would result in immediate termination of employment. The radiographer and the radiographer trainee had their employment terminated.

State Agency — The licensee was cited for violations of the radiation safety program and an escalated enforcement conference was conducted. As a result, inspection of the licensee's program and the radiographers' audit frequency was increased. A "Preliminary Report for Assessment of Administrative Penalties" was compiled and the licensee requested a settlement conference with the State agency.

This event is closed for the purpose of this report.

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AS 99-3 Industrial Radiography Overexposure to a Member of the Public at Professional Service Industries, Inc. in Seattle, Washington

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.1, "For All 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 total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more will be considered an AO.

Date and Place — December 16, 1998; Professional Service Industries, Inc.; Seattle, Washington.

Nature and Probable Consequences — The Washington State Department of Health was notified by Professional Service Industries, Inc. (PSI), that on December 16, 1998, a contractor's employee (member of the public) had accidentally handled a source guide tube containing a 2.22 terabecquerel (60 curie) iridium-192 radiography source at a temporary job site in Seattle, Washington.

A radiographer and a radiographer's assistant working for PSI were performing radiography at a large parking garage of an office building. The building entrances and the place where radiographs (exposures) were taken were properly posted. Two of the contractor's employees were allowed inside the parking garage along with the radiographer in order to mark locations for future radiographs. The radiographer was talking with the contractor's employees while a radiograph was in process. One of the contractor's employees needed a ladder and approached the ladder in the garage that was being used to support the radiography source collimator. The radiography source collimator was positioned on the top of the ladder. The

contract employee's actions dislodged the collimator from the source guide tube. The radiographer's assistant, who was monitoring the floor above the parking garage, came back to the garage and saw the contractor's employee trying to reassemble the collimator and the guide tube. The radiographer's assistant immediately shouted a warning and the radiographer, being alerted, ran to crank in the source to a safe position.

PSI's radiation safety officer (RSO) at the Seattle office and the corporate RSO were notified and PSI began an immediate investigation, including a re-enactment. Preliminary shallow-dose equivalent estimates for the extremities ranged from 6 to 17 sievert (Sv) (600 to 1700 rem). The Washington State Department of Health's Radiation Control Program was notified approximately 4 hours after the incident occurred ~~and~~ an investigation team was dispatched the next morning. The Washington Radiation Control Program estimated that the individual received a shallow-dose equivalent of (1) 6.8 Sv (680 rem) to the right thumb, (2) 1 Sv (100 rem) to the right index finger, and (3) 1.7 Sv (170 rem) to the palm of the left hand. The TEDE was estimated to be less than 0.05 Sv (5 rem). A cytogenetic study by the Department of Energy's Radiation Emergency Assistance Center/Training Site in Oak Ridge, Tennessee, determined that the TEDE was in the range of 0.01 to 0.15 Sv (1 to 15 rem).

No physical signs of radiation damage to the contract employee's hands were observed by the primary physician during the weeks following the incident. The exposed individual and his physician were kept informed of the findings of the investigation.

Cause or Causes — The cause of the incident was attributed primarily to the radiographer's failure to (1) maintain direct surveillance of a radiography operation and (2) warn individuals in the area that an exposure was underway.

Actions Taken To Prevent Recurrence

Licensee — PSI has complied with the corrective actions recommended by the State by (1) completing a 2-day training for the Seattle PSI radiography personnel based on the incident, (2) accelerating the schedule of field audits of the PSI Seattle radiography personnel, and (3) performing a cytogenetic study for the contractor's employee.

State Agency — PSI was cited for violations that resulted in the overexposure of a member of the public and for failure to maintain direct surveillance of the radiography operation by allowing a member of the public to enter a high-radiation area.

This event is closed for the purpose of this report.

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AS 99-4 Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at University of Maryland Medical Systems in Baltimore, Maryland

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. 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 equal to or greater than 10 gray (Gy) (1,000 rad) to an organ (other than a major portion of the bone marrow, lens of

the eye, or gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered an AO.

Date and Place — December 16, 1997; University of Maryland Medical Systems; Baltimore, Maryland. The State agency was notified of this misadministration on December 17, 1997, and performed an investigation of the event. The investigation was completed on October 23, 1998.

Nature and Probable Consequences — A patient was prescribed a radiation therapy treatment using a gamma knife device for a brain metastasis involving three lesions. The patient was prescribed 1,600 centigray (cGy) (1,600 rad) to the first lesion. However, because of an error in the treatment plan, the first lesion received 2,600 cGy (2,600 rad).

The neurosurgeon prepared the treatment plan for the first lesion. While treating the first lesion, the neurosurgeon prepared the treatment plans for the second and third lesions. However, the treatment plan for the second lesion unintentionally included the settings for a treatment of a focal point of the first lesion. The neurosurgeon and the oncologist reviewed the treatment plans but failed to identify any deviation from the prescribed dose. After the three lesions had been treated, the medical physicist who reviewed the dose calculations determined that an error occurred that resulted in an overdose to the first lesion. The licensee's oncologist determined that the administered overdose was within the range of acceptable prescribed dose for intra-cranial lesions. It was not anticipated that any complications would occur in addition to those normally seen with this type of therapy treatment.

The neurosurgeon notified the patient and the referring physician of the event on December 17, 1997. A letter confirming the discussion of the event was also sent to the patient on January 8, 1998. The patient died on January 20, 1998, of lung cancer.

Cause or Causes — This misadministration was caused by human error in preparing the treatment plans. The neurosurgeon and the oncologist did not follow procedures describing the team approach in treatment planning. Furthermore, the treatment planning procedure did not accurately reflect the role and responsibilities of each type of authorized user. Finally, the neurosurgeon and the oncologist reviewed and signed the treatment plan without identifying the unintended dose.

Actions Taken To Prevent Recurrence

Licensee — The licensee immediately implemented measures to ensure that treatment will only be carried out after planning for all treatment sites is completed. The medical physicist will participate in the entire treatment planning process and will review the treatment plan before the plan is executed. The neurosurgeon and the oncologist will collaborate at critical points in the process, such as dose selection, approval of the written plan, and initiation of treatment.

State Agency — The licensee was cited for violations that included training deficiencies, failure of the radiation safety committee and the radiation safety officer to assume their duties and responsibilities, failure to apply for and receive license amendments before changing

procedures, and failure to comply with notification requirements. Enforcement action is pending.

This event is closed for the purpose of this report.

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AS 99-5 Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at Good Samaritan Hospital in Los Angeles, California

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

Date and Place — October 15, 1998; Good Samaritan Hospital; Los Angeles, California.

Nature and Probable Consequences — A patient was prescribed treatment of 9,000 centigray (cGy) (9,000 rad) to the left trigeminal nerve. However, the treatment was administered to the patient's right trigeminal nerve.

The licensee's medical physicist prepared a treatment plan for the wrong treatment site (right trigeminal nerve). The radiation oncologist, who was an authorized user on the license, signed the treatment plan without verifying the neurosurgeon's request, which listed the correct treatment site (left trigeminal nerve). Because the head restraint was positioned correctly on the patient, the medical physicist experienced difficulty positioning the patient in the gamma knife for the incorrect treatment site. In response to questions from the medical physicist, both the patient and the nurse informed him that the correct treatment site was the left trigeminal nerve. Inexplicably, this did not lead the medical physicist to recognize that he was about to treat the wrong trigeminal nerve. The error was discovered after the procedure was completed. As a result, the patient received a dose of 9000 cGy (9000 rad) to the wrong treatment site. During this procedure, the medical physicist was training another medical physicist on how to use the facility's gamma knife equipment. The patient's neurosurgeon was not present during this procedure because of a scheduling conflict, even though it was the licensee's standard practice for the neurosurgeon to be present.

Treatment of the intended left trigeminal nerve was postponed pending evaluation of the medical outcome of the treatment of the wrong trigeminal nerve. The patient's physician stated that the patient might experience increasing numbness on the affected area of the face within 1 to 18 months. If the numbness occurs, it may affect the plan for treating the prescribed left site.

Cause or Causes — The misadministration occurred because (1) the medical physicist prepared a treatment plan for the wrong treatment site, (2) the radiation oncologist signed the treatment plan without properly verifying it, and (3) the neurosurgeon was not present during the procedure, which differed from standard licensee practice. The radiation oncologist had

not conferred with the patient before the treatment, which may have contributed to the incorrect site treatment. Although it is possible that his training of the other medical physicist distracted the medical physicist, this could not be determined as a contributing cause.

Action Taken To Prevent Recurrence

Licensee — The licensee revised the gamma knife treatment procedure to require that (1) the treatment plan be verified before each procedure by the neurosurgeon, the radiation oncologist, and the medical physicist, (2) two of the three individuals (the neurosurgeon, the radiation oncologist, and the medical physicist) verify that the treatment program coordinates are correctly set, (3) either the neurosurgeon or the radiation oncologist verify the prescribed treatment site after the patient is positioned, and (4) the neurosurgeon and either the radiation physicist or the radiation oncologist be physically present during the treatment. Also, the radiation oncologist shall examine the patient before the treatment and verify the treatment site.

State Agency — The State cited the licensee for failure to report the therapeutic misadministration within 24 hours as required. The licensee was also cited for failure of the authorized user to verify the dosimetry plan and treatment programming.

This event is closed for the purpose of this report.

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AS 99-6 Therapeutic Radiopharmaceutical Misadministration of Iodine-131 to the Wrong Individual at Hermann Hospital in Houston, Texas

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.1, "For All 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 total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads of 2,500 mSv (250 rem) or more will be considered an AO.

Date and Place — August 4, 1999; Hermann Hospital; Houston, Texas.

Nature and Possible Consequences — A patient was scheduled to receive a 1010 megabecquerel (MBq) (27.3 millicurie [mCi]) dosage of iodine-131 (I-131) for a thyroid treatment. However, because of an identification error, the wrong individual was administered the I-131.

Two middle-aged female Asian patients were at the licensee's nuclear medicine department for different procedures. The patient who was scheduled to receive the I-131 dosage left the waiting room. The licensee's technologist approached the other patient to verify her name and date of birth by stating the name and date of birth of the patient who was to receive the I-131 treatment. The patient responded with "yes," although she did not understand the questions. She also indicated she understood the instructions previously given to her about the I-131

treatment. Therefore, she was administered the dosage of I-131. Later it was found that the I-131 was administered to the wrong individual. The licensee ordered another dosage of I-131, which was administered to the correct patient as prescribed.

The licensee estimated that (1) the dose to the patient's thyroid as a result of the misadministration was about 220 gray (22,000 rad), (2) the patient has about an 85 percent chance of losing thyroid function, and (3) replacement thyroid hormone will be required indefinitely. The patient's attending physician was contacted and remedial action was taken.

Causes or Causes — The patient who received the misadministration spoke English as a second language. She was asked identification questions that could be answered "yes" or "no" without her actually understanding the meaning of the questions. No further verification of the patient's identification was performed.

Actions Taken To Prevent Recurrence

Licensee — The licensee has changed procedures for all outpatient therapy treatments that involve radioactive materials. The format of questions for patient identification will be revised to read "What is your name?" and "What is your date of birth?" instead of "Is your name ...?" or "Is your date of birth ...?" Outpatients will also be asked to show a picture form of identification. In the case of pediatric patients, the child's parent or guardian must confirm the patient's identification.

State Agency — The licensee was cited for administering a therapeutic dosage of I-131 to the wrong individual, who had a normally functioning thyroid, and for the authorizing physician user not being physically present when therapy procedures were being performed. Enforcement action is pending.

This event is closed for the purpose of this report.

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AS 99-7 Therapeutic Radiopharmaceutical Misadministration of Iodine-131 to the Wrong Individual at Milton Hospital in Milton, Massachusetts

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Criterion I.A.1, "For All 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 total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual sum of the deep dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads of 2,500 mSv (250 rem) or more will be considered an AO.

Date and Place — July 31, 1998; Milton Hospital; Milton, Massachusetts. The information on this event was sent to the NRC staff in March 1999.

Nature and Possible Consequences — A patient was prescribed a diagnostic dosage of 270.1 megabecquerel (MBq) (7.3 millicurie [mCi]) of technetium-99m (Tc-99m) for a thyroid

scan. However, the patient was erroneously administered a therapeutic dosage of 318.2 MBq (8.6 mCi) of iodine-131.

The licensee's technologist administered the patient the diagnostic dosage of 270.1 MBq (7.3 mCi) of Tc-99m. After this procedure was finished, the patient was asked to remain in the waiting room while the thyroid scan was processed. Because of an identification error, the patient was taken again into the treatment area by the authorized user and was administered the therapeutic dosage of I-131. This dosage was intended for another patient who was still in the waiting room. The patient was informed of the error.

The licensee believes that no harm was done because the patient's condition required additional thyroid treatment using I-131.

Causes or Causes — The authorized user, who also was the primary care physician for both patients, was aware that both patients were to have I-131 treatment. However, on the day of the incident, the patient should have received only the Tc-99m dosage. Since the authorized user failed to follow the established Quality Management Program (QMP) procedures requiring verification of the patient's identity by more than one method before administering radioactive material, the wrong individual was administered the I-131.

Actions Taken to Prevent Recurrence

Licensee — The licensee modified its procedures as follows: (1) the authorized user will review the chart for each therapy patient, (2) each chart will contain a photograph of the patient, (3) each patient will be identified by checking the photograph in the chart, (4) preceding the administration of radiopharmaceuticals, a band will be placed on the wrist of the identified therapy patient, and (5) the authorized user and the technologist will be present during the radiopharmaceutical administration. The written directive form for iodine therapy dosages was modified to include the changes made in the procedures.

State Agency — The State investigated this event on September 10 and 11, 1998, and the licensee was issued a Notice of Violation on September 14, 1998, for not following its submitted procedures for radiopharmaceutical therapy as outlined in the QMP. The State acknowledged the action taken by the licensee to prevent recurrence of this incident.

This event is closed for the purpose of this report.

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AS 99-8 Therapeutic Radiopharmaceutical Misadministration of Samarium-153 at Merle West Medical Center in Klamath Falls, Oregon

The following information pertaining to this event is also being reported concurrently in the *Federal Register.* Appendix A (see Criterion IV, "For Medical Licenses") to this report states, in part, that a medical misadministration that results in a dose that is 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 will be considered an AO.

Date and Place — March 10, 1999; Merle West Medical Center; Klamath Falls, Oregon.

Nature and Probable Consequences — A patient with metastatic prostate cancer was prescribed a dosage of 2,294 megabecquerel (MBq) (62 millicurie [mCi]) of samarium-153 (Sm-153) to palliate bone pain. However, because of an error, the patient was administered a dosage of 3,589 MBq (97 mCi) of Sm-153. The recommended dosage for the Sm-153 procedure is "1 mCi per kg of body weight" (37 MBq per kilogram [kg]) (1 mCi per 2.2 pounds [lb]).

The misadministration resulted in an additional dose of 200 centigray (cGy) (200 rad) to the bone marrow. The patient's other organs received additional doses that were below 1,000 cGy (1,000 rad). The hospital checked with the manufacturer, DuPont Merck Pharmaceutical Company, concerning possible side effects of the misadministration. The pharmaceutical company indicated that other studies have been done using 74 to 92.5 MBq per kg (2.0 to 2.5 mCi per 2.2 lb) of Sm-153 with no significant side effects.

Both the attending physician and the patient's family were notified of the misadministration.

Cause or Causes — This event was caused by a human error. The licensee indicated that the dosage was calculated using the patient's weight in pounds instead of kilograms.

Actions Taken To Prevent Recurrence

Licensee — The incident was discussed with the Radiation Safety Committee (RSC). The licensee revised its Quality Management Program (QMP) for the use of Sm-153 and strontium-89 therapy to require the prescribing physician to calculate and personally order the dosage. The RSC approved the changes to the QMP. The technologist involved in the procedure was counseled concerning therapy procedures, dosage administrations, and the importance of rechecking calculations.

State Agency — The State cited the licensee for failure to report the misadministration within the required time.

This event is closed for the purpose of this report.

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AS 99-9 Sodium Iodide Radiopharmaceutical Misadministration at St. Edward Mercy Medical Center in Fort Smith, Arkansas

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

Date and Place — December 7, 1998; St. Edward Mercy Medical Center; Fort Smith, Arkansas.

Nature and Probable Consequences — A patient was prescribed a thyroid scan using 222 megabecquerel (MBq) (6 millicurie [mCi]) dosage of technetium-99m (Tc-99m) pertechnetate. However, the patient was administered about a 148 MBq (4 mCi) dosage of iodine-131 (I-131).

The medical center routinely received unit dosages from a nuclear pharmacy packaged in appropriately sized syringes ready for injection to patients. However, in this case, instead of being in a syringe, the dosage was in a glass vial within a large lead container. The shipping package also contained two dispensing straws. The shipping container, the lead "pig," and the vial were labeled by the nuclear pharmacy as 222 MBq (6 mCi) of Tc-99m. The licensee's staff surveyed the incoming package but saw nothing unusual. The licensee's staff attributed the change in the appearance of the package (a glass vial instead of a syringe and the presence of the dispensing straws) to a mistake made by the nuclear pharmacy. Therefore, the oral solution of the I-131 dosage, mislabeled as Tc-99m, was drawn into a syringe and was injected into the patient.

The licensee's medical physicist determined that the dose to the patient's thyroid based on the radiopharmaceutical manufacturer's package insert was about 48 gray (4,800 rad). The patient was notified of the misadministration by the licensee's radiation safety officer (RSO). The patient's attending physician was also notified of the circumstances and possible complications. The RSO advised the patient to continue long-term follow-up with the primary care physician.

Cause or Causes — This event was caused by the nuclear pharmacy mislabeling a radiopharmaceutical dosage. Also, it appears that the medical center's nuclear medicine staff did not question or address the unusual package upon receipt.

Actions Taken To Prevent Recurrence

Licensee — The licensee reported this event to the Arkansas Department of Health on December 7, 1998, and submitted a written report on December 8, 1998. The center's management revised the policy and procedure for the receipt of radiopharmaceuticals from the nuclear pharmacy. The revision states that only I-131 radioactive dosages will be accepted in glass vials. Any suspect or other labeled isotope received in glass vials will be questioned or returned to the pharmacy for isotope verification. The nuclear pharmacy indicated that policies and procedures for dispensing radiopharmaceutical therapy products have been revised to prevent recurrence of similar incidents.

State Agency — The State staff performed an on-site investigation at the medical center and the nuclear pharmacy on December 8, 1998.

The investigation discovered violations associated with license conditions and regulations for activities conducted at the nuclear pharmacy.

This event is closed for the purpose of this report.

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APPENDIX A

ABNORMAL OCCURRENCE CRITERIA AND GUIDELINES FOR OTHER EVENTS OF INTEREST

An accident or event will be considered an abnormal occurrence (AO) if it involves a major reduction in the degree of protection of public health or safety. This type of incident or event would have a moderate or more severe impact on public health or safety and could include, but need not be limited to, the following:

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

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

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

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

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

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

Abnormal Occurrence Criteria

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

I. For All Licensees.

A. Human Exposure to Radiation from Licensed Material.

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

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

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

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

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

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with § 20.1301 using §§20.1302 (b) (1) or 20.1302 (b) (2) (ii).

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

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

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A_2 or 0.01 times the A_1 values, as listed in Table A-1, for normal form

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

(unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.

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

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

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

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

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

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

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

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

II. For Commercial Nuclear Power Plant Licensees.

A. Malfunction of Facility, Structures, or Equipment

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

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

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

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

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

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

III. For Fuel Cycle Facilities

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

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

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

IV. For Medical Licensees.

A medical misadministration that:

A. Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, *or* (2) equal to or greater than 10 Gy (1000 rads) to any other organ; and

B. Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive *or* (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical,[2] or (ii) is delivered by the wrong route of

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

administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

Guidelines for "Other Events of Interest"

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

APPENDIX B

UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

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

APPENDIX C

OTHER EVENTS OF INTEREST

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

NUCLEAR POWER PLANTS

1. Fire in Hydrogen Storage Facility at James A. FitzPatrick

This event received significant public and media attention. This event caused NRC to increase its attention to the licensee's overall safety program. This event did not meet the AO reporting criteria since it did not involve a major reduction in the degree of protection of public health or safety.

On January 14, 1999, an "Unusual Event" was declared at the FitzPatrick Nuclear Plant located 12.8 kilometers (8 miles) northeast of Oswego, New York, due to a fire. The unit was operating at 100 percent power when a fire was observed in the hydrogen storage facility. The hydrogen storage facility is located remotely from the main structures of the plant. The closest plant equipment having safety significance (the diesel generators) is 82.3 meters (270 feet) away. The hydrogen is used for reactor coolant system water chemistry control and turbine generator cooling.

The licensee determined that the root cause of the fire was three separate valve failures. The event was initiated when the diaphragm for a pressure control valve (PCV) ruptured and allowed full hydrogen system pressure to exist at the outlet of the PCV. The PCV outlet isolation valve had a known packing leak and because of hydrogen's low ignition energy, the hydrogen self-ignited from friction and static generated by hydrogen leaking through the packing. The third valve to fail was a pressure relief valve, which did not initially lift and was later determined to be improperly sized for its application.

The licensee's fire brigade responded to the fire, as did two local fire departments and a fire brigade from a local aluminum production facility. To ensure firefighter safety, the licensee de-energized two offsite electric power lines and initiated operation of the unit's four emergency diesel generators. The generators operated at no load for 4 hours during the 8-hour event. The fire was under control in less than 1 hour and subsequent firefighting activities were limited to continuously spraying the cylinders with water until all the hydrogen had escaped and there was no possibility of reflash. The Unusual Event was terminated approximately 8 hours after the start of the fire based on having the fire out and restoring the off-site power supply. The unit remained at 100 percent power throughout the event. The Region I Incident Response Center entered the monitoring phase of normal mode and remained in this phase throughout the event.

Following the fire, the NRC staff evaluated the risks associated with hydrogen storage systems at other nuclear power plant sites. The staff concluded that, based on previous generic and plant-specific reviews, there was a low probability of fires and explosions from on-site hydrogen storage facilities posing a risk to safe facility operation. Plant designs have bulk storage of combustible gases outside of structures housing safety-related equipment. Flammable gases such as hydrogen are stored outdoors on trailers and in separate storage areas. Further, high-pressure gas storage containers are typically placed with the long axis parallel to building walls and at a substantial standoff distance to minimize the possibility of wall penetration in the event of a catastrophic failure of a container.

In conclusion, this hydrogen fire did not threaten safe-shutdown equipment, nor did it cause an event that would require the use of safe-shutdown equipment. Further, the fire did not pose a threat to the health and safety of the public, the environment, or national security.

This event is closed for the purpose of this report.

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2. Scram and Partial Loss of Vital Power at Indian Point Unit 2

A scram at Indian Point Unit 2 on August 31, 1999, involved a number of complications and produced unnecessary burdens on the licensee's operational personnel. The event revealed lapses in configuration control and management oversight that caused NRC to increase its attention to the licensee's overall safety program and caused significant public and media interest. This event did not meet the AO reporting criteria since it did not involve a major reduction in the degree of protection of public health or safety.

At 2:31 p.m., the Indian Point Unit 2 reactor was automatically tripped from 99 percent power. About 3 minutes after the reactor trip, the normal offsite power breakers to all four vital electric power buses tripped; all three emergency diesel generators as designed started and began to load. Almost immediately, the output breaker of one diesel generator tripped, leaving its associated vital bus de-energized.

The de-energized bus resulted in a loss of power to one of the two motor-driven auxiliary feed-water pumps, to a battery charger, and to some emergency core cooling components. The bus remained de-energized while technicians isolated and checked for a suspected vital bus fault, which could have caused the loss of power. The battery discharged over the next 7 hours. After it was fully depleted, it caused a loss of power to the loads on the direct current bus and on the associated instrument bus.

The loss of the direct current bus and associated instrument bus resulted in unavailability of half of the bleed and feed capability of the unit, challenged operators in controlling decay heat removal from one of the four steam generators, and disabled most of the control room annunciators for safety-related systems.

The next day, about 1:00 a.m., the vital bus was re-energized with the diesel generator; by 9:00 p.m., normal off-site power had been restored.

The NRC sent an Augmented Inspection Team (AIT) to examine the circumstances surrounding the event, principally because the event was complicated by significant, unexpected system interactions involving safety-related equipment. The team was also instructed to examine the adequacy of the licensee's response to the event, particularly the vital bus power restoration efforts. The delay in restoration of the vital bus led to significant additional complication of the operators' efforts to stabilize the plant. The team's report is presented in Inspection Report 50-247/99-08, dated October 19, 1999.

The team found that a significant contributor to the event was inadequate upkeep of electrical components. The failures were caused by two equipment problems: the voltage controller for the station auxiliary transformer had been left in the "manual" position and the circuit breaker for the diesel was not set properly. Also, station management missed a number of opportunities to recognize and fully assess degrading plant conditions and did not establish viable plans and contingencies for plant restoration.

Even though the event represented a significant degradation in plant reliability, at no time was public health or safety in danger. Multiple means of core cooling remained available throughout the event. Following the plant trip, reactor decay heat was removed using the motor-driven and turbine-driven auxiliary feed-water pumps. One of two motor-driven pumps and the turbine-driven auxiliary feed-water pump remained available throughout the event.

The licensee presented a Recovery Plan which addressed the management, human performance, process, and equipment problems highlighted by the plant trip. The Plan also provided the structure and guidance to the organization to address those problems and included condition assessments to determine if similar problems exist in other areas. NRC evaluation of the Recovery Plan and its implementation has not yet been completed. There will be additional inspection activities. The AIT concluded that station management implemented adequate interim corrective actions to review and address both equipment and personnel performance in response to the reactor trip event.

This event is closed for the purpose of this report.

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NRC AND AGREEMENT STATE MATERIALS LICENSEES

During FY 1999, there were 732 reported materials events. NRC and Agreement States have received 188 reports of events that resulted in licensed materials entering the public domain in an uncontrolled manner: 74 events were reported by NRC licensees and 114 events were reported by Agreement State licensees. In some cases, the material caused radioactive contamination or radiation exposures.

The 188 events 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, and assembled machinery (e.g., jet engines) and in ceramics. Of these events, loss of portable moisture density gauges were the most commonly reported events involving lost or stolen licensed devices.

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

For illustration purposes, the following two examples, which occurred in FY 1999, are provided.

1. Loss of a Radiography Camera Owned by NDT and Inspections of Pembroke Pines, Florida

This event resulted in significant media interest.

On March 17, 1999, the State of Florida notified the NRC staff of a reported theft of a radiography camera from a trailer that was parked outside a radiographer's house. The NRC Operations Center entered the monitoring phase of normal mode. The field office of the Federal Bureau of Investigation (FBI) in Miami, Florida, initiated an investigation of the loss of the camera.

The camera contained a 3.3 terabecquerel (88.3 curie) source of iridium-192 and was owned by NDT and Inspections of Pembroke Pines, Florida. The exposure rate at the surface of the device was calculated to be about 1.1 millisievert per hour (105 millirem per hour). Numerous conference calls were held between the Department of Energy (DOE), NRC, FBI, and the State of Florida. The FBI requested the assistance of DOE for radiological monitoring to locate the device. After extensive searching for the missing source, DOE terminated its effort without recovering the camera. The FBI will inform the State of Florida of any information that may be found about the lost source. At the time of this report no additional information was reported to the State.

In the case of lost sources, particularly those lost from potential criminal activity, it is not unusual that the source cannot be located. At some point a decision must be made that it is no longer practical to continue the search. However, there are other factors that may eventually lead to the recovery of the source. These factors include that the source is typically contained in a well marked container and the source itself has identification markers, many public landfills have radiation detectors, the scrap metal recycling industry has radiation detectors, and a report file (and possibly also a criminal investigation file) is maintained. There is a possibility that eventually the source may be found, identified, and properly disposed. In cases where the source is never found, there are no health and safety concerns if the source remains in its original device. However, if the source is removed from its device there may be severe radiation consequences to individuals involved in handling the device and the source.

This event is closed for the purpose of this report.

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2. Improper Firing of Depleted Uranium Munitions in Vieques Island, Puerto Rico

This event has been perceived by the public to be of high health and safety significance and has received significant media coverage.

On February 19, 1999, during a training exercise, two U.S. Marine Corps Harrier aircraft inadvertently fired 263 rounds of depleted uranium (DU) armor-piercing munitions into the live-impact area of the firing range on the island of Vieques in Puerto Rico. Each round contained 148 grams (0.33 pound) of DU in the form of a pencil-shaped penetrator. The live- impact area covers approximately 6.5 square kilometers (2.5 square miles) on the eastern tip of the island. It is normally a restricted area. DU rounds are designated as "war reserve" and, as such, are restricted from peacetime or training use.

A team of Navy health physicists deployed to the area between March 10 and 19, 1999. The team members performed visual and radiological surveys and recovered a total of 57 penetrators. Because of the possibility of hidden, unexploded conventional ordnance in the dense vegetation in portions of the affected area, the search was suspended. The radiological risk associated with the expenditure of these munitions is very low. DU is about 40 percent less radioactive than natural uranium and is used in civilian industry as shielding and as stabilizers in aircraft and boats. It is very unlikely that any individuals would be exposed to significant doses.

The Navy planned to resume recovery operations in May 1999, after the area had been cleared by ordnance specialists. However, following an unrelated accidental civilian death in April 1999, caused by naval bombing exercises, local protesters moved onto the range and adjacent areas, and began living there. Media and congressional interest followed the death, and the DU contamination issue became incorporated into an overall review of the naval operations on the island.

The Navy will send ordnance specialists to the firing range to recover any unexploded ordnance when the protesters vacate the area. Then, Navy health physicists will resume recovery of the DU munitions. A naval message was issued to all applicable ammunition activity personnel reemphasizing the prohibition against firing DU rounds for peacetime and training use. A self-inspection checklist for compliance with U.S. Navy procedures was forwarded to all storage facilities. Specific DU munition information has been included in applicable ordnance occupational training courses.

When the Navy resumes recovery operations, NRC will perform on-site inspections to ensure that the Navy's recovery and remediation operations are appropriate.

This event is closed for the purpose of this report.

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11. ABSTRACT *(200 words or less)*

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 (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 requires that AOs be reported to Congress on an annual basis. This report includes those events that NRC has determined to be AOs during fiscal year 1999.

This report addresses 13 AOs. Four of these events involved NRC licensees/certificate holders and nine involved Agreement State licensees.

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