DRAFT REPORT TO CONGRESS

on

ABNORMAL OCCURRENCES

FISCAL YEAR 2003

draft

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Office of Nuclear Regulatory Research
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event which 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 describes those events which have been determined to constitute AOs by the NRC during Fiscal Year 2003.

The report describes five medical events at facilities licensed by the NRC. Three events involved patients undergoing therapeutic brachytherapy treatments, one event involved an unintentional therapeutic dose of sodium iodide (I-131) to an embryo/fetus, and one event involved a diagnostic overexposure of a minor. The report also discusses nine AOs at facilities licensed by Agreement States. Agreement States are those states which have entered into a formal agreement with the 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 33 Agreement States. Seven events were medical events (five therapeutic and two diagnostic), one event involved overexposure to a radiographer, and one event involved overexposure to members of the public from a damaged gauge. Appendix A to this report presents the criteria for selecting AOs and the guidelines for selecting "Other Events of Interest". Appendix B, "Update of Previously Reported Abnormal Occurrences," gives updates on previously reported AOs and an event of interest. Appendix C, "Other Events of Interest", describes three nuclear power reactor events and one materials event.

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PREFACE

INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines is significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually. This report discusses those events that the NRC or an Agreement State determined were AOs during Fiscal Year 2003.

The NRC used the criteria in Appendix A to define AOs for the purpose of this report. The criteria were initially promulgated in the NRC policy statement that was published in the *Federal Register* on February 24, 1977 (42 FR 10950), followed by several revisions in subsequent years. The newest revision, as documented in Appendix A (Criterion IV, For Medical Licensees) to this report replaces the term “misadministration” with the term “medical event”. The term change does not alter the criteria used to identify an AO and should not result in any more or fewer AOs being reported. The revision will be included in the *Federal Register* announcing the publication of this report.

The 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. The information reported for each AO includes the date and place, the nature and probable consequences, the cause or causes, and actions taken to prevent recurrence.

Appendix A to this report presents the criteria for selecting AOs and the guidelines for selecting "Other Events of Interest”. Appendix B contains updates of previously reported AOs. Appendix C presents information on events that are not reportable to Congress as AOs, but are included in the AO report as "Other Events of Interest” based on guidelines provided by the Commission and listed in Appendix A to this report. NRC licensees and Agreement States must report these events to the NRC.

To disseminate information widely to the public, the NRC issues a *Federal Register* notice describing AOs at facilities licensed or otherwise regulated by the NRC or an Agreement State. Information on activities licensed by Agreement States is also publicly available from the Agreement States.

THE REGULATORY SYSTEM

The system of licensing and regulation by which the NRC carries out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations* (10 CFR). Public participation is an element of the regulatory process. To accomplish its objectives, the NRC regularly conducts licensing proceedings, inspection and enforcement activities, operating experience evaluations, and confirmatory research, and maintains programs for establishing standards and issuing technical reviews and studies.

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

REPORTABLE OCCURRENCES

Review and response to operating experience is essential for ensuring that licensed activities are conducted safely. Licensees are required to report certain incidents or events to the NRC. Such reporting helps to identify deficiencies and to ensure that corrective actions are taken to prevent recurrence.

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

Except for records exempt from public disclosure by statute or regulation, the NRC routinely disseminates information on reportable occurrences at facilities licensed or otherwise regulated by the NRC to the industry, the public, and other interested groups when the occurrences happen. The dissemination is done by special notifications to licensees and other affected or interested groups and by public announcements. Congress is routinely informed of significant events occurring in facilities licensed or otherwise regulated by the NRC.

AGREEMENT STATES

Section 274 of the Atomic Energy Act, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes, and the States assume, regulatory authority over byproduct, source, and special nuclear materials in quantities not capable of sustaining a chain reaction. Agreement States must maintain programs that are adequate to protect public health and safety and are compatible with the Commission's program for such materials. Currently, there are 33 Agreement States.

In early 1977, the Commission determined that events that meet the criteria for AOs at facilities licensed by Agreement States should be included in the quarterly report to Congress. Therefore, AOs reported by the Agreement States to the NRC are included in the AO report and in the *Federal Register* notice issued to disseminate the information about each AO to the public. 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 materials events to determine those that should be reported as AOs. The AO criteria in Appendix A are applied uniformly to events at facilities regulated by the NRC and the Agreement States.

FOREIGN INFORMATION

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

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

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

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ACRONYMS and ABBREVIATIONS

AEA	Atomic Energy Act
AIT	Augmented Inspection Team
AO	abnormal occurrence
Bq	becquerel
CAL	confirmatory action letter
cGy	centigray
CFR	*Code of Federal Regulations*
CNSC	Canadian Nuclear Safety Commission
cSv	centisievert
CT	computerized tomography
Ci	curie
Cs-137	cesium-137
CS	containment spray (system)
DOJ	Department of Justice
ECCS	emergency core cooling system
ERA	Energy Reorganization Act
ESWG	Electric System Working Group
FR	*Federal Register*
GBq	gigabecquerel
GDC	general design criteria
Gy	gray
Gy/min	gray per minute
HDR	high-dose-rate afterloader
HPI	high pressure injection
I-131	iodine-131
Ir-192	iridium-192
in	inch
IVB	intravascular brachytherapy
LAD	left anterior descending (artery)
LLTF	Lessons Learned Task Force
LOCA	loss-of-coolant accident
LOOP	loss of offsite power
KRHTA	Kentucky Radiation Health & Toxic Agents
MBq	megabecquerel
mCi	millicurie
mm	millimeter
mrem	millirem
NOV	Notice of Violation
NWG	Nuclear Working Group
mSv	millisievert
NJDEP	New Jersey Department of Environmental Protection
NPPs	nuclear power plants
NRC	Nuclear Regulatory Commission
PSEG	Public Service Electric & Gas

ACRONYMS and ABBREVIATIONS

QA	quality assurance
REAC/TS	Radiation Emergency Assistance Center/Training Site
RSO	radiation safety officer
SAR	safety analysis report
STC	Schlumberger Technology Corporation
Sr-90	strontium-90
Sv	sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
Tl-201	thallium-201
TLD	thermoluminescent dosimeter
TS	technical specification
µCi	microcurie
VSC	Veterinary Service Center

ABNORMAL OCCURRENCES
IN FISCAL YEAR 2003

NUCLEAR POWER PLANTS

During this period, no events occurred at U.S. nuclear power plants that were significant enough to be reported as AOs.

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FUEL CYCLE FACILITIES
(Other Than Nuclear Power Plants)

During this period, no events occurred at U.S. fuel cycle facilities that were significant enough to be reported as AOs.

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

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

03-01 Intravascular Brachytherapy (IVB) Medical Event at the Queen's Medical Center in Honolulu, Hawaii

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — October 9, 2002; the Queen's Medical Center; Honolulu, Hawaii

Nature and Probable Consequences — A patient undergoing IVB treatment for cardiac restenosis received an underdose because the strontium-90 (Sr-90) source contained in the device's source train (catheter) did not reach the intended treatment site. The patient undergoing IVB was prescribed treatment of 18.4 Gray (Gy) (1840 rad) to the left anterior descending (LAD) artery to prevent scar tissue blockage. Sixteen Sr-90 seeds with a total activity of 2.224 gigabecquerel (GBq) (60.11 millicuries [mCi]) were positioned in the patient using fluoroscopy. Because the radiation oncologist and cardiologist believed that they could see the proximal and distal markers of the source train on the fluoroscopy monitor, the physicist did not perform a survey to ensure that the source train was in the patient's chest.

After the end of the treatment, the radiation oncologist was unable to retrieve all of the Sr-90 radioactive sources. After a second attempt to retrieve the sources failed, the oncologist pulled the treatment catheter from the patient and placed it in the bailout box. The bailout box is an acrylic box approximately 12 inches (in) by 10 in by 6 in with a hinged acrylic lid. Acrylic is used because of its shielding properties to attenuate the beta radiation from the catheter system. While inspecting the catheter, the oncologist discovered a kink at the location wherein the distal seed and marker became lodged. The kink was attributed to the patient's anatomy (small curves in the blood vessel, branching off the aorta where the catheter was inserted). A review of the cinematography images revealed that only one Sr-90 seed reached the intended treatment site while 5 seeds were positioned in the beginning LAD and 10 seeds were outside the cinematography field of view. Instead of receiving the intended 18.4 Gy (1,840 rads), the LAD received approximately 1.25 Gy (125 rads). The remaining dose was delivered to an unintended section of the LAD and aorta. No adverse effects due to this medical event are expected.

Cause or Causes — This medical event was caused by human error as the licensee did not perform a survey to verify that the radioactive sources were in the proper location. The patient's anatomy was a contributing factor in that there were curves in a small blood vessel branching off the aorta.

Actions Taken To Prevent Recurrence

Licensee — Based on the cause and contributing factors of the medical event, the licensee modified its procedures to require additional documented verification of the position of the markers by the radiological technologist and medical physicist in addition to the required verification by the radiation oncologist and cardiologist.

NRC — On November 13, 2002, the NRC issued a Notice of Violation (NOV) to the licensee for the failure to follow the manufacturer's operation procedures for the IVB device as specified in its license.

This event is closed for the purpose of this report.

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03-02 Dose to Fetus at Community Hospital of Anderson in Anderson, Indiana

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that a medical event that results in any unintended radiation exposure to any minor (an individual less than 18 year 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 will be considered for reporting as an AO; and,

Criterion I.A.3, "Human Exposure to Radiation from Licensed Material," states 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 for reporting as an AO.

Date and Place — August 8, 2003; Community Hospital; Anderson, Indiana.

Nature and Probable Consequences — On August 8, 2003, the Community Hospital of Anderson reported that a 35-year-old female patient was administered 1.1 GBq (29.8 mCi) of sodium iodide-131 (I-131) for the treatment of hyperthyroidism. At the time of the therapy, the patient was unaware that she was pregnant and, as a result, an unintentional dose to her embryo/fetus was delivered. On August 25, 2003, the patient's gynecologist informed the hospital and the patient that she was approximately 15 weeks pregnant at the time of the therapy.

The NRC staff contracted with a medical consultant to review the possible deterministic effects of the dose to the embryo/fetus as a result of the event. The medical report indicated that the total effective dose equivalent (whole body) to the embryo/fetus was approximately 7.4 cGy (rads) and the committed dose equivalent to the embryo/fetal thyroid was approximately 27,814 cGy (27,814 rads). The NRC medical consultant, contracted to review this event, also anticipated that the fetal thyroid would be ablated. The licensee anticipated that the fetal thyroid would be ablated.

Cause or Causes — The event appeared to be an isolated occurrence. The root cause of the event was determined to be human error. Although the authorized physician user and the chief technologist asked the patient on several occasions, prior to the administration of the I-131 dosage, if she was pregnant or believed that she could possibly be pregnant, the patient denied the possibility of pregnancy. Due to other preexisting medical conditions and consultations by other physicians informing the patient that she was unable to conceive, the patient believed that she could not become pregnant and declined taking a pregnancy test prior to the I-131 therapy. Further, the hospital staff, knowing that the patient was also a physician on staff at the hospital, did not pursue a pregnancy test because they believed that the patient was aware of her pregnancy status.

Actions Taken To Prevent Recurrence

Licensee — The licensee conducted a thorough investigation of the event, including identification of the root cause. The root cause of the event was identified as human error by the patient. The event appeared to be an isolated occurrence. No further actions were deemed necessary to prevent recurrence.

NRC — The NRC conducted an inspection on August 26 and 27, 2003, with continued in-office review through September 30, 2003. The inspectors determined that the licensee made the required notifications to the patient, referring physician, and the NRC. No violations of NRC requirements were identified.

This event is closed for the purpose of this report.

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03-03 IVB Medical Event at Washington Hospital Center in Washington, D.C.

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater

than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — May 6, 2003; Washington Hospital Center, Washington, D.C.

Nature and Probable Consequences — A patient undergoing IVB treatment of two areas within the right coronary artery for the treatment of restenosis was prescribed a dose of 23 Gy (2,300 rads) to each treatment site. Some difficulty was experienced in inserting the catheter to the first treatment site, but in the judgement of the treatment team, the catheter appeared to be inserted properly. Fluoroscopy was used to guide insertion and to position the source train. Upon completion of the first treatment, the catheter was moved to the second treatment position, as planned. When the source train was sent out for the second treatment, resistance was met and this time the catheter was replaced. The second treatment was successfully given.

In documenting the treatment, the licensee reviewed the films taken during the treatment and printed a copy of the films for the patient's record. During this documentation, the medical physicist noted that the source markers were not in the right position and suspected that the treatment area was not covered for the first treatment given. The radiation oncologist and interventional cardiologist reviewed the films and determined that the source train was approximately 40 millimeters (mm) (1.6 in) proximal to the intended treatment site.

The NRC contracted a medical consultant to review the medical event and assess the probable deterministic effects of the treatment to the wrong area of the patient's coronary artery. The medical consultant concluded that the dose to the normal segment of the right coronary artery reported in this case was well below the tolerance dose for coronary arteries and no effect was expected other than fibrosis of the right coronary artery vessel wall.

Cause or Causes — This medical event was caused by human error, in that the licensee did not properly visualize the placement of the source train due, in part, to a lapse (this refers to a lapse in time) in the fluoroscopy performed during the treatment and the inherent inability to differentiate between the proximal and distal markers of the source train. In addition, a kink in the catheter may have prevented the source train from traversing to the correct area of the right coronary artery.

Actions Taken To Prevent Recurrence

Licensee — The licensee immediately implemented measures to further enhance source positioning verification prior to initiation of future treatments. The measures included verification of fluoroscope calibration, reinstruction of the treatment team to fully appreciate the movement of both ends of the source train at the site prior to treatment, and the recommendation that the device manufacturer redesign the proximal and distal markers to make them more radiographically distinct from each other and the guiding catheter marker.

NRC — No violations of NRC requirements were identified. The NRC issued Information Notice 2003-09 describing medical events resulting from source positioning errors and is in the process of reviewing all events related to IVB since inception of this technology.

This event is closed for the purpose of this report.

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03-04 Iodine-125 (I-125) Brachytherapy Seed Medical Event at Guthrie Healthcare System in Sayre, Pennsylvania

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — May 24, 2001 (identified on June 12, 2003); Robert Packer Hospital (part of Guthrie Healthcare System), Sayre, Pennsylvania.

Nature and Probable Consequences — In 2001, a patient received a permanent brachytherapy implant using I-125 seeds as treatment for prostate carcinoma. The authorized user prescribed a dose of 14,400 cGy (rads) to the prostate. The implant was performed under ultrasound guidance using 18 needles and 50 radioactive sources, as prescribed in the written directive. In June 2003, the patient returned for consultation regarding additional treatment after a diagnostic test indicated that the prostate cancer may have returned. A computerized tomography (CT) scan taken May 27, 2003, revealed that many of the seeds were not in the prostate but in adjacent tissue where they would have been ineffective in the treatment. The CT scan showed the configuration of the seeds approximately 3 centimeters from the prostate. A review was then conducted of the May 2001 CT scan performed shortly after the initial implant procedure. This CT scan showed the array of I-125 seeds in the same location as in the May 2003 CT scan. The seed configuration resulted in a negligible dose to the prostate and a dose of 6,000 to 8,000 cGy (rads) to an adjacent structure, the penile bulb. The probable deterministic effects to the patient are being determined by NRC medical consultants. The patient and the patient's referring physician were notified of the event.

Cause or Causes — The cause of this event is under investigation by the licensee.

Actions Taken To Prevent Recurrence

Licensee — This event occurred in 2001 and involved an entirely different radiation oncology team than is currently employed by the licensee. The current radiation oncology team uses a different prostate implant protocol than was used in 2001. Reviews of the licensee's current prostate implant program by both the NRC and an independent physics consultant indicate that treatments performed since October 2002 have been accurate.

NRC — The NRC staff conducted a special safety inspection on June 19, 2003. Subsequent to this inspection, the licensee (Guthrie Healthcare System) began to audit other prostate implants performed in 2001 and identified additional cases of possible treatment errors. On July 28, 2003, the NRC issued a Confirmatory Action Letter (CAL) specifying actions the licensee agreed to perform, including evaluation of the root cause of the events and performance of an audit of past and current prostate implants. The NRC conducted a second special inspection on August 14, 2003. As of the date of this report, the licensee has reported a total of 21 possible medical events and is continuing the actions required by the CAL. It appears that the

treatment errors may have been less extreme for the additional 20 cases reported by the licensee. An NRC medical consultant is currently evaluating these cases. NRC staff will consider enforcement options upon the completion of the licensee's and NRC's investigations.

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

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03-05 Diagnostic Medical Event at Deaconess Hospital in Evansville, Indiana

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

Date and Place — March 28, 2003; Deaconess Hospital in Evansville, Indiana.

Nature and Probable Consequences — A nine-year-old patient who had been prescribed a dosage of 148 kilobecquerel (4 μCi) in an I-131 capsule for a thyroid uptake study, instead received 15.6 MBq (421 μCi) of I-131 in liquid form. Because the patient was unable to swallow the capsule, the technologist placed a telephone request to a local commercial radiopharmacy for liquid I-131; however, the technologist erroneously ordered 15.6 MBq (421 μCi) of I-131 for the patient. The licensee identified the error while reviewing related paperwork on April 2, 2003. The referring physician, the patient, and the patient's family were informed of this event on April 3, 2003. The intended thyroid dose was approximately 13 cGy (rads), but the NRC's contracted medical consultant estimated that the patient received a thyroid dose of 13.7 Gy (1,370 rads) and an effective dose equivalent of 42 cGy (rads). According to the medical consultant, no acute radiation effects were anticipated to any organ, since no organ (except the thyroid) received more than 1.0 cGy (rad). The 13.7 Gy (1,370 rads) dose will not cause radiation thyroiditis. The medical consultant also stated that there was insufficient data on juveniles to be reassured that a radiation dose in excess of 13.7 Gy (1,370 rads) to the thyroid would have no long-term consequences, given the increase in radiosensitivity of the thyroid glands of children.

Cause or Causes — This medical event was caused by human error in ordering the correct dosage.

Actions Take To Prevent Recurrence

Licensee — Corrective actions include (1) develop and use a standardized order form for liquid I-131 that will be faxed to the local nuclear pharmacy as written confirmation of the dosage ordered; (2) modify the computerized unit dose manager system to prevent an inappropriate dosage of I-131 from being entered into the computer system; (3) provide the local nuclear pharmacy with typical dosage ranges used by the licensee, which will be put into the nuclear pharmacy's computer and used as a secondary check to verify that the dosage ordered is appropriate for the study or treatment to be performed; and (4) provide in-service training to the nuclear medicine technicians regarding the medical event.

NRC — On August 29, 2003, a NOV was issued for a violation that included the failure to order the correct quantity of I-131 as directed by the authorized user, to have a written directive dated and signed by an authorized user prior to the administration of the 15.6 MBq (421 μCi) I-131 dosage, and to administer a dosage within 20% of the prescribed dosage range for a thyroid uptake study using I-131.

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

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AGREEMENT STATE LICENSEES

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

AS 03-01 IVB Medical Event at Union Memorial Hospital in Baltimore, Maryland

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — May 22, 2003, Union Memorial Hospital, Baltimore, Maryland.

Nature and Probable Consequences — During a cardiac brachytherapy procedure conducted at the licensee's facility, a malfunction of the drive mechanism occurred with an IVB device containing a phosphorous-32 source with an activity of 3.48 GBq (94 mCi). The malfunction occurred during the treatment of the third of three patients. The first two treatments were completed without incident. The treatment of the third patient was initiated with the dummy source successfully reaching the proper dwell position (confirmed visually via fluoroscopy) and returning to the cartridge. The active source was then advanced into the catheter, but when the source movement light continued to blink well after the anticipated transit time, the licensee initiated a fluoroscopic view of the treatment site. The source was not observed in the fluoroscopic field of view, so the licensee assumed a machine malfunction had occurred and initiated emergency procedures. Radiation surveys were performed, which confirmed that the source had stopped inside the patient. The indicator light on the console continued to indicate that the source was in transit even after the licensee confirmed the source was in the patient and not at the treatment site. The licensee was unable to retract the source to its shielded position using the machine interrupt, the system stop button, or the handwheel. At that point, the attending physician removed the catheter and source from the patient and accidently dropped them on the operating room floor. After the power cord was removed from the wall receptacle, the source retracted into its shielded position. The licensee stated that it took approximately 45 to 60 seconds to remove the source from the patient. The manufacturer's representative present during the treatment indicated that this period was 60 to 90 seconds. The licensee estimated a worst case dose to the wall of the patient's artery as approximately 1,038 cGy (rads) based on a 60-second exposure time. The source delivery unit was taken to the licensee's "hot" laboratory after the event and the daily quality assurance (QA) checks were performed in the physics and clinical modes. The unit passed both QA checks. The manufacturer's representative present during the procedure immediately notified the manufacture's technical center. The device was returned to the manufacturer for evaluation and a new device was provided to the licensee.

Cause or Causes — This medical event was caused by equipment malfunction. The manufacturer was able to simulate a similar type of failure on two occasions and is focusing on a timer chip as the possible cause of the malfunction. The manufacturer believes that a

hardware problem and not the device's software caused the failure. The State of Maryland ruled out human error as the cause of the drive mechanism malfunction.

Actions Taken To Prevent Recurrence

Licensee — Corrective actions included the implementation of revised procedures regarding dosimetry, emergency response, and notification of incidents. Training for the revised procedures was completed on November 12, 2003. The licensee also revised its annual Radiation Safety Training Program to ensure compliance with pertinent State regulations and revised procedures.

State Agency — The State of Maryland conducted an investigation, and the State concurs with the licensee corrective actions that included implementation of revised procedures and an annual emergency exercise.

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AS 03-02 Industrial Radiography Occupational Overexposure at a Temporary Jobsite in Ghent, Kentucky

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

Date and Place — On November 12, 2002, the Kentucky Radiation Health & Toxic Agents (KRHTA) Branch was notified, by the licensee, that for the month of October 2002, a radiographer's total annual occupational dose was exceeded while working at a temporary jobsite near Ghent, Kentucky.

Nature and Probable Consequences — The licensee reported an overexposure to a radiographer of 31.4 cSv (rem). A 3.81 terabecquerel (TBq) (103 Ci) Ir-192 source was being retracted after an exposure. The radiographer who had entered the area was in the area for approximately 3 minutes before realizing the source was not fully retracted. Upon realizing that the source was not fully retracted, the radiographer immediately left the area, extended the source, and then retracted it to the housed position. The radiographer's dosimetry was sent to Landauer for processing and results indicated a whole body exposure of only 4.86 cSv (rem). However, the licensee, with assistance from the source manufacturer's Radiation Safety Officer (RSO), completed a reconstruction of the whole body exposure to the radiographer. The final result indicated an exposure of 30 cSv (rem) whole body from the event. This exposure was added to the radiographer's year-to-date exposure of 1.4 cSv (rem), for a total yearly whole body exposure of 31.4 cSv (rem). Discussions with the KRHTA Branch, along with independent calculations, confirmed the 30 cSv (rem) event exposure. The licensee stated that the thermoluminescent dosimeter (TLD) and operating ratemeter were in the radiographer's pocket, an area that did not reflect true whole body exposure, and the alarm ratemeter was never heard in an alarming condition.

Cause or Causes — This event was caused by inadequate operating procedures for the exposure device, improper placement of the TLD in the radiographer's pocket (rather than on his body), improper storage of the alarm ratemeter in his pocket (rather than on his body), and failure to survey the exposure device upon completion of the radiograph.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions included revision of the operating procedure for retracting the source into the exposure device, personnel training on the revised procedure and proper wearing of dosimetry devices, and annual refresher training on proper operation and responses of survey instrumentation. Additionally, the radiographer involved will receive an additional 40 hours of radiation safety training prior to returning to work in radiography, and will be evaluated at least once a month for the next year.

State Agency — The KRHTA Branch conducted an onsite investigation and concurred with the licensee's dose assessment and identification of the causes of the event. The licensee was issued a NOV and has provided corrective actions to the Commonwealth of Kentucky.

This event is closed for the purposes of this report.

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AS 03-03 Diagnostic Medical Event at Rush Copley Medical Center in Aurora, Illinois

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is the wrong radiopharmaceutical will be considered for reporting as an AO.

Date and Place — July 28, 2003; Rush Copley Medical Center; Aurora, Illinois.

Nature and Probable Consequences — The Illinois Emergency Management Agency received a call on July 29, 2003, from a nuclear medicine technician at Rush Copley Medical Center in Aurora, Illinois. The technician reported that a patient who was to receive 148 MBq (4 mCi) of thallium-201 (Tl-201) for a heart test instead received 148 MBq (4 mCi) of I-131 on July 28, 2003. The patient had been admitted the day before the event with an order to perform a treadmill heart stress test. The patient remained hospitalized at the facility until discharged after July 30, 2003.

The circumstances of the event, as reported by the technician, indicate that both the exterior lead container and the syringe were labeled as containing a diagnostic unit dose of Tl-201. Although the injection occurred the previous day, it was not determined that I-131 was involved until the morning of July 29, 2003. Service engineers were called to the site on both days to inspect the gamma cameras used after attempts to image the patient failed. The reason became evident when a gamma camera flood source that had been made from what was thought to be the remaining Tl-201 material in the syringe from July 29 showed peaks consistent with I-131, rather than the expected Tl-201. The syringe had been assayed by the

medical center before injection. The assayed amount showed the dose to be within the prescribed range for a typical 148 MBq (4 mCi) Tl-201 diagnostic administration.

On Friday, July 25, 2003, the nuclear pharmacy received an order for five unit dose syringes of I-131 for the Veterinary Service Center (VSC) and two unit dose syringes of Tl-201 for Rush Copley Medical Center. When the computer generated orders and associated labels were segregated, one of the prescriptions for the Tl-201 was mistakenly substituted for I-131. The pharmacist did not realize the error and the I-131 dose (syringe) and its container were labeled with one of the Tl-201 labels generated for the original order. On Monday, July 28, 2003, the pharmacy facility manager noted that only four I-131 prescriptions had been filled for VSC. Assuming the I-131 dose had not been filled with the others the previous Friday, July 25, 2003, he filled an additional syringe with I-131 to complete the order for VSC.

The medical center estimates that a small amount of residual activity remained adhered to the walls of the syringe. Therefore, it estimates the amount of injected I-131 to be 148 MBq (4 mCi). Based on the package insert information for this material and assuming that an injected sodium iodide solution of I-131 results in a radiation absorbed dose similar to oral administration and that the patient had normal thyroid function (25% uptake), the dose to the patient's thyroid is approximately 5,195 cGy (rads).

The medical center technician indicated that the patient involved had been contacted by the referring physician, onsite oncologists, and the medical center's administrator and lawyer and was informed as to what had happened at the initial time of discovery of the event. Later, a copy of the medical center's report to the agency was also provided to the patient. The medical center offered to perform routine blood analysis throughout the year to monitor any changes in thyroid activity. The patient had been advised as to the potential health effects of the medical event during that time and the need for routine followup testing. The patient has not returned to the medical center for any additional testing, diagnosis, or consultation.

The medical center's oncologist indicated that it is very unlikely that any medical changes will be noted in the patient because the dose administered is only slightly larger than that typically ordered for whole body scans using I-131. Blood tests were taken immediately following the discovery of the event. Those tests suggest that the patient was hypothyroid as a preexisting condition to admittance.

Cause or Causes — The medical event was caused by the mislabeling of the I-131 unit dose syringe. Other factors that led to the medical event include improper segregation of the prescriptions at the pharmacy and lack of a second means of verifying proper completion of the order.

Actions Taken To Prevent Recurrence

Licensee — The pharmacy ceased dispensing therapeutic quantities of I-131 in unit dose syringes. Therapeutic doses of I-131 will only be dispensed in capsule form. This will preclude the possibility of a unit dose of diagnostic material being mistakenly filled with a quantity of therapeutic material. Additional corrective actions included (1) retraining of pharmacists, (2) implementation of a dual verification system for all prescriptions received,

(3) implementation of a triple check system for dispensing compounds, and (4) testing a new bar code system for tracking all prescriptions.

State Agency — On July 30, 2003, the State agency sent an investigator to the medical center and the nuclear pharmacy to observe licensed activities and to review the circumstances of the event. During those onsite visits, preliminary information reported by the medical center and pharmacy was confirmed. The pharmacy was cited for failure to properly fill the prescription as ordered by the physician. The State agency is holding this action item open pending enforcement action and will include a review of the corrective actions taken during the next routine inspection. The agency does not expect any additional significant information to be received or other notable action to be taken outside of the enforcement process.

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

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AS 03-04 High Dose-Rate Afterloader (HDR) Medical Event at Saint Joseph's Hospital in Houston, Texas

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — June 9, 10, and 11, 2003; Saint Joseph's Hospital, Houston, Texas.

Nature and Probable Consequences — A cancer patient undergoing therapeutic radiation treatment for breast cancer received a superficial skin dose of 70 Gy (7,000 rads) to a circular area approximately 1 centimeter (cm) (.4 in) in diameter. This error occurred using an HDR device. Deeper absorbed doses of 34 Gy (3,400 rads), 15 Gy (1,500 rads), and 10 Gy (1,000 rads) have been estimated at depths of 1 cm (.4 in), 2 cm (.8 in), and 3 cm (1.2 in), respectively. These deeper doses were absorbed by the subcutaneous fat and muscle of the lower left chest wall. The patient had a slight erythema of the skin which measured ½ to 1 cm (.2 to .4 in) in diameter approximately 2 weeks after the radiation therapy injury.

The incorrect placement of the source in the catheter was detected on June 11, 2003, between treatment fractions 5 and 6. The patient and referring physician were notified of the treatment error and the facts involved with this treatment. The patient elected to continue treatment with a modified treatment plan after the source location was corrected. A new plan was generated representing a composite of the unintended dose to the skin of the lower left chest wall and the intentional dose prescribed in the original treatment plan.

The attending physician, who was present during treatment, followed the patient's progress for any needed medical intervention due to exposure to the HDR source. The patient's erythema of the skin failed to heal and developed into an ulceration. The ulceration was surgically excised by the referring physician. After excision, the area fully healed within a period of approximately two months. The patient continues to be monitored by the referring physician.

Causes or Causes — During the setup of the HDR unit with the approved treatment plan, the source was instructed to stop at the 20th position from the catheter tip. The 20th stop resulted in the source stopping at 20 cm (7.9 in) from the catheter tip instead of the planned 20 mm (.8 in) from the catheter tip. This was due to failure to correct the default value step size from 10 mm to 1 mm (.4 in. to .04 in) as specified in the treatment plan. This failure was a human error in the copying of the treatment plan into the device's control console after the initial QA test. After the QA test the physician requested that the plan instruction be copied into a new plan, after the initial QA films had been approved. This procedure is required as the device manufacturer does not have a separate QA mode that allows QA without recording the QA tests as a fractional treatment.

Actions Taken To Prevent Recurrence

Licensee — The facility instituted a policy of comparing the console instructions to the approved QA record prior to each treatment fraction. In addition the medical physicist has made two suggestions for product improvement (1) the addition of a physics QA mode to allow the physicist to test a treatment plan without having it recorded as a treatment fraction to the patient; and (2) the placement of a display on the operator's console that graphically displays the actual position of the source within the catheter. Presently, the source position must be deduced by multiplying the current dwell stop by the step size.

State Agency — The licensees comments and suggested product improvements were forwarded to the manufacturer's regulatory affairs office. The licensee was cited for failure to verify that the specific details of the administration were in accordance with the treatment plan and the written directive. Escalated enforcement actions were taken against the licensee.

This event is closed for the purposes of this report.

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AS 03-05 Overexposure at Monsanto Chemical Plant in Luling, Louisiana

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

Date and Place — June 28, 2003, to July 10, 2003; Monsanto Chemical Plant, Luling, Louisiana.

Nature and Probable Consequences — The licensee notified the Louisiana Office of Environmental Services on July 10, 2003, that a radiation overexposure had occurred to members of the public due to a loss of control of a 37 GBq (1 Ci) cesium-137 (Cs-137) source that became dislodged from a damaged fixed gauge. The licensee stated that on June 29, 2003, a Monsanto maintenance technician noticed that the gauge's handle mechanism had

broken off and fallen to the floor. The technician picked up the broken pieces and placed them on the Monsanto Planner's desk. The Planner was not present. The Planner returned to work on July 1, 2003, but did not discover the pieces until July 10, 2003. The Planner thought the parts were the gauge's locking mechanism and went to the area where the fixed gauge had been mounted and realized that the gauge's source was missing. After realizing that the parts contained the unshielded Cs-137 source, the licensee evacuated the building and secured the area. On July 11, 2003, a representative from a consulting company arrived on-site to perform an area survey, retrieved the source from the Planner's desk and placed the source in a secure storage area. The licensee requested that the manufacturer evaluate the failed gauge and conduct an assessment of the remaining gauges. On July 19, 2003, a representative from the device manufacturer removed the source from the Monsanto plant.

It was determined that the Planner occupied the desk for approximately 50 to 60 hours and received a whole body dose of approximately 400 mSv (40 rem). This determination was based on an analysis of the Planner's schedule and work habits together with the radiation dose rate of the source. The technician who carried the source to the Planner's desk received an extremity dose of approximately 18 Sv (1,800 rem) to the hand. Reenactments were performed to estimate the exposures to 100 individuals employed by the plant. The estimates were determined by the time spent and proximity to the source. The highest exposure was estimated to be 740 mSv (74 rem) and the next highest exposure 180 mSv (18 rem). Altogether, 42 nonradiation workers exceeded the 1 mSv (100 mrem) exposure limit to members of the general public. The workers are considered to be members of the public, and not radiation workers, because they are not exposed to radiation from licensed radioactive material as a normal part of their work. Others may have also been exposed at lower levels. Blood tests were performed for seven individuals, but revealed no cell changes. No one has shown signs of sickness or erythema.

The licensee is in contact with the Radiological Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, and has requested its assistance in having a cytogenetic blood study performed for the Planner. The licensee reported that it appears that vibration of the gauge caused the source holder and the attached source to fall. Surveys of the relevant areas and wipe tests on the source did not reveal any source leakage.

Cause or Causes — Monsanto believes the cause of the incident was corrosion of the epoxy that holds the source in place. However, the end plate was held in place by one tack weld and the vibration of the gauge could have compromised the shielding of the device.

Actions Taken To Prevent Recurrence

Licensee — The decision has been made to take this type of device out of service and replace it with a newer model. Until the devices are removed from service, weekly visual inspections on the devices will be performed. The Planner and Monsanto engineers/technicians were trained only to recognize the radiation posting on the device. Now the safety training includes pictures of the device, its components, and the radioactive capsule.

State Agency — The licensee was cited for two violations. One violation was for the exposure of a nonradiation worker in excess of 1 mSv (100 mrem) in a year, and the other was for

creating a radiation area in an unrestricted area that exceeded 20 μSv (2 mrem) in any one hour. The event was referred to State of Louisiana's Enforcement Section.

This event is closed for the purpose of this report.

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AS 03-06 Brachytherapy Medical Event at University Hospitals of Cleveland in Cleveland, Ohio

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — May 13, 2003; University Hospitals of Cleveland, Cleveland, Ohio.

Nature and Probable Consequences — On May 22, 2003, the Ohio Department of Health notified the NRC Operations Center of an apparent brachytherapy medical event at University Hospitals of Cleveland. The licensee reported a radiation treatment to the wrong target area during a brachytherapy prostate procedure using 59 I-125 seeds, each containing 13 MBq (0.351 mCi) for a total activity of 765 MBq (20.71 mCi). The treatment resulted in a distribution of seeds in areas other than prescribed.

An unintended area of the prostate gland received approximately 140 cGy (rads) due to seeds implanted outside of the intended cancer cell site. The licensee determined that 31% of the bladder received 7,200 cGy (rads) and 3% of the rectum received 7,200 cGy (rads).

Cause or Causes — Unusual anatomical aspects of the seminal/prostate vesicle under ultrasound hampered the physician's ability to correctly place the seeds fully within the intended preplan margins. In addition, seed visualization on fluoroscopy was suboptimal.

Actions Taken To Prevent Recurrence

Licensee — Faculty and staff will increase efforts to identify unusual prostate anatomical features during the preplanning process; specifically, continue to cross-check and verify seed position in relation to underlying anatomy. Corrective actions taken by the licensee include (1) the introduction of stabilization needles to assist in keeping the prostate fixed relative to the base plate, the ultrasound probe, and surrounding tissues during the localization and the seed deposition process and (2) the use of a more radio-opaque seed to facilitate positive location during procedures viewed under fluoroscopy. The patient and referring physician were notified of the medical event.

State Agency — The Ohio Department of Health performed an investigation of the event.

This event is closed for the purpose of this report.

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AS 03-07 Diagnostic Medical Event at Christus Santa Rosa in San Antonio, Texas

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

Date and Place — June 11, 2003; Christus Santa Rosa, in San Antonio, Texas.

Nature and Probable Consequences — A patient received 85.1 MBq (2.3 mCi) of I-131 instead of the prescribed dosage of 11.1 MBq (300 μCi) of I-131. The licensee discovered the error when the patient returned after 48 hours for a scan. The physician's written order requesting a thyroid scan for thyroiditis was misunderstood by the technologist as a request for a "whole body image" instead of a "thyroid up-take and scan". As a result, the technologist ordered the wrong dose for the prescribed procedure. Both the referring physician and the patient have been informed of the error.

Cause or Causes — The medical event was caused by human error. The wrong dosage was administered to the patient because the written order for the I-131 procedure was misread by the administering technologist.

Actions Taken to Prevent Recurrence

Licensee — The licensee implemented revised procedures mandating that a physician review all prescriptions requiring the use of I-131 and concur on the correct dosage.

State Agency — The State accepted the licensee's report and corrective actions as appropriate.

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AS 03-08 Therapy Medical Event at Marian Medical Center in Santa Maria, California

Criterion IV to Appendix A to this report states, in part, that a medical event that 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 to the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

Date and Place — April 25, 2002; Marian Medical Center, Santa Maria, California. This event was not determined to be an AO until the preparation of the FY 2003 report.

Nature and Probable Consequences — A patient was prescribed a therapeutic dose to the thyroid of I-131 with an activity of 296 MBq (8 mCi) but was erroneously administered 3.7 GBq (100 mCi) of I-131 instead. The error was discovered immediately and was reported to the

RSO and the referring physician. After consultation, the RSO and referring physician prescribed suppressive and hydration therapy to the patient immediately in order to minimize the patient's absorbed dose. The suppressive therapy blocked the thyroid from absorbing the total dose and the hydration therapy was given to accelerate the excretion of the radioactivity from the body.

The dose to the patient was calculated to be 3 cGy (rads) to the whole body and 38.7 Gy (3,870 rads) to the thyroid. No adverse health effects are expected.

Cause or Causes — The State found that the medical event occurred due to human error. Two I-131 capsules had been delivered that day for two patients who were to receive iodine therapy. The capsule containing 3.7 GBq (100 mCi) was given to the first patient. The error was recognized before the second patient was treated; therefore, the second I-131 capsule was never administered. The technologist failed to check the labeling and did not verify the dose using a dose calibrator.

Actions Taken To Prevent Recurrence

Licensee — Corrective actions included (1) counseling the technologist to review the labels on the vial and to check the dose in the dose calibrator before administration, (2) providing in-service training to technologists on proper procedures, (3) implementing new procedures requiring the doctor to check the label to assure the patient will be administered the correct dose, and (4) administering I-131 to no more that one patient daily.

State Agency — The State has reviewed and accepted the licensee's corrective actions.

This event is closed for the purposes of this report.

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AS 03-09 Gamma Stereotactic Radiosurgery Device Medical Event at Bayfront Medical Center, Inc., in St. Petersburg, Florida

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

Date and Place — Between August and October 2002; Bayfront Medical Center; St. Petersburg, Florida.

Nature and Probable Consequences — On October 31, 2002, the Florida Bureau of Radiation Control was notified that 10 patients undergoing Gamma Stereotactic Radiosurgery (gamma knife) had received a dose or doses at least 50% greater than prescribed. The prescribed treatments ranged from 12-24 Gy (1,220-2,400 rads) at the 50% isodose curve; however, the delivered doses to the patients ranged between 19.2-38.4 Gy (1,920-3,840 rads) at the 50%

isodose curve, which is 60% greater than the treatment prescribed. The patients were diagnosed with a variety of brain disorders (vascular diseases, tumors, and functional targets such as selected nerves). A treatment plan was developed and reviewed by the physicist, and the doses were administered using a gamma knife device. On October 30, 2002, while performing a routine QA, the RSO discovered that the physics parameters in the treatment planning file had an incorrect calibration factor. Further investigation identified that the system had an older calibration date which resulted in an incorrect information that the sources had 60% less activity. The medical events were discovered during a review of all patient files.

The medical events were reported to two authorized users and three referring physicians. Notification of the medical event was provided to nine of the patients or patients' responsible guardians and they were subsequently provided a copy of the report pertinent to that patient. The authorized user does not anticipate any change in the patient's condition from the additional exposure. The licensee's authorized users noted that these doses are still within the published literature. During the notifications it was discovered that one of the patients had died as a result of the patient's disease. The licensee's authorized users stated that this patient was given palliative treatment for four metastatic lesions that were not close to any critical structure. The patient died approximately 2 months after the treatment, which was the typical period of life expectancy for a patient with this type and stage of disease.

Cause or Causes — The State was not able to identify how the calibration date was changed in the treatment planning software physics protocol file. However, it is the licensee's responsibility, through an effective quality management program, to ensure that the treatment is administered with high confidence as directed by the authorized user.

Actions Taken To Prevent Recurrence

Licensee — The licensee has revised its quality management program to include additional daily checks to verify that the expected dose rate agrees with the dose rate shown on the treatment planning software physics protocol output to within 1%. The gamma knife manufacturer issued a notice dated November 4, 2002, to all customers utilizing the treatment planning system specific to the gamma knife used to treat these patients. The notice requested customers to check the physics protocol and to run tests to verify dose calibration factors after any treatment planning system service or software reinstallation.

State Agency — The State conducted an onsite investigation that included interviews with licensee personnel involved and a representative from the device's manufacturer on November 12-13, 2002. In the licensee's medical event report, the licensee indicated the device manufacturer installed a peripheral printer on August 26, 2002. The licensee's report also indicated that on this date the source calibration information was changed. During the investigation the manufacturer stated that it was unable to recreate the occurrence. Telephone interviews were conducted with service personnel from the device manufacturer. The State also consulted with an independently contracted physicist with experience specific to the gamma knife and its treatment planning system to determine the state of the equipment. It was

determined that the licensee's quality management program did not routinely verify calibration information as compared to treatment planning dose rates. State actions for this case are still pending.

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.

<u>Abnormal Occurrence Criteria</u>

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

I. For All Licensees.

A. Human Exposure to Radiation from Licensed Material

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

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

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

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

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

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

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

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

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

[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 ERA of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

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) [10 CFR 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

1. 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.

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

3. 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 event 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 to the gonads, *or* (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and

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

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

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, there was significant new information regarding two abnormal occurrences previously reported in the FY 2002 Report to Congress on Abnormal Occurrences.

NUCLEAR POWER PLANTS

1. Performance Deficiency Resulting in Reactor Vessel Head Degradation at Davis-Besse Nuclear Power Station in Oak Harbor, Ohio (previously reported as AO 02-1 in NUREG-0900, Volume 25).

Date and Place — March 6, 2002; Davis-Besse Nuclear Power Station, Oak Harbor, Ohio.

Background — On March 6, 2002, licensee personnel at the Davis-Besse Nuclear Power Station, a pressurized-water reactor plant designed by Babcock and Wilcox Company, operated by First Energy Nuclear Operating Company, and located near Oak Harbor, Ohio, discovered an area of significant degradation of the reactor vessel head in the vicinity of one of the vessel head penetrations. The full details of the event are discussed in the FY 2002 abnormal occurrence report as Event 02-1. At the time that report was issued, the event was listed as open.

Update on Actions Taken To Prevent Recurrence

Since the identification of the reactor vessel head degradation at Davis-Besse, the plant has been shut down. Davis-Besse has implemented a comprehensive return-to-service plan that includes detailed reviews of systems both inside and outside of the containment and all systems subject to potential boric acid corrosion.

The licensee has also addressed deficiencies that it identified in its safety conscious work environment and safety culture. Many senior managers were replaced, and the licensee contracted with an independent consultant to evaluate what actions the licensee needed to take to address the issues. The licensee continues to implement corrective actions to address the previously identified concerns with its safety conscious work environment and safety culture.

The NRC placed Davis-Besse under Inspection Manual Chapter 0350, “Oversight of Operating Reactor Facilities in a Shutdown Condition With Performance Problems,” on April 29, 2002. The NRC developed a Restart Checklist, which contains the issues identified by the Oversight Panel which need to be resolved before a restart decision can be made. The NRC staff continues to monitor the licensee’s efforts to ensure activities planned to be completed to correct the previously-identified deficiencies in plant and human performance are effectively implemented. However, restart will not be considered until all items on the Restart Checklist are satisfactorily resolved. As of January 15, 2004, 24 of 31 items had been resolved. Further inspections and assessment of Davis-Besse performance will be performed before plant restart is considered. The NRC also chartered a Lessons Learned Task Force (LLTF). The objective of this task force was to independently evaluate the NRC’s regulatory processes related to

assuring reactor pressure vessel head integrity in order to identify and recommend areas for improvement that may be applicable to either the NRC or the nuclear industry. The LLTF completed its evaluation and its conclusions were reviewed by a Senior Management Review Team to determine appropriate agency actions. The recommendations of the Senior Management Review Team were issued November 26, 2002. A Commission meeting was held on January 14, 2003, to brief the Commission on the Senior Management Review Team recommendations. The Commission approved proceeding with the recommendations. NRC implementation of the recommendations is ongoing.

The U.S. Department of Justice (DOJ) is currently reviewing this case. The NRC will consider enforcement options after DOJ has completed its review.

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

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2. Unplanned Radiological Exposure of Oil Rig Workers in Montana From Radioactive Materials Associated With Well Logging Operations (previously reported as "Other Event of Interest," No. 8, in NUREG-0090, Volume 25).

Date and Place — May 21 and May 23, 2002, Schlumberger Technology near Havre, Montana.

Background — On May 23, 2002, Schlumberger Technology Corporation (STC [the licensee]) notified the NRC's Operations Center of the temporary loss of control of a well logging source containing approximately 44 GBq (1.2 Ci) of Cs-137. The licensee reported that following well logging operations on May 21, 2002, near Havre, Montana, the well logging crew failed to transfer the sealed source from the well logging tool to its shielded transport container. As a result, the source was left unshielded on the rig floor for approximately 2 days, exposing 31 rig workers to radiation from the unshielded source. The rig workers are considered to be members of the public, and not radiation workers, because they are not exposed to radiation from licensed radioactive material as a normal part of their work.

In a written report of the incident dated June 25, 2002, the licensee stated that its three-person well logging crew had failed to conduct two required independent radiation surveys to ensure that the Cs-137 source was in its shielded container before the crew left the job site in Havre, Montana. The crew's failure to return the source to its shielded container and failure to conduct the surveys resulted in the Cs-137 source being left unshielded on a portable drilling rig for more than 2 days. Consequently, 31 rig workers who were not radiation workers received radiation exposure from the unshielded source. The licensee's initial estimates for the doses ranged from less than 10 mSv (1 rem) to as high as 64 mSv (6.4 rem). This included 10 workers between 20 mSv and 64 mSv (2 and 6.4 rem; respectively), 15 workers between 10 mSv and 20 mSv (1 rem and 2 rem, respectively), and six individuals less than 10 mSv (1 rem).

Actions Taken To Prevent Recurrence

The licensee's corrective actions for this event included (1) terminating the employment of the individuals deemed responsible for the loss of control of the Cs-137 source; (2) sending an

"STC Alert" describing the incident to all STC logging facilities in the United States, (3) implementing a planned modification to the licensee's training program to provide more detailed and graphic information regarding potential injuries to individuals that could occur if logging sources are not adequately secured, and (4) implementing a planned modification to the licensee's training program to include additional emphasis on the legal responsibilities of employees and managers and the potential penalties for individuals who violate company procedures.

Region IV conducted a prompt followup inspection in May 2002, but deferred further action pending the results of dose assessments, including cytogenetic studies of certain individuals who were believed to have received the highest radiation doses. On September 4, 2002, when preliminary results of cytogenetic studies indicated the potential for one individual to have received a radiation dose on the order of 2 Sv (200 rem), an Augmented Inspection Team (AIT) was chartered to review the incident, including dose estimates.

Based on an extensive review of the circumstances of the event and additional cytogenetic studies, the AIT concluded that if the postulated 2 Sv (200 rem) radiation dose of one individual was valid, it was not associated with this event. However, the AIT concluded that the loss of control of the source resulted in an unintended radiation dose to 31 members of the public, 13 of whom were estimated to have received a dose above NRC's annual dose limit of 1 mSv (100 mrem) for a member of the public, with the highest radiation dose estimated at 4 mSv (400 mrem). The AIT also determined that inclement weather on the second day of the incident prevented workers from receiving higher radiation doses.

On October 14, 2003, the NRC issued a NOV and Proposed Imposition of Civil Penalties in the amount of $90,000 to STC for the violations of NRC regulations that caused the radiation exposures to members of the public. The licensee paid the proposed civil penalty and provided NRC with a summary of corrective actions which was reviewed by the NRC and deemed to be adequate. Additionally, NOVs were issued to two individuals previously employed by STC whose actions contributed to the event.

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

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APPENDIX C

OTHER EVENTS OF INTEREST

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

NUCLEAR POWER PLANTS

1. Northeastern Electrical Power Outage

The following event did not meet the AO reporting criteria since it did not involve a serious degradation in the reactor coolant system pressure boundaries at the involved plants or a major reduction in the protection of public health or safety. However, the event did receive significant media coverage.

On August 14, 2003, the northeastern U.S. and Canada experienced a widespread electrical power outage affecting an estimated 50 million people. Nine U.S. Nuclear Power Plant (NPP) units experienced rapid shutdowns (reactor trips) as a consequence of the power outage and eight of the nine plants also experienced a loss of offsite power. The nine affected plants were Fitzpatrick, Ginna, Indian Point Units 2 and 3, and Nine Mile Point Units 1 and 2 in New York; Oyster Creek in New Jersey; Perry in Ohio; and Fermi in Michigan. The Davis-Besse NPP in Ohio lost offsite power as a result of the grid problems, but was already shut down for significant degradation of its reactor vessel head (see Appendix B, "Update of Previously Reported Abnormal Occurrences", to this report). NPPs in Canada and nonnuclear generating plants in both countries also tripped during this event. Numerous other NPPs in both countries observed disturbances on the electrical grid but continued to generate electrical power without interruption.

In response to the power outage, the U.S. and Canada established the Joint Power System Outage Task Force with three working groups, Nuclear Working Group (NWG), Electric System Working Group, and Security Working Group. The NWG was charged with identifying all relevant actions by nuclear generating facilities in connection with the outage. Nils Diaz, U.S. NRC Chairman, and Linda Keen, President and CEO of the Canadian Nuclear Safety Commission (CNSC), are co-chairs of NWG. The Joint Power System Outage Task Force investigation consists of two phases. During Phase I, NWG focused on collecting and analyzing data from each plant to determine what happened and whether any activities at the plants caused or contributed to the power outage or involved a significant safety issue. Phase II, tentatively scheduled for completion for early 2004, will review design features, operating procedures, and the regulatory requirements that could improve safety at power plants as well as grid reliability.

The NWG developed a set of technical questions to obtain data from the NPPs that would enable its staff to review the response of the nuclear plant system in detail. The plant data obtained was compared against the plant design to determine if the plant responses were as

expected; if they appeared to cause the power outage or contributed to the spread of the outage; and if all applicable safety requirements were met. The NWG coordinated their investigation with the other two working groups.

On November 2003, the Joint Power System Outage Task Force issued "Interim Report: Causes of the August 14th Blackout in the United States and Canada". In the report, the NWG concludes the following: all the nuclear plants that shut down or disconnected from the grid responded automatically to grid conditions; all the nuclear plants responded in a manner consistent with the plants' designs; safety functions were effectively accomplished and the nuclear plants that tripped were maintained in a safe shutdown condition until their restart; the NPPs did not trigger the power system outage or inappropriately contribute to its spread (i.e., to an extent beyond the normal tripping of the plant at expected conditions). Rather, they responded as anticipated in order to protect equipment and systems from the grid disturbances.

The severity of the grid transient caused generators, turbines, or reactor systems at the plants to reach a protective feature limit and actuate a plant shutdown. NWG received no information that points to the control room operators deliberately taking action to isolate NPPs from instabilities on the grid. In short, only automatic separation of nuclear units occurred.

Regarding the 95 other licensed commercial NPPs in the United States that did not experience rapid shutdowns, 4 were already shut down at the time of the power outage, one of which experienced a grid disturbance; 70 operating plants observed some level of grid disturbance but accommodated the disturbance and remained on line, supplying power to the grid; and 21 operating plants did not experience any grid disturbance.

This event is closed for the purpose of this report.

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2. <u>Potential Clogging of Emergency Sump at Davis-Besse Due to Debris in Containment</u>

The following event did not meet the AO criteria since it did not involve a serious degradation in the reactor coolant system boundary at the involved plant or a major reduction in the protection of public health or safety

In September 2002, with the Davis-Besse reactor defueled and in an extended outage, the licensee determined that had a design-basis loss-of-coolant accident (LOCA) occurred when the plant was operating, the existing amount of unqualified coatings (paint) and other debris inside containment could have potentially blocked the emergency sump intake screen, degrading the ability of the sump to act as a sufficient water source for the emergency-core-cooling-system (ECCS) and containment spray (CS) system. This could occur during the recirculation phase of a LOCA.

After the injection phase of ECCS in response to a LOCA where cooling water from a storage tank has been injected into the reactor vessel, the emergency sump is designed to provide the source of the spilled reactor coolant to the ECCS and the CS systems (recirculation phase). During the recirculation phase, the function of the ECCS is to remove heat from the nuclear fuel by recirculating the spilled reactor coolant back to the reactor vessel. The CS system is

designed to remove heat and fission product iodine from the post-accident containment environment and consists of two independent trains capable of taking suction from the emergency sump during the recirculation phase.

During the inspections of the containment that were performed by licensee personnel in 2002, licensee staff concluded that the free-flow area of the emergency sump strainer could be challenged by debris generated in the containment after a LOCA clogging in excess of 50% of the strainer area. The debris could include unqualified coatings that peel in the post-accident containment environment and insulation including fibrous insulation that becomes dislodged during the accident. Also, during the inspections a small opening was found in the as constructed strainer that could have allowed material greater than the galvanized wire 1/4 inch square screen openings (mesh) to flow to the ECCS and CS system. Additionally, the mesh size was larger than an internal ECCS high pressure injection (HPI) pump orifice for cooling water flow, which could result in debris blockage of the cooling water flow.

Some of the contributing causes for the use of unqualified coatings in containment were lack of appropriate engineering controls and process compliance for coatings used and items installed in the containment during original construction and subsequent outages; the installation of equipment in containment with the manufacturer's standard unqualified finishes; or applications of qualified coating material over the manufacturer's standard finish. Fibrous insulation was installed prior to recognition that the insulation could potentially represent a debris source. The root cause for the debris in containment was the failure to quantify and control the introduction of this material into containment. Considering other potential debris in the containment along with the unqualified coatings in the containment, the potential to block in excess of 50% of the strainer surface area was increased. This condition existed concurrent with the reactor vessel head degradation and the potential for the HPI pumps to fail due to injection of fibrous material.

As corrective actions, the old sump screen has been removed and a new strainer has been designed, fabricated, and installed. The new sump strainer expanded the screen surface area from 50 square feet available to approximately 1200 square feet of available area and is constructed of perforated plate with a smaller screen opening of 3/16 in diameter holes. To address the unqualified coatings and other debris inside containment, several components had the unqualified coatings removed. These components were left uncoated or a qualified coating was applied. Also, accessible fibrous insulation was removed from the containment. For the fibrous material and unqualified coatings left in containment, the amount of material was inventoried and an analysis was performed that determined that design criteria would not be exceeded. Procedures and specifications were revised to require verification that coatings to be used in the future be qualified, and if fibrous insulation was to be used, a requirement was put in place to evaluate its acceptability prior to installation. Additionally, the HPI pumps were modified to prevent clogging of the cooling water orifice. This modification included moving the location of the internal pump cooling port and installation of a fine mesh screen over the port.

Finally, the licensee performed an analysis based on the presence of potential debris that could clog the new sump. The analysis showed that with the new sump, sufficient surface area was available to ensure that the ECCS and the CS would be able to perform their intended functions after a design-basis LOCA. In addition, in all cases where components were left with unqualified coating systems and not reworked, the components were identified and tracked in the unqualified coating inventory.

The NRC has conducted a thorough review of the modifications, and concluded that the modifications will correct the deficiencies identified by the licensee.

The NRC has issued a bulletin (2003-001) to all pressurized water reactor owners to address generic implications. The bulletin requests that all affected licensees evaluate the conditions that could exist inside containment after a loss-of-coolant accident that could potentially affect safe operation, specifically the operability of the emergency sump and inform the Commission of what was found.

On October 2, 2003, the NRC issued a NOV for a violation involving the failure to implement corrective actions for design control issues.

This event is closed for the purpose of this report.

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3. Salem Unit 1 Spent Fuel Pool Leak

This event is included in this report because the issue has been the subject of inquiries from members of Congress and numerous other external stakeholders. The event was the subject of a briefing with a staff member from U.S. Senator Tom Carper's office on October 24, 2003. There has also been local media coverage of this event.

On September 18, 2002, Public Service Electric & Gas (PSEG), a reactor licensee in Hancocks Bridge, New Jersey, identified low-level personnel shoe contamination on personnel attempting to exit the Salem Unit 1 Auxiliary Building, a radiologically controlled area. The licensee initiated an investigation to determine the cause of the contamination. The investigation identified that a leak containing radioactive contaminated water, due to blocked drains under the spent fuel pool, had caused the personnel contamination. On November 20, 2002, PSEG informed the NRC that tritium activity had been detected in the ground adjacent to the Fuel Handling Building, which enclosed the spent fuel pool.

In early December 2002, NRC initiated an evaluation of PSEG's actions to characterize the leakage and its potential impact on workers, the public, and the environment. NRC regional management also conducted an onsite review and discussed the matter with PSEG management during a site visit. Inspection activities were coordinated with the State of New Jersey Department of Environmental Protection (NJDEP).

Additionally, NRC conducted a special team inspection at the Salem Unit 1 facility during the period June - August 2003. The special inspection team assessed potential impact on workers, the public, and the fuel pool structure. The team also evaluated potential generic implications. The inspectors did not identify any radiological dose consequences for workers or the public, or any adverse impact on the spent fuel pool structure. NJDEP representatives accompanied the inspectors during portions of the special inspection and were kept informed of ongoing activities. No onsite or offsite dose consequences or violations of NRC effluent release limits were identified. The NRC confirmed that PSEG initiated appropriate actions to determine the source of the contamination, assess the potential for offsite release, evaluate the radiological significance to onsite workers and members of the public, and prevent further contamination of the affected area. Although PSEG took appropriate actions once the leakage was identified, the NRC determined that PSEG was not effective in recognizing early conditions that were

indicative of degraded performance of the spent fuel pool leak detection system and in implementing corrective actions to resolve or better control the adverse conditions. On October 15, 2003, the NRC issued an inspection report to the licensee. In the inspection report, the NRC identified a non-cited violation for the failure to identify and correct a condition adverse to safety.

Subsequently, NRC followup confirmed PSEG is effectively implementing action to characterize the contamination and mitigate its effect on the environment. There has not been, nor is there expected to be, any radiological consequence to onsite workers, members of the public, or the environment due to the existing onsite tritium contamination in the ground. PSEG has taken effective action to control and collect the leakage and monitor the contaminated portion of the site. Actions have been initiated to remediate the affected area. PSEG has confirmed that the structural integrity of spent fuel pool systems has not been compromised, and has initiated action to better maintain its spent fuel pool leak detection systems to preclude recurrence. NRC continues to monitor PSEG's activities as part of the normal inspection program and to coordinate inspection and regulatory activities with the NJDEP.

This event is closed for the purpose of this report.

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OTHER NRC LICENSEES

4. Overexposure to a Radiographer at U.S. Inspection Services, Charleston, West Virginia

The following event is not an AO because it did not result in a dose to an individual that met the AO reporting criteria. However, the event is included because an individual received high radiation doses and may be of public interest.

An NRC Region III industrial radiography licensee, U.S. Inspection Services, conducted radiography at a temporary job site in Charleston, West Virginia on September 9, 2003. The radiographer and a radiographer's assistant (radiography personnel) were unknowingly exposed to radiation when a 762 GBq (20.6 Ci) Ir-192 source was not properly return to its shielded position.

After a radiography exposure and source retraction evolution, the radiography personnel conducted a post-exposure survey and did not note any unusual radiation levels. The radiography personnel also did not receive or hear any alarms originating from their alarming ratemeters. Therefore, the radiography personnel moved the radiography equipment from one area to another and prepared for the last radiograph that day. Subsequent to conducting the last radiography exposure of the day, the radiography personnel attempted to retract the source into its shielded position and realized that the source was already in the radiography camera. The radiography personnel speculated that the source had been retracted into the camera at the start of the last exposure when they thought it was being extended. Subsequently, the radiography personnel determined that their self-reading dosimeters were off-scale.

Upon notification by the radiography personnel of the potential overexposure, the licensee requested immediate processing of the radiography personnel's whole body dosimeters. Results received from the commercial dosimetry vendor indicated that the radiographer's dosimeter received more than 140 mSv (14 rem), and the radiographer's assistant's dosimeter received more than 6 mSv (0.6 rem). The licensee reported to the NRC that on September 9,

2003, a radiographer had a dose of 140 mSv (14 rem) reported on his whole body dosimeter as a result of an incident in which the source had apparently not been fully retracted into its shielded position.

Subsequently, the licensee and its contractor conducted a detailed time-motion study of the event, which included consideration of the likely source and dosimeter locations, and developed a revised dose assessment. Based upon these results, the licensee determined that the radiation source was fully extended out of the radiography camera during the entire period between the second-to-last radiograph and the last radiograph. The licensee reported that the radiographer received maximum doses of 205 mSv (20.5 rem) to his whole body, 215 mSv (21.5 rem) annual whole body dose, 1400 mSv (140 rem) to the skin of his whole body (thigh), and 2,350 mSv (235 rem) to his hands, all doses that are in excess of NRC annual dose limits. The licensee also concluded that the radiographer's assistant received maximum doses of 10 mSv (1 rem) to his whole body, 70 mSv (7 rem) to the skin of his whole body, and 170 mSv (17 rem) to an extremity, all doses that are within NRC annual dose limits.

The root cause of the event was attributed to licensee management's focus on production which resulted in poor management oversight of radiographic equipment operation and maintenance activities. Several apparent violations were identified involving failure to (1) properly conduct required survey instrument calibration and safety equipment operability checks; (2) ensure that modifications of radiographic equipment did not compromise the design safety features of the equipment; and (3) follow radiography operations procedures. NRC staff will consider enforcement options upon the completion of the licensee's and its investigations.

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

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