REPORT TO CONGRESS

ON

ABNORMAL OCCURRENCES

FISCAL YEAR 2002

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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 2002.

The report describes five AOs at facilities licensed by the NRC. One event involved the degradation of the reactor head at a nuclear power plant, the second event involved unaccounted for irradiated fuel rods at a nuclear power plant, the third event involved the failure to accurately record the location of two containers of strategic special nuclear material at a fuel cycle facility, the fourth event involved a gamma stereotactic radiosurgery misadministration and the fifth event involved an overexposure of a radiopharmacist at a materials facility. The report also discusses seven events at facilities licensed by Agreement States. Agreement States are 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 32 Agreement States. One of the Agreement State AOs involved elevated radiation levels from a package during its transport, three events involved radiography overexposures and three events involved medical misadministrations, two therapeutic and one diagnostic. In addition, Appendix C of the AO report, “Other Events of Interest,” describes two nuclear power reactor events, including a generic event of interest regarding an emerging issue involving reactor vessel head degradation, and four materials events.

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ABBREVIATIONS

AEA	Atomic Energy Act
AIT	Augmented Inspection Team
ANP	authorized nuclear pharmacist
AO	abnormal occurrence
ATI	Accurate Technologies Incorporated
Bq	becquerel
CAL	Confirmatory Action Letter
cGy	centigray
CFR	Code of Federal Regulations
Ci	Curie
Co-60	Cobalt-60
CPN	Campbell Pacific Nuclear
CRDM	control rod drive mechanism
Cs-137	cesium-137
DOT	United States Department of Transportation
F-18	fluorine-18
FR	Federal Register
Gamma Knife	Gamma Stereotactic Radiosurgery
Gbq	gigabecquerel
GDC	General Design Criterion
Gy	gray
I-123	iodine -123
I-131	iodine -131
Ir-192	iridium-192
IN	Information Notices
IVB	Intra Vascular Brachytherapy Misadministration
LLTF	Lessons Learned Task Force
LLW	low-level waste
LOCA	loss of coolant accident
MC&A	material control and accounting
MBq	megabecquerel
mCi	millicurie
mrem	millirem
mSv	millisievert
NRC	Nuclear Regulatory Commission
NMT	nuclear medicine technologist
PWR	pressurized water reactor
PWSCC	primary water stress corrosion cracking
RCPB	reactor coolant pressure boundary
REAC/TS	Radiation Energy Assistance Center/Training Site
RPV	reactor pressure vessel
RSO	Radiation Safety Officer
SAR	safety analysis report
SI	Special Inspection
SPEC	Source Production and Equipment Company
SNM	special nuclear material

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ACRONYMS and ABBREVIATIONS (con't)

Sr-90	strontium-90
SSNM	strategic special nuclear material
Sv	sievert
TBq	terabecquerels
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TI	transportation index
TIDs	tamper-indicating devices
TS	technical specification
U-235	uranium-235
U-238	uranium-238
VHP	vessel head penetration
µCi	microcurie

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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 Agreement State determined were AOs during Fiscal Year 2002.

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 criteria were published in the *Federal Register* on April 17, 1997 (62 FR 18820).

The NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described herein meet the AO criteria for being reported as AOs. 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 on previously reported AOs (during FY 2002, there was no significant new information regarding previous 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. Historically, the body of the AO report and Appendix C describe events meeting AO categorization. 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 State.

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

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regulated by the NRC. An inspection and enforcement program assists in ensuring compliance with the regulations. The NRC is seeking to make the regulatory system more risk-informed and performance-based, where appropriate.

REPORTABLE OCCURRENCES

Operating experience is 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 32 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 annual report to Congress. Therefore, AOs reported by the Agreement States to the NRC are included in the AO report and in the *Federal Register* notice issued to disseminate the information 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 materials events at facilities regulated by the NRC and the Agreement States.

FOREIGN INFORMATION

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

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UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

The NRC provides updates to 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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ABNORMAL OCCURRENCES
IN FISCAL YEAR 2002

NUCLEAR POWER PLANTS

Using the criteria and guidelines in Appendix A to this report, the following event that occurred at a U.S. nuclear power plant during this reporting period was significant enough to be reported as an Abnormal Occurrence (AO):

02-1 Reactor Vessel Head Degradation at Davis-Besse Nuclear Power Station in Oak Harbor, Ohio

Appendix A (see Criterion II.A.2, “For Commercial Nuclear Power Plant Licensees”) to this report states, in part, that an event will be considered for reporting as an AO if it involves a serious degradation of the primary coolant pressure boundary.

Date and Place — March 6, 2002; 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.

Nature and Probable Consequences — On February 16, 2002, the Davis-Besse facility began its 13th refueling outage, which included inspections of the control rod drive mechanism (CRDM) nozzles in accordance with NRC Bulletin 2001-01, "Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles,” issued on August 3, 2001. These nozzles penetrate through the reactor pressure vessel (RPV) head and are attached by welds. Nozzle cracking was first discovered in the industry in the late 1980s. The concern with cracking is the potential loss of control rod drive function (rod ejection) and the resultant loss of coolant accident (LOCA) should the cracks reach a critical size and orientation. Also of concern is the potential for the reactor coolant to leak through small cracks in CRDM nozzles and cause boric acid corrosion of the RPV head. The RPV head is an integral part of the reactor coolant pressure boundary (Figure 1) and loss of its integrity can likewise result in a LOCA.

On February 27, 2002, the licensee notified the NRC that non-destructive examination of CRDM Nozzles 1, 2 and 3 identified that those nozzles contained small through-wall cracks. The licensee decided to repair these three nozzles plus two other nozzles with identified cracks that did not appear to be through-wall. The repair process included machining away the lower portion of the CRDM nozzle to a point above the cracks in the nozzle material. During this activity, CRDM nozzle 3 loosened in the head and on March 6, 2002, the licensee began an investigation to identify the cause. At the same time, activities were underway to remove boric acid deposits from the top of the RPV head caused by leakage of reactor coolant from the cracks and past leaking CRDM flanges. After removing the boric acid deposits, the licensee identified a large corrosion cavity in the head material adjacent to CRDM Nozzle 3 (Figure 2). The cavity was approximately 6 inches in length and four to 5 inches in width. Within this area the 6.63 inch thick low alloy steel head was corroded away leaving only the stainless steel cladding layer on the inside. The remaining cladding layer ranged in thickness from 0.20 to 0.31 inches. Subsequent metallurgical examination of this section of cladding identified a shallow crack approximately 3/8 inch in length. This cladding layer is designed as a corrosion resistant layer and is not designed to retain reactor operating pressure. In addition to the cavity adjacent

to Nozzle 3, a comparatively small cavity was identified adjacent to Nozzle 2. This cavity was approximately 1.75 inches wide, 4 inches long, and 0.25 inches deep.

Region III sent an Augmented Inspection Team to the site to determine the facts and circumstances of the head degradation, beginning on March 12, 2002, and held a public exit meeting on April 5, 2002. A follow-up inspection identified several apparent violations of Agency regulations. The apparent violations will be processed in accordance with Agency procedure.

On April 8, 2002, prior to discovery of the crack in the cladding, the licensee submitted a safety significance assessment for the degraded RPV head to the NRC. This assessment determined that the as-found stainless steel cladding layer would have remained intact during anticipated operational occurrences and postulated accidents. Further, this assessment determined that had the RPV head failed due to the corrosion: a) adequate core cooling could have been established and maintained for the long term, b) the reactor could have been placed and maintained in a safe shutdown condition, and, c) the integrity of containment would not have been compromised. The NRC staff is performing an independent assessment and reviewing the adequacy of the licensee's assessment.

Cause or Causes — On April 18, 2002, the licensee submitted its Root Cause Analysis Report to the NRC. In this report, the licensee concluded that the most probable technical cause of the RPV head degradation was boric acid corrosion resulting from leakage through a crack in the CRDM penetration nozzle attributable to primary water stress corrosion cracking. Further, this corrosion had occurred over a period of several years. Absent more definitive information, the licensee's technical root cause analysis represents a plausible scenario for the degradation.

The licensee has completed a number of activities designed to identify management and human performance issues which contributed to this event. Several management and human performance issues were subsequently identified by both the licensee and NRC. NRC continues to monitor these activities and independently assess the effectiveness of the licensee's efforts in this area.

Actions Taken to Prevent Recurrence

Licensee — The licensee elected to replace the damaged head with one procured from the owners of the cancelled Midland nuclear power plant located in Michigan. The licensee has also completed a number of activities designed to identify the management and human performance deficiencies which contributed to the degradation of the reactor vessel head and implemented a series of inspections and evaluations to identify and correct any other potentially problematic plant issues.

NRC — Region III issued Confirmatory Action Letter (CAL) 3-02-001 on March 13, 2002, and Revised CAL 3-02-001A on May 15, 2002, which detailed specific licensee actions to be taken before NRC would consider restart of Davis-Besse. The NRC issued two Information Notices (IN) and two Bulletins to promptly inform the industry of the event: IN 2002-11, "Recent Experience with Degradation of Reactor Pressure Vessel Head"; IN 2002-13, "Possible Indicators of Ongoing Reactor Pressure Vessel Head Degradation"; Bulletin 2002-01, "Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity"; and Bulletin 2002-02, "Reactor Pressure Vessel Head and Vessel Head Penetration Nozzle Inspection Programs."

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The NRC placed Davis-Besse under the Inspection Manual Chapter 0350 "Oversight of Operating Reactor Facilities In a Shutdown Condition With Performance Problems" on April 29, 2002. 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 RPV 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.

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

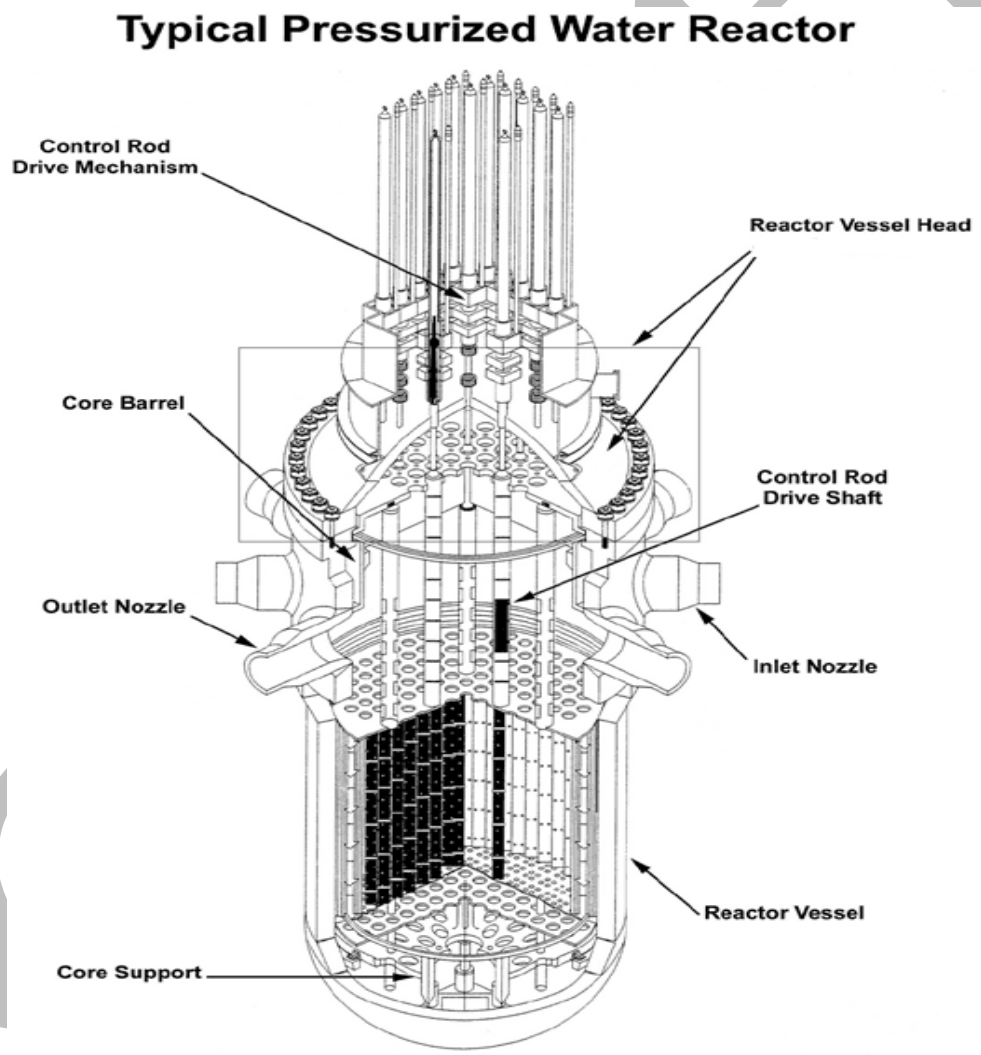

Figure 1. Typical Pressurized Water Reactor (PWR)

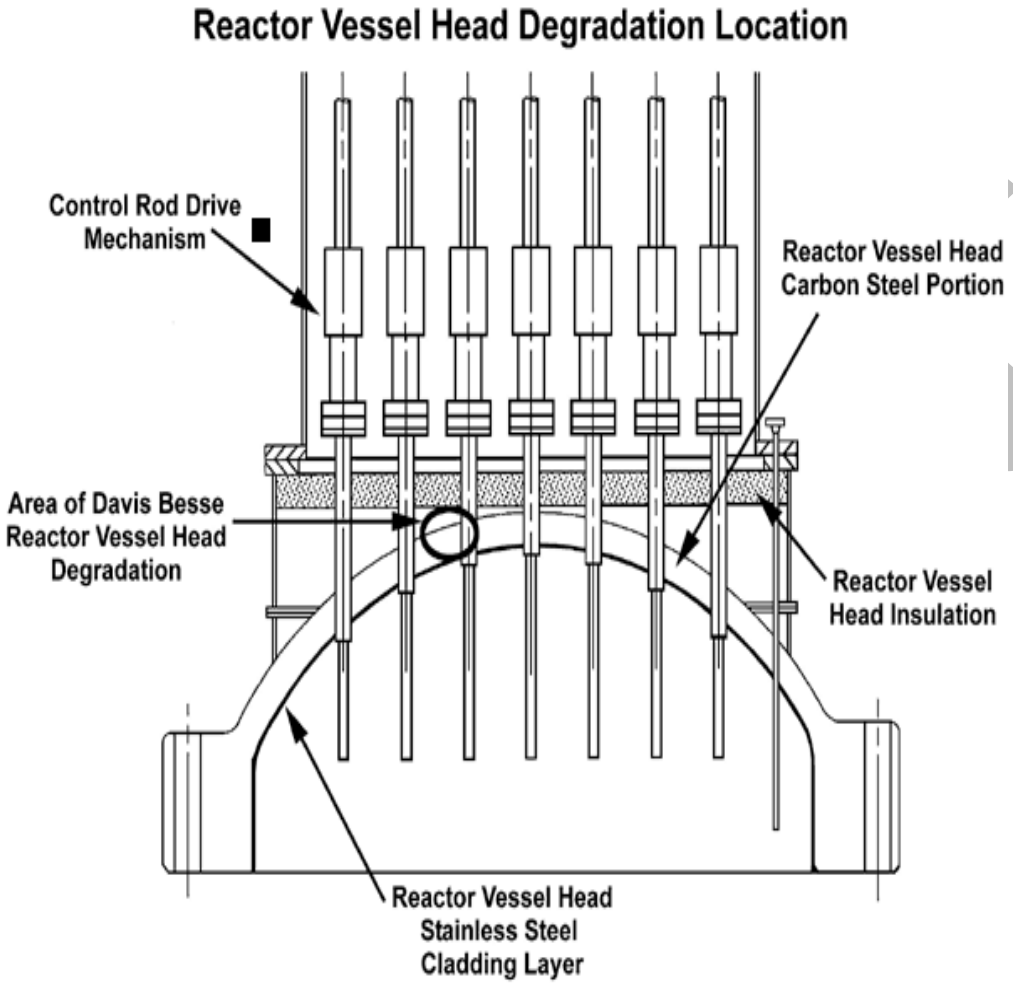

Figure 2. Reactor Vessel Head Degradation Location at Davis-Besse

Using the criteria and guidelines in Appendix A of this report, the following event that occurred at a U.S. nuclear power plant during this period was significant enough to report as an Abnormal Occurrence (AO):

02-2 Unaccounted for Fuel Pins at Millstone Unit One in Waterford, Connecticut

Appendix A (see Criterion I.C.3, "For All Licensees ") to this report states, in part, that an event will be considered reporting as an AO if it involves a substantiated loss of special nuclear material that is judged to be significant relative to normally expected performance and that is judged to be caused by a substantial breakdown of the accountability system.

Date and Place — December 14, 2000; Millstone Unit 1, a decommissioned boiling water reactor operated by Northeast Nuclear Energy Company located in Waterford, Connecticut.

Nature and Probable Consequences — On December 14, 2000, the licensee (Northeast Utilities) made a telephone report to the NRC Operations Center stating the location of two full-length irradiated fuel rods were unaccounted for in the special nuclear material accounting records. The licensee also submitted a written follow-up Licensee Event Report on January 11, 2001. This issue raised considerable public and media attention.

In 1972, an irradiated fuel assembly with damaged fuel rods was disassembled to allow examination and testing. When the assembly was reconstructed in 1974 two of the fuel rods could not be incorporated in the assembly for long term storage. These two fuel rods were therefore put into a fuel rod canister used to store individual fuel rods. Records dated 1979 and 1980 show the fuel rods stored in the canister in the northwest corner of the spent fuel pool, however records created after April 1980 do not show the fuel rods or canister in the fuel pool. Significant work, including two reracks and shipments of miscellaneous irradiated components from the spent fuel pool, took place from 1980 to 1992. In November 2000, a records reconciliation and verification effort, undertaken by the licensee to support the sale of the Millstone site to Dominion Resources, determined that the location of two full-length irradiated fuel rods was not properly reflected in special nuclear material records.

The licensee formed a team to search for the fuel rods and determine how they were misplaced. While the fuel rods were not found, the investigation concluded that the fuel rods were safely located in a facility that is licensed to either store or dispose of radioactive material. The NRC conducted a special inspection from October 9 through December 21, 2001 which determined that the licensee’s investigation was thorough and complete, and the conclusions were reasonable and supportable.

Based on the staff's knowledge to date, the current risk to human health from the unaccounted for fuel rods appears to be insignificant. If the rods are still in the spent fuel pool in an undetermined location (which appears highly unlikely based on the licensee's investigations), they would have been and are subject to all of the controls for protecting workers and the public that are in place for handling spent fuel in that area. If the rods were inadvertently shipped offsite, they would have been packaged in shielded shipping containers due to their high radiation levels, even if they were mistaken for some other non-fuel component, such as a local power range monitor, and would therefore have met the requirements for external exposure limits. The licensee's radiation monitoring program would have detected the high radiation levels

from the rods, an easily identifiable characteristic of the hazard if they were unshielded. Furthermore, the radiation detection instruments at the potential offsite locations would also have detected unshielded spent fuel. After transport, there are only three plausible locations for the rods, if they were shipped offsite - General Electric' s Vallecitos, California nuclear fuel research facility, where they would be safely stored in a manner similar to the fuel rods at the Millstone site, or a low-level radioactive waste disposal site in either Barnwell, South Carolina or Richland, Washington facility. The NRC determined that the potential presence of the two rods at either low-level waste facility would not constitute a present or future risk to public health and safety or the environment.

The very high radiation level of the material makes theft difficult, dangerous, and very unlikely. The radiation levels also makes the material of limited or no economic value. Moreover, the amount and chemical form of the fissile material contained in the two spent fuel rods make it unlikely that the rods could be used to manufacture a weapon. The NRC has no indication that the Millstone fuel rods were stolen from the site, the low-level radioactive waste sites or the GE facility in Vallecitos, California. Therefore, there is no evidence that the Millstone fuel rods could be used for a radiological dispersal device. The uranium in the fuel rods is low-enriched uranium and the amount is very small. The plutonium created in each rod during its time in the reactor core is also very small. In general, the proliferation consequences are small for special nuclear material quantities unless large quantities are present.

Cause or Causes — The licensee determined that organizational and process weaknesses in implementing their special nuclear material inventory and control procedures was the root cause for the loss of the two fuel pins. Contributing elements identified by the licensee's team included weaknesses in special nuclear material inventory and radioactive waste characterization, weaknesses in coordination of spent fuel pool activities and in procedure compliance, and inconsistent supervision and oversight of spent fuel pool activities.

The NRC found the licensee's root cause analysis to be comprehensive and concurred with the conclusions. The NRC also concluded that management controls and supervision of activities related to handling of special nuclear material and irradiated fuel were insufficient at the time to prevent the loss of the two fuel rods. These conclusions resulting in the NRC citing the licensee for the failure to : 1) keep adequate records of special nuclear material (SNM), 2) establish adequate procedures for control and accounting of SNM, and 3) conduct adequate physical inventories of SNM.

Actions Taken to Prevent Recurrence

Licensee — The licensee's investigation determined that the rods are: (a) in an undetermined location in the Unit 1 spent fuel pool; (b) at the Vallecitos, California facility; or (c) at one or both of the low-level radioactive waste disposal facilities in Barnwell, South Carolina or in Richland, Washington. Further, the licensee investigation concluded that the likelihood that the rods remain in the Unit 1 spent fuel pool or are at the Vallecitos facility was low, and that the low-level radioactive waste facility in Barnwell had the most significant opportunity to receive the rods.

NRC — In the NRC inspection report issued on February 27, 2002, the NRC concurred in the licensee's conclusion that the low level radioactive waste facility at Barnwell had the most significant opportunity to receive the rods, with an opportunity also existing to some small degree for the inadvertent shipment of the fuel rods to Hanford. The NRC team also concluded that,

while it is highly unlikely the rods in their entirety remain in the Millstone Unit 1 spent fuel pool, it is possible that fuel pellets or fragments remain on the spent fuel pool floor as a result of the cutting methods used to process waste hardware. A layer of sediment exists over portions of the spent fuel pool floor. Inspection methods were sufficient to assure intact fuel rods or large segments would not be in the sediment. The NRC inspection team did not concur with the licensee that the Vallecitos facility was a potential location for the fuel rods, and determined that the Vallecitos facility was not a plausible location.

As a result of the inspection findings, on June 2, 2002, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $288,000 to Dominion Nuclear Connecticut, Inc. (now the plant operator) due to the unprecedented loss of the fuel rods and to further emphasize the importance of adequate accounting of spent fuel at nuclear power plants.

This event is closed for the purpose of this report.

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Fuel Cycle Facilities
(Other Than Nuclear Power Plants)

Using the criteria and guidelines in Appendix A to this report, the following event, that occurred at a U.S. fuel cycle facility during this reporting period was significant enough to be reported as an AO:

02-3 Accountability Failure at Nuclear Fuel Services in Erwin, Tennessee

Appendix A (see Criterion I.C.4, "Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach") to this report states that 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 will be considered for reporting as an AO.

Date and Place — June 21, 2001, through August 23, 2001; Nuclear Fuels Services, Inc., Erwin, Tennessee

Nature and Probable Consequences — In June 2001, there were several failures to follow procedures at Nuclear Fuels Services, Inc. (NFS) that resulted in two containers of strategic special nuclear material (SSNM) not being recorded in the licensee's computerized inventory of material. These two containers remained at the site, inside secure storage at all times, but their location was not tracked in the licensee's records system. The material remained protected at all times by the licensee's physical security system.

On June 22, 2001, two containers of SSNM were sealed with tamper-indicating devices (TIDs) and moved from one location to another inside of a secured material access area without the appropriate computer transactions being performed that track and account for the SSNM. Shortly thereafter, the licensee's material control and accounting (MC&A) program identified that two TIDs were not with other unused TIDs and computer records did not show that they had been used to seal SSNM-bearing containers. The licensee searched for the TIDs and, when they could not be found, concluded that they had been lost. On August 10, 2001, the licensee conducted a routine semi-annual physical inventory of the material stored on site and found two containers of SSNM in secure storage, but not listed in the inventory records. On August 23, 2001, during the process of reconciling the inventories, the licensee determined that these two containers had been sealed with the missing TIDs and placed in secure storage without the appropriate computer records being made. The containers were originally sampled by the operator when the items were generated and the samples were sent to the analytical laboratory for measurements. When the items were found in the August 2001 inventory, they were opened, weighed and sampled again. All measurements matched those initially made. In April 2002, this material discrepancy came to the NRC's attention, and subsequently, the NRC initiated the review of the event and continued follow-up activities with the licensee.

The failure to record the containers had also not been detected by an additional feature of the licensee's material control program, referred to as process monitoring. In process monitoring, mass balances are calculated around various process steps, comparing the amount of material put into a process with the amount removed from the process. As a result of errors in records of

both input to and output from a process, the process monitoring system did not detect the failure to record in the computer that the material had been placed in the containers.

The consequence of the errors in the material control program was that there was no record that the material had been removed from the process area and placed in the storage area. The licensee apparently failed to meet several regulatory requirements for accounting for SSNM.

Cause or Causes — One cause was the failure of licensee personnel to follow procedures. Another cause was failure by the licensee to adequately investigate indications of the problem at the time it occurred. The licensee initiated and completed an investigation to identify root and contributing causes to ensure appropriate corrective to prevent recurrence as described in the next section.

Actions Taken to Prevent Recurrence

Licensee — Corrective actions have included: (1) providing MC&A supervisory oversight on all operating shifts, (2) more frequent reconciliation of MC&A discrepancies, (3) retraining of responsible individuals, and (4) upgrading the licensee's investigative procedures for missing TIDs. As a result of the licensee's root cause investigation, completed in November 2002, additional corrective actions to prevent reoccurrence were identified and are being implemented. These include enhancements to the computerized MC&A systems, improved procedural compliance, and revision of their system of checks and balances to prevent such discrepancies in the future and to promptly identify any if they occur.

NRC — In April 2002, the NRC became aware of the potential occurrence of a problem associated with the Material Control and Accounting (MC&A) program regarding identification and location of containers. The NRC requested the licensee to review the potential occurrence. As a result of correspondence with the licensee, the NRC determined in July 2002 that there had been an actual event, and it was potentially significant enough to warrant special inspection.

During August 26-27, 2002, the NRC conducted an inspection of the circumstances involved and the corrective actions taken after initial discovery. Several apparent violations of regulatory requirements were identified. The NRC held a management meeting with NFS on October 3, 2002, to further discuss the issues, their root causes, and planned corrective actions. The NRC issued a Confirmatory Action Letter (CAL) to NFS on October 15, 2002, to document specific commitments to corrective actions discussed by NFS in the meeting. NFS responded in writing to certain elements of this CAL on October 29, 2002 and provided additional information and a MC&A performance enhancement program at the management meeting with the NRC at the Region II Office on November 21, 2002. The NRC is continuing its review of licensee actions and is planning inspections to further review the licensee's MC&A systems and procedural compliance. The NRC is also evaluating its own procedures for performing oversight of licensees' MC&A programs to determine if changes might be needed so that such issues are identified by the NRC more promptly. Enforcement actions are under review.

This event is closed for the purpose of this report.

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OTHER NRC LICENSEES

(Industrial Radiographers, Medical Institutions, etc.)

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

02-4 Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at St. Luke's Medical Center in Milwaukee, Wisconsin

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

Date and Place — July 10, 2001; St. Luke's Medical Center; Milwaukee, Wisconsin

Nature and Probable Consequences — A patient undergoing Gamma Stereotactic Radiosurgery (Gamma Knife) was prescribed treatment of 20 Gy (2,000 rad) to a portion of the brain. During the treatment, the licensee completed three of eight treatment fractions and approximately one-half of the fourth fraction when the medical physicist and radiation therapist realized that the administered treatment utilized the treatment parameters for another patient, resulting in a dose of 12.8 Gy (1,280 rad) to an unintended portion of the brain (i.e., wrong treatment site).

For treatment, the licensee's medical physics staff prepared treatment plans for two patients, to be treated on the same day. The treatment plan for Patient A consisted of a prescribed dose of 18 Gy (1,800 rad). Prior to initiating treatment of Patient A, someone on the licensee's staff handed the plan of treatment for Patient B to the licensee's radiation therapist; later, the therapist could not recall who had handed her the plan. Using Patient B's treatment plan, the treatment team set up and delivered the first three fractions to Patient A and began delivery of the fourth fraction. The error was discovered by the medical physicist during delivery of the fourth fraction. Once notified of the error, the radiation oncologist terminated the treatment.

The medical physicist determined that the treatment delivered a dose of 12.8 Gy (1,280 rad) to an unintended region of the patient's brain. The radiation oncologist determined that the location of the unintended site was far enough away from the intended site to proceed with the intended treatment. The licensee subsequently administered the intended treatment without incident. The radiation oncologist did not anticipate any immediate adverse effects to the patient because of the treatment to the wrong site. He was not certain of the potential for any long-term effects as a result of the misadministration.

The NRC contracted with a medical consultant to evaluate the medical data associated with the July 10, 2001, misadministration and assess any probable deterministic effects to the exposed patient. The consultant agreed with the licensee's assessment. With regard to long-term affects, the NRC's consultant concluded that the misadministration may be at the threshold of late central nervous system injury and may produce symptoms. The consultant further opined that long-term follow up was indicated for the patient and that the patient was eligible for

inclusion in the Department of Energy's Office of Epidemiology and Health Surveillance voluntary life-time morbidity study.

The licensee notified the patient's referring physician, who was also the attending neurosurgeon, immediately after the event. The radiation oncologist informed the patient of the event the following day and subsequently provided a copy of the report submitted to the NRC.

Cause or Causes — This misadministration was caused by human error, in that licensee staff failed to verify that the treatment plan used was for the patient being treated. Licensee staff who participated in the treatment did not follow procedures requiring verification of patient-specific treatment parameters prior to delivering the radiation dose.

Actions Taken to Prevent Recurrence

Licensee — The licensee immediately implemented measures to ensure that patient-specific parameters are confirmed and verified prior to initiation of treatment. The measures included labeling each page of the treatment plan with the patient's name prior to initiation of treatment and maintaining the treatment plan in the Radiation Oncology Department binder for the patient.

NRC — The licensee was cited for violations that included failure to verify that the treatment parameters implemented were for the patient being treated.

This event is closed for the purpose of this report.

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02-5 Extremity Exposure in Excess of Regulatory Limits at Pacific Radiopharmacy, Limited, in Honolulu, Hawaii

Appendix A (see Criterion I.A.1, "Human Exposure to Radiation from Licensed Material") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more, will be considered for reporting as an AO.

Date and Place — March 26, 2002; Pacific Radiopharmacy, Limited, Honolulu, Hawaii.

Nature and Probable Consequences — During a routine, unannounced inspection conducted by the NRC on March 6, 2002, an inspector observed a radiopharmacist drawing 3700 megabecquerels (MBq) [100 millicurie (mCi)] bulk doses of technetium-99m (Tc-99m) utilizing a vial shield without a shielded top. The inspector observed that the radiopharmacist used his left index finger to hold the vial containing the Tc-99m in the shield when he inverted the vial to draw a dose. After questioning the individual, the inspector determined that this was a routine practice. Following the inspection, a licensee consultant calculated the exposure to the individual's left index finger to be 7000 mSv (700 rem) for calendar year 2001. The exposure was reported to the NRC Operations Center on March 26, 2002. In addition, the licensee's consultant calculated the exposure to the individual's left index finger to be 1400 mSv (140 rem) from January 1, 2002 through March 13, 2002. The exposure was reported to the NRC Operations center as a thirty day report on March 28, 2002. The radiopharmacist's extremity

exposure was chronic and not acute, occurring over the entire calendar year. The inspector viewed the individual's left index finger and did not identify any visible skin reddening.

Cause or Causes — Licensee management and the Radiation Safety Officer failed to effectively train Pacific Radiopharmacy employees on NRC requirements and failed to provide effective oversight of its radiation safety program.

Actions Taken to Prevent Recurrence

Licensee — The licensee has obtained additional vial shields with shielded tops, placed them at the second drawing station, and has required the radiopharmacist to use them. The licensee also reviewed the adequacy of the radiation safety officer's oversight of the radiation safety program, determined it to be inadequate, and has replaced the radiation safety officer with another individual. The new radiation safety officer conducts unannounced inspections of the radiopharmacy to ensure compliance with their procedures requiring the use of vial shields with shielded tops during dose drawing procedures.

On March 29, 2002, the NRC issued Confirmatory Action Letter (CAL) 4-02-003 to the licensee associated with the extremity exposure in excess of regulatory limits. On April 8, 2002, the licensee responded to the CAL with corrective actions which included: (1) removing the radiopharmacist from working with radioactive materials throughout the remainder of calendar year 2002; (2) contracting with a local consultant to provide safety training, conduct random unannounced audits, and provide Radiation Safety Officer (RSO) services; and (3) replacing its current RSO with the new consultant and requiring the RSO to attend quarterly board meetings to provide safety reports to the board.

NRC — In addition to issuance of CAL 4-02-003, NRC staff also met with licensee representatives in a Predecisional Enforcement Conference on October 10, 2002, to discuss the inspection findings. Enforcement action is currently pending.

This event is closed for the purpose of this report.

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AGREEMENT STATE LICENSEES

Using the criteria in Appendix A to this report, the 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 02-1 Loss of Package Integrity and Elevated Radiation Levels Measured at Federal Express Facility in Kenner, Louisiana

Appendix A (see Criterion I.B.2.a, "Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement") to this report states that radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in a radiation dose rate of 10 millisievert (mSv) (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material will be considered for reporting as an AO.

Date and Place — January 2, 2002, Federal Express facility at New Orleans International Airport, in Kenner, Louisiana.

Nature and Probable Consequences — A package containing iridium-192 (Ir-192) with elevated surface radiation levels was discovered at the Federal Express facility located at the New Orleans airport. The package was identified as a routine shipment for Source Production and Equipment Company (SPEC), located in St. Rose, Louisiana. After being notified by Federal Express authorities, a representative of SPEC picked up the package from the Federal Express facility. While loading the package, known as the SAFKEG, onto his truck, the individual noticed that his survey meter was offscale and his pocket dosimeter showed a reading of 1.6 mSv (160 mrem). The SAFKEG was transported back to SPEC facilities and entombed in high-density concrete bricks in its secured warehouse. The individual's total exposure during these activities was later determined to be 3.45 mSv (345 mrem).

The SAFKEG was shipped from a Swedish Company, Studsvik AB, and contained three vials loaded with a total of 1078 Ir-192 discs. The total activity was 366 terabecquerels (TBq) [9893 curie (Ci)]. Shipping papers accompanying the package indicated that the Ir-192 was solid metal, in a Type B(U) package with a yellow radioactive III label, and a transportation index of 2 [radiation levels of 0.02 mSv/hr (2 mrem/hr) at one meter from the surface]. Photographs taken by SPEC personnel, in St Rose, Louisiana, prior to the SAFKEG entombment confirmed that the appropriate U. S. Department of Transportation (DOT) labeling was affixed to the package. Surveys conducted at about the same time at 15 feet from the cask revealed measured radiation levels of 10 mSv/hr (1 rem/hr). The package remained entombed until a hot cell capable of remote inspection was constructed. After the SAFKEG's contents were removed, in the hot cell, and before it's shipment from the St. Rose facility, surveys for radiation levels and leak tests conducted for removable contamination showed no removable contamination.

The SAFKEG was originally shipped by Federal Express. A Health Physicist/Consultant to Federal Express performed dose estimate calculations for personnel exposed to the package during its transit. Personnel monitoring devices were worn by the flight crews for both the flights; specifically, from Sweden to Paris and from Paris to Memphis. The First Officer for the Paris to Memphis flight received 0.05 mSv (5 mrem) for the January-February 2002 monitoring period

and 0.39 mSv (39 mrem) for the November-December 2001 period. The consultant concluded that there were no excessive radiation levels from the SAFKEG on either flight. The consultant's calculations estimated the highest dose to any Federal Express employee at 20 mSv (2 rem). The French and Swedish regulatory agencies evaluated the portions of the event that occurred within their jurisdications.

Cause or Causes — On February 7, 2002, after construction of the hot cell, appropriate SPEC personnel opened the SAFKEG utilizing robotics. The tamper seal was intact; after it was broken, it was sealed in plastic and put aside. The interior shielded pot was removed and placed into a small lead shield. The shielding pot lid is normally secured with six allen head screws; however, one of the six screws was found loose. The plug assembly accessing the cavity containing the three vials of Ir-192 disks was removed, revealing that two of the three vials were open. The screw tops for the vials and a large number of Ir-192 disks were visible along the lip of the inner cavity. It is presumed the screw tops became unscrewed during transportation, resulting in the elevated external radiation levels.

Actions Taken to Prevent Recurrence

Licensee — The licensees involved in this occurrence are the package shipper, Studsvik AB, the package manufacturer, Croft, and the U. S. recipient, SPEC. The shipper and package manufacturer are pursuing corrective actions, but these have not been formalized as of the date of this report.

The inner-shielded pot of the package remained in the hot cell of the SPEC facility at the time of this report. SPEC had no plans to attempt further decontamination of the pot.

DOT — Prior to the opening of the cask, DOT issued a revision to the certificate of compliance for this type of package requiring that all vials used for this type of transportation must be sealed in such a way as to require that the vial must be destroyed to remove the contents. Since the opening of the keg revealed that the capsules had unscrewed, the DOT notice should prevent this type of occurrence in the future. DOT has discussed possible enforcement action as a result of this event.

State Agency — The State of Louisiana had the lead role in the investigation of this event and has concluded its investigation.

This event is closed for the purpose of this report.

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AS 02-2 Industrial Radiography Occupational Overexposure at Longview Inspection in Channahon, Illinois

Appendix A (see Criterion I.A.1, "Human Exposure to Radiation from Licensed Material") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in a 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 — The Illinois Department of Nuclear Safety (the Department) was notified on January 15, 2002, by the licensee's RSO, that in June 2000, a radiographer experienced an overexposure and subsequent injury at a temporary job site near Channahon, Illinois.

Nature and Probable Consequences — On January 15, 2002, the licensee reported a potential overexposure to a radiographer and a subsequent injury that could have resulted from the overexposure. The overexposure occurred in June 2000, and involved a 3.0 TBq (81.2 Ci), Ir-192 source at a temporary job site near Channahon, Illinois. The radiographer, believing that the source was secured following the radiographic exposure, approached the guide tube area and knelt down without looking at his survey meter. The radiographer's alarming rate meter was inoperable because of a low battery. After changing the radiography film for the next shot and unhooking the guide tube, he noticed the source drive cable was still in the guide tube and his survey meter showed an off-scale reading. He immediately cranked the source back into the shielded position. His self-reading pocket dosimeter was off-scale. The radiographer did not inform the licensee of the incident. Approximately two weeks after the incident, the radiographer noticed skin redness in a two centimeter sized area of his left calf. Over the next year, the wound became ulcerated and would not heal. A physician examined the individual and concluded that it could have resulted from radiation. In January 2002, the licensee's RSO became aware of the condition and reported it to the Department. Prior to commencing an extensive investigation, the Department recommended that the licensee seek immediate assistance from Oak Ridge Radiation Emergency Assistance Center/Training Site (REAC/TS). The REAC/TS concluded that the injury could have resulted from the overexposure in June 2000. The Department performed interviews and extensive time-motion studies and concluded that the incident could have occurred as described by the radiographer. The radiographer underwent skin grafting on February 26, 2002. The estimated dose to the individual was 15,000 mSv (1,500 rem) to the extremity.

Cause or Causes — The cause was identified as a failure to conduct a lockout survey of the camera after the source was retracted, the failure to conduct radiation surveys and the failure to utilize an operable alarming rate meter due to a low battery.

Actions Taken to Prevent Recurrence

Licensee — The licensee terminated the radiographer's employment and incorporated the event into the annual refresher training at all thirty-one Longview Inspection offices.

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State Agency — The Department conducted an investigation and concluded that the subsequent injury could have resulted from the overexposure. The Department imposed a suspension of the radiographer's certification for one year.

This event is closed for the purpose of this report.

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AS 02-3 Industrial Radiography Occupational Overexposure at McShane Industries in Baltimore, Maryland

Appendix A (see Criterion I.A.1, "Human Exposure to Radiation from Licensed Material") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in a 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 — September 25, 2001, McShane Industries, Baltimore, Maryland. The NRC was informed of this event in September 2001; however, this event was not documented as an AO in the "Report to Congress on Abnormal Occurrences, Fiscal Year 2001" because of its investigation at that time.

Nature and Probable Consequences — On September 25, 2001, a radiographer employed by Accurate Technologies Incorporated (ATI) of Tinton Falls, New Jersey, was overexposed while conducting industrial radiography in Baltimore, Maryland. (On December 20, 2001, the licensee changed its name to United Evaluation Services Incorporated.) The radiographer was using an Amersham 660A radiography exposure device (camera) when the sealed source containing 2.16 TBq (58.4 Ci) of Ir-192 failed to retract into the shielded position inside the camera following the previous radiographic exposure. The radiographer thought that the source was completely retracted into the shielded position when he relocated the camera, crank, guide tube and its extension tube in preparation for next exposure. The radiographer did not use a survey meter and was not wearing a pocket dosimeter, a whole body badge, or an alarming rate meter. The radiographer changed the film and identification, then secured the tip of the guide tube on to a different pipe weld for the next exposure. While attempting to unlock the camera for the next exposure, the radiographer noticed that the self-locking device on the camera was not in the locked position. Using the crank, the radiographer retracted the source into the shielded and secured position inside the camera. On September 29, 2001, the radiographer experienced burning and itching sensations in his fingers. On October 1, 2001, the radiographer notified the Radiation Safety Officer and visited a physician. The physician reported that, on October 1, 2001, the radiographer had erythema on his fingers and palms. On October 5, 2001, State Inspectors observed radiation burns and blisters on the radiographer's hands. At the request of the State of Maryland, the United States Department of Defense, Armed Forces Radiobiology Research Institute, analyzed a 30 milliliter blood sample obtained from the radiographer, using cytogenetic biological dosimetry techniques, and reported a mean whole body dose estimation of approximately 2,670 mGy (267 rad). The assistant radiographer on site during this incident was not exposed.

Cause or Causes — The root cause of this radiation injury was identified as a failure by the radiographer to follow licensed radiation safety procedures, to comply with Maryland Regulations

regarding radiation safety requirements for industrial radiographic operations, and to properly use required radiation detection and measurement devices. Specifically, the radiographer failed to wear an audible alarming rate meter or any type of dosimetry. He also failed to use a radiation survey meter. He inadvertently entered a very high radiation area caused by the Ir-192 sealed source that did not retract into the shielded position inside the camera. Finally, he failed to ensure that the source was secured in the shielded position prior to relocating the equipment from one location to another.

Actions Taken to Prevent Recurrence

Licensee — On October 4, 2001, the licensee agreed to discontinue all licensed activities until the completion of the departmental investigation.

State Agency — The licensee was cited for violations of Maryland Regulations for Control of Radiation. Specifically, the licensee was cited for exceeding occupational exposure limits; failure to conduct radiation surveys; failure to secure the device after the exposure; failure to wear and properly use a pocket dosimeter, alarming rate meter and film badge; failure to notify the Agency of an overexposure; failure to maintain a utilization log; failure to report a bankruptcy to the Agency; failure to notify the Agency before vacating premises; failure to authorize the RSO on the license; and several other associated violations. On October 25, 2001, the Agency issued a Cease and Desist Order to the licensee, prohibiting all industrial radiography activities in Maryland. ATI's Maryland radioactive materials license expired on December 31, 2001, and was terminated. The incident has been referred for escalated enforcement.

This event is closed for the purpose of this report.

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AS 02-4 Intra Vascular Brachytherapy Misadministration (IVB) at Rhode Island Hospital, Providence, Rhode Island

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

Date and Place — January 28, 2002; Rhode Island Hospital, Providence, Rhode Island

Nature and Probable Consequences — A patient was prescribed a dose of 8 Gy (800 rad) to the coronary artery during a Cordis Checkmate IVB procedure using 10 Ir-192 seeds, 8991 Mbq (243 mCi). On January 31, 2002, during a review of dosimetry and physician records, the licensee discovered that the diameter of the artery was used in the treatment plan calculation instead of the radius. This error resulted because the physicians (authorized users) using the CORDIS device were more familiar with the procedures for a NOVOSTE device also in use at this institution. The Novoste device uses the diameter of the artery in the dosimetry calculations

whereas the Cordis device uses the radius. The authorized user provided the wrong dimension (diameter instead of radius) which led to an incorrect dose being calculated. As a result the patient received an actual dose of 14.6 Gy (1,460 rad) to the outer coronary artery site instead of the prescribed 8 Gy (800 rad). The licensee indicated that there will probably be no adverse health effect to the patient.

Cause or Causes — As stated, the misdministration occurred due to human error in the use of the diameter of the artery instead of the radius of the vessel as required when using the Cordis system. The physicians' (authorized users) familiarity with the procedures for a Novoste device was a contributing factor.

Actions Taken to Prevent Recurrence

Licensee — The licensee informed the State of Rhode Island the next day by telephone of the potential misadministraton and provided a written report of the incident on February 14, 2002. In-service training has been conducted concerning the misadministration. In addition, the prescription form has been modified to indicate if the radius or the diameter of the vessel is being used for the treatment plan.

State Agency — The Agency has been in contact with the licensee concerning this matter and the effectiveness of the corrective measures implemented. The licensee indicated that there will probably be no adverse health effects to the patient. To date there has been no recurrence of the problem.

This event is closed for the purpose of this report.

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AS 02-5 Strontium-90 Eye Applicator Brachytherapy at South Broward Hospital District in Hollywood, Florida

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

Date and Place — January 4, 2002; South Broward Hospital District, Hollywood, Florida

Nature and Probable Causes — A patient was prescribed radiation treatment for pterygium in his left eye. The patient was to receive a total dose of 30 Gy (3,000 rad) in three 10 Gy (1,000 rad) fractions spaced approximately a week apart. Due to human error, the third and final fraction, given on January 4, 2002, was 24.84 Gy (2,484 rad) instead of the prescribed 10 Gy (1,000 rad).

The prescribed dose was to be administered via a 3M Company Model 6D1A eye applicator using a 973 MBq (26.3 mCi) strontium-90 (Sr-90) source. The written directive called for each fraction to consist of a treatment duration of 44 seconds to deliver a 10 Gy (1,000 rad) dose.

The correct fractionated dose was administered as planned on December 20, 2001, and December 28, 2001. A routine administration of the eye applicator required one person to time the event with a stopwatch while the authorized user administered the dose. The nurse and the authorized user became distracted in conversing with the patient and lost track of the time. The stopwatch used was the old style that simply counted time up and the nurse lost focus in trying to make the patient more comfortable and at ease. The authorized user had to remind the patient to gaze in a certain direction to treat the affected area. As a result, the third fractionated treatment time was 109 seconds instead of the prescribed 44 seconds resulting in a dose of 24.84 Gy (2,484 rad).

The patient was counseled about the slight increase in late effects including cataract formation and scleral scar tissue formation.

Cause or Causes — The State found and the licensee agreed that the misadministration occurred due to human error and the failure of staff to attend to details as required in licensee's procedures.

Actions Taken to Prevent Recurrence

Licensee — The licensee has identified and made changes in their procedures for use of the Sr-90 ophthalmic applicator. The facility purchased a digital stopwatch that has a large display, counts time down and not "up", audiblizes the time in the last 10 seconds, and alarms at the end of treatment. In addition, the nurse has been counseled and all personnel have received training in the revised procedures using the new stopwatch.

State Agency — The Florida Bureau of Radiation Control performed an on-site investigation February 7, 2002, to review licensees corrective actions which were found adequate by the State. The State also determined that while the patient was informed verbally of the misadministration, the licensee did not inform the patient in writing as required. The licensee was cited for failure to notify the patient in writing within 15 days.

This event is closed for the purposes of this report.

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AS 02-6 Industrial Radiography Occupational Overexposure at Technical Welding Laboratory, Inc. in Houston, Texas

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

Date and Place — April 10, 2002, Technical Welding Laboratories Inc., Houston, Texas.

Nature and Probable Consequence — On April 10, 2002, a radiographer received an overexposure calculated at 0.70 Sv (70 rem). The exposure occurred while conducting radiography using an Amersham 660 radiography exposure device (camera) containing a 1.30 TBq (35 Ci) Cobalt-60 radiography source. The radiographer stated that although the camera's automatic locking mechanism was inoperable while performing radiography, he did not stop work and proceeded to complete the job. On the contrary, the licensee hired a consultant to check the equipment's operability and found no problem. The equipment was placed back in service.

At the conclusion of a radiograph, the radiographer cranked the source to the shielded position without conducting a survey and then repositioned the source guide tube for the next radiograph. When he attempted to crank out the source for the next radiograph; the radiographer realized the source had not been retracted to its fully shielded position and was contained at the end of the guide tube. The radiographer notified the Radiation Safety Officer and returned to the office. The licensee then notified the State of Texas.

The radiographer was sent to a doctor, underwent blood tests and participated in a chromosome aberration study. Although the blood tests results were negative, the chromosome aberration study indicated a radiation exposure ranging from 0.70 Sv (70 rem) to 1.52 Sv (152 rem) with a 95 percent confidence level. In addition, due to the radiographer's difficulty in performing a good reenactment, a dose calculation of the exposure was difficult, however a consultant determined that a exposure of 0.70 Sv (70 rem) did occur. Although the radiographer stated that he could have possibly touched the end of the guide tube where the source was located, no erythema or blistering of the hand, as expected with an incident of this type was seen. A second consultant conducted calculations for a possible extremity exposure which resulted in a possible 2.01 Sv (201 rem) exposure to the right hand.

Cause or Causes — It was determined that the cause involved the radiographer's failure to: (1) wear his alarming rate meter; and, (2) wear a personnel monitoring device.

Actions Taken to Prevent Recurrence

Licensee — The licensee terminated the radiographers employment and reviewed the incident with other radiographers employed by the company. A licensee consultant evaluation of the equipment determined that the camera was functioning properly.

State Agency — The licensee and radiographer were cited for not performing a lockout survey after a radiographic exposure, not using an alarming rate meter during radiographic operations; not using a collimator during radiographic operations; and not using an individual monitoring device during radiographic operations. The licensee was also cited for allowing an individual to receive an exposure in excess of regulatory limits.

The licensee has since terminated its license and the radiographer no longer works in the industrial radiography industry.

This event is closed for the purposes of this report.

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AS 02-7 Diagnostic Misadministration at Cedars-Sinai Medical Center in Los Angeles, California

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that (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, or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s), will be considered for reporting as an AO.

Nature and Probable Consequences — A patient was erroneously administered 111 MBq (3 mCi) of iodine-131 (I-131) for a neck scan instead of receiving a diagnostic uptake scan of 7.4 MBq (.2 mCi) of iodine-123 (I-123). This resulted in a dose of 30.8 Gy (3,087 rad) from the I-131 to the patient's remaining thyroid tissue, rather than 0.07 Gy (7 rad) that would have resulted from the prescribed I-123.

The elderly patient was from another country, had some language difficulties, and had no medical records. The patient had a scar on her neck, and answered affirmatively when the referring physician (who was not an endocrinologist) asked if she had a thyroidectomy. Because there were no medical records, and because she had symptoms indicating a potential thyroid dysfunction, the referring physician ordered a "thyroid scan," and in the referral noted that the patient had a thyroidectomy. A temporary scheduling clerk at the administering hospital noted the thyroidectomy information and, after conferring with a nuclear medicine technologist (NMT), scheduled a dosage of 111 MBq (3 mCi) of I-131 for the patient. When the patient arrived at the licensee's facility, the NMT received confirmation from the patient that a scar on the patient's neck was the result of a thyroidectomy, the NMT proceeded to administer the scheduled neck scan with I-131. Neither the temporary scheduling clerk nor the NMT consulted with the authorized user or the referring physician to confirm their use of 111 Mbq (3 mCi) of I-131 instead of 7.4 MBq (0.2 mCi) of I-123. It was determined later that the patient had only a partial thyroidectomy, with approximately 50% of her thyroid mass remaining. The dose to the patient's remaining thyroid tissue 30.87 Gy (3,087 rad) from the I-131, instead of 0.07 Gy (7 rad) had I-123 been administered. Because of a possible reduction of thyroid function, the patient's physician will follow her medical needs.

Cause or Causes — The misadministration occurred due to human errors and inadequate procedures. The patient had language barriers that impeded clear communication with medical providers and licensee staff failed to consult the authorized user to obtain clarification from the referring physician. Finally, training and written instructions were not adequate to have prompted the temporary scheduling clerk or the NMT to seek appropriate assistance to resolve the dosage scheduled and administered.

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Actions Taken to The Prevent Recurrence

Licensee — Corrective actions taken to prevent recurrence included modifying the Nuclear Medicine Department procedures and ensuring that scheduling for all I-131 administrations, no matter what the activity, are performed by the Thyroid Treatment Coordinator or by the Chief, NMT.

State Agency — The California Department of Health Services has reviewed and approved the licensees corrective actions. The State is considering enforcement actions.

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

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

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

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

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

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

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

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special

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

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

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

(b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive *or* (2) a prescribed dose or dosage that (i)

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is the wrong radiopharmaceutical,[2] or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

Guidelines for "Other Events of Interest"

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

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

APPENDIX B

UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, there was no significant new information regarding previous abnormal occurrences.

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

NUCLEAR POWER PLANTS

1. Generic Communications Related to Reactor Vessel Head Degradation and Nozzle Cracking

The following events did not meet the AO reporting criteria since they 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.

The NRC previously issued Bulletin 2001-01, "Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles," in August 2001 in response to cracking identified in two of the control rod drive mechanisms at the Oconee Nuclear Station, Unit 3. As a result of more intensive and effective inspections resulting from implementation of this Bulletin, additional circumferential cracking and leakage from vessel head penetration (VHP) nozzles has been identified and remediated at several plants considered to be among the most susceptible to the primary water stress corrosion cracking (PWSCC) mechanism responsible for the degradation. Close-out letters have been issued to all of the pressurized water reactor (PWR) licensees.

Following the discovery of reactor vessel head degradation at Davis-Besse, as described in Section 02-1 of this document, the NRC issued Bulletin 2002-01, "Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity," in March 2002, to assess the status of licensee actions to assure the integrity of the reactor pressure vessel (RPV) head and other reactor coolant pressure boundary (RCPB) components. Based on a review of licensee responses to this Bulletin, the NRC staff concluded that no other plant had degradation, or the conditions that could lead to degradation, similar to that identified by the Davis-Besse plant. The NRC staff is continuing to gather information from PWR licensees regarding their actions to assure the integrity of the other reactor coolant pressure boundary components exclusive of the RPV head.

Bulletin 2001-01 and the RPV head portion of Bulletin 2002-01 provided information on the integrity of VHP nozzles and RPV heads at the time of issuance of the Bulletins and at the next refueling outages. To ensure the adequacy of future inspection plans for the RPV head and VHP nozzles, the NRC issued Bulletin 2002-02, "Reactor Pressure Vessel Head and Vessel Head Penetration Nozzle Inspection Programs," in August 2002, to advise PWR licensees that visual examination of the RPV head and VHP nozzles may need to be supplemented with additional

measures (e.g., volumetric and surface examinations) to demonstrate compliance with applicable regulatory requirements and to provide reasonable assurance of the public health and safety. As a result of the example supplemental inspections described in this Bulletin, additional plants have performed volumetric and surface examinations of their VHP nozzles in fall 2002 outages, and other plants will be performing such inspections at their next refueling outages. North Anna Unit 2 identified cracking in 63 out of 69 J-groove welds; the licensee subsequently decided to replace the RPV head prior to restart. Two other plants have identified numerous nozzles requiring repair. Oconee Unit 2 identified 15 nozzles (out of 69) and Arkansas Nuclear One Unit 1 identified 8 (out of 69). At this time 20 percent of the PWR plants have plans to replace their RPV heads with new heads fabricated using a material that has been found to be more resistant to PWSCC than the original heads.

NRC continues to work with the industry and the American Society of Mechanical Engineers to develop long-term inspection requirements to ensure continued integrity of VHP nozzles and the RPV head at PWR plants.

This event is closed for the purpose of this report.

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2. Potential Loss of All Auxiliary Feedwater at Point Beach

This event did not meet the AO reporting criteria since it did not involve a serious degradation of the reactor coolant system pressure boundary or a major reduction in the protection of public health and safety.

On November 29, 2001, after reviewing an issue identified by a Point Beach risk analyst, managers at Point Beach concluded that under certain transient scenarios, all four auxiliary feedwater pumps could fail because of overheating. The auxiliary feedwater system is a backup system that provides cooling water to the reactor's steam generators when the normal feedwater system is not available. Under certain transient conditions, such as a loss of off-site power and a loss of instrument air, the normal feedwater system would not be available and auxiliary feedwater would be required to remove heat from the reactor coolant system. Upon loss of instrument air, overheating of the auxiliary feedwater pumps would occur after the closure of valves that allow recirculation of cooling water through the pumps when the discharge or flow control valves for the pumps are closed or nearly closed. The recirculation valves would close, as the system was designed, during certain accident scenarios in which the plant's instrument air system would become unavailable. The discharge control valves could be closed or nearly closed by reactor operators as part of the expected response to certain scenarios. Also, because the design vulnerability associated with the auxiliary feedwater pumps had not been previously recognized, plant emergency operating procedures did not provide sufficient guidance to reactor operators to ensure adequate flow was maintained through the auxiliary feedwater pumps to prevent overheating of the pumps. With the pumps operating and the discharge and recirculation valves closed or nearly closed, the pumps would overheat and fail in one to 2 minutes. The potential for failure of the pumps had existed since the two reactors began commercial operations in the early 1970s.

There were no actual consequences due to this problem because none of the particular accident scenarios occurred, but if the pumps had failed in this way, the probability of damage to the reactor core would have increased significantly. After review of the results of a special NRC inspection in December 2001 and of further information supplied by Point Beach personnel during a meeting with the NRC on April 29, 2002, the NRC concluded on July 12, 2002, that this amount of increase corresponded to the highest level in the NRC's four-level, color-coded safety significance hierarchy and designated the problem as a "Red" inspection finding.

The cause of this problem was a combination of inadequate design of the auxiliary feedwater system and emergency operating procedures that didn't address the design vulnerability that had not been identified since the system was put into operation in the early 1970s. Point Beach personnel modified the auxiliary feedwater system to provide a back-up pneumatic supply to the recirculation valves so they do not close upon the loss of the instrument air system. In addition, emergency operating procedures have been revised to alert reactor operators of the need to ensure there is adequate flow through the auxiliary feedwater pumps.

On July 12, 2002, a Notice of Violation was also issued for a violation associated with the Red inspection finding involving the potential common mode failure of the auxiliary feedwater pumps during specific accident scenarios. The violation cited the licensee's failure to ensure that activities affecting quality were prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and failure from at least 1997 to 2001, to promptly identify and correct a condition adverse to quality.

This event is closed for the purpose of this report.

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OTHER NRC LICENSEES

3. <u>Overexposure to the Extremities of Two Nuclear Pharmacist's at Bristol-Myers Squibb Radiopharmaceuticals, Inc. Facility in Rio Piedras, Puerto Rico</u>

This event has caused the NRC to increase its attention to or oversight of a program area. This event did not meet the AO reporting criteria since it did not involve a major reduction in the degree of protection of public health or safety.

On April 12, 2002, Bristol-Myers Squibb Radiopharmaceuticals, Inc. reported that, as a result of an investigation of high extremity dosimeter readings and in response to NRC's IN 2000-10, "Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits," they conducted a study which revealed that dose to the fingertips could be a factor of three to seven times the dose recorded on ring badge dosimetry used to measure dose to the hands. Based on recorded annual extremity doses of 0.27 Sv (27 rem) and 0.34 Sv (34 rem) to two operators, the licensee believed that the doses to their fingertips for calender year 2002 exceeded the regulatory limit of 0.50 Sv (50 rem). Based on the actual dose received, the NRC concluded that it is unlikely that the radiation dose received by the operators resulted in any significant health effects. The licensee reported that corrective actions included the conduct of additional audits of the program

and comprehensive improvements in the handling techniques. The licensee's failure to limit the annual dose to the extremity of two employees to 0.50 Sv (50 rem) shallow dose equivalent exposures and failure to perform adequate surveys to evaluate the exposures to the fingertips to the two employees were identified as violations as required by 10 CFR 20.1201(a)(2)(ii) and 1501, respectively. On August 22, 2002, the NRC issued a Notice of Violation for the two violations which were categorized collectively as a Severity Level II problem because the exposures were greater than two times the regulatory limit. In accordance with the NRC's Enforcement Policy, a civil penalty was not proposed because the licensee took proactive, aggressive corrective actions that led to the identification of the overexposures and changes to licensee handling procedures that significantly reduced subsequent extremity exposures.

This event is closed for the purpose of this report.

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4. Overexposure to a Nuclear Pharmacist's Extremities at Eastern Isotopes, Inc. Facility in Sterling, Virginia

This event has caused the NRC to increase its attention to or oversight of a program area. This event did not meet the AO reporting criteria since it did not involve a major reduction in the degree of protection of public health or safety.

On October 24, 2001, inspectors conducted an inspection at Eastern Isotopes in Sterling, Virginia to review the circumstances surrounding the extremity overexposure of an authorized nuclear pharmacist (ANP) of approximately 1.27 and 0.86 Sv, (127 and 86 rem) to the right and left index fingers, respectively. The ANP handled radiopharmaceuticals licensed by both NRC (e.g. technetium-99m) and the State [e.g., fluorine-18 (F-18)]. The ANP routinely worked at one of the licensee's nuclear pharmacy locations with NRC-licensed materials only and, on several occasions, filled in for other ANPs at another of the licensee's facilities working with both NRC- and State-licensed materials. As a result, the individual received a majority of the extremity dose that led to the overexposure during the months of September and October 2001 from the improper handling of F-18 labeled radiopharmaceuticals. The NRC retained the services of a medical consultant to review the circumstances surrounding the event. Based on that review, the NRC concluded that it is highly unlikely that the dose received by the pharmacist resulted in any significant health effects. However, because the actual consequence of the violation was an exposure to an employee greater than two times the regulatory limit and the potential existed for a much greater radiation exposure, the violation was categorized at Severity Level II, in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600. On July 30, 2002, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $4,800 was issued for the Severity Level II violation involving an overexposure to a pharmacist in excess of NRC requirements.

This event is closed for the purpose of this report.

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5. Exposure to a Member of the Public at St. Joseph Mercy Hospital, Ann Arbor, Michigan

This event did not meet the AO reporting criteria since it did not involve an exposure in excess of 0.25 Sv (25 rem) total effective dose equivalent.

An NRC Region III medical licensee, St. Joseph Mercy Hospital, Ann Arbor, Michigan, provided a letter to the NRC on October 1, 2002, detailing the final summary of events concerning the incident involving a dose to a member of the public in excess of 1 mSv (100 mrem). The exposure occurred to the adult daughter of a radiopharmaceutical therapy patient. In accordance with the authorized physician user's written directive, the hospital staff administered 10.5 GBq (285 mCi) of sodium iodide on July 1, 2002, to a 72-year old female patient diagnosed with metastatic thyroid carcinoma. Because of the patient's condition, the licensee hospitalized the patient and established radiological restrictions for visitors. The patient died on July 7, 2002, due to complications of her illness. The death does not appear to have been related to the radiopharmaceutical therapy treatment.

During the patient's hospitalization, licensee staff frequently noted that the patient's daughter was not complying with visitor restrictions, and she was discovered numerous times to be sitting next to the patient's bedside. The licensee's radiation safety committee and RSO determined on July 17, 2002, that the possibility existed that the patient's daughter, and several other family members, received a dose of radiation in excess of the 10 CFR Part 20 limit of 1 mSv (100 mrem). The NRC's regulations, in 10 CFR 20.2203, require that licensees notify the NRC of such exposures in a 30-day written report following discovery of the event.

The licensee submitted its initial report of the event to the NRC on August 15, 2002. However, because of difficulties in reconstructing events and developing a dose estimate, the licensee submitted its final written report on October 1, 2002. The report included a dose estimate for the patient's daughter that included more specific information regarding the daughter's location within the patient's hospital room and her time of exposure. The licensee's final dose estimate for the daughter was 30 to 56 mSv (3 to 5.6 rem). Based on this more technically supportable estimate, NRC Region III management chartered a Special Inspection (SI) Team to evaluate the circumstances of the event and the daughter's resultant exposure. The SI Team completed its inspection on October 16, 2002.

The Team's assessment of the daughter's exposure was 150 mSv (15 rem). The assessment was based upon details provided by the daughter that were not recalled during previous discussions with licensee representatives. In these discussions, the daughter stated that no other family member remained in the patient's room for as long as she. Based on that and other information developed, the Team estimated that as many as ten other family members could have received doses in excess of 1 mSv (100 mrem), but not exceeding 5 mSv (500 mrem). Since NRC regulations have been recently amended to allow members of the public to receive up to 5 mSv (500 mrem) in situations such as this, the SI Team did not pursue those exposures. The NRC has contracted with a medical consultant to evaluate the exposure to the daughter.

Nuclear Regulatory Commission staff are reviewing the outcome of the inspection and considering the appropriate enforcement action.

This event is closed for the purpose of this report.

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6. Unplanned Radiological Exposure of Oil Rig Workers in Montana from Radioactive Materials Associated with Well Logging Operations

This event did not meet the AO criteria for this reporting period. However, this event has caused the NRC to increase its attention to or oversight of a program area and has resulted in licensed materials entering the public domain in an uncontrolled manner.

An NRC well-logging licensee, Schlumberger Technology Corporation (the licensee), notified the NRC Operations Center, on May 23, 2002, of an incident involving loss of control of a radiation source and possible unplanned exposures of several oil rig workers. The incident occurred between May 21 and May 23, 2002, at an oil rig site near Havre, Montana approximately 16 kilometers (10 miles) from the Canadian border.

The radioactive source involved was a cesium-137 well-logging source of 44 GBq (1.2 Ci) nominal activity. NRC conducted a special inspection on May 25-26, 2002, to determine the facts of the event, interview the workers involved, and calculate preliminary dose estimates for the exposed workers.

The licensee submitted its report of the event to the NRC on June 26, 2002. In its report, the licensee estimated that the highest dose to any worker, based on time-and-motion reconstructions of the event and some conservative assumptions, was 64 mSv (6.4 rem). To support its bounding dose calculations, the licensee had blood tests performed on ten of the workers involved in the event. These tests were routine blood counts done at a local hospital, and were intended to rule out high radiation exposures by showing that there were no abnormally low blood counts. The licensee also advised the workers to forward their test results to the REAC/TS for interpretation, and six of the ten workers who took the tests sent their blood test results. Based on the review by REAC/TS, one of the workers was advised that a cytogenetic test should be done. The Armed Forces Radiobiology Research Institute in Bethesda conducted this test, and the NRC was informed of the cytogenetic test results on August 30, 2002. The results showed a significantly higher dose than originally estimated. In response to these test results, NRC upgraded its ongoing special investigation to an Augmented Inspection Team (AIT). The AIT investigation is still ongoing at the time of this report.

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

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NRC AND AGREEMENT STATE MATERIALS LICENSEES

During FY 2002, 603 events involving materials licensees were reported to the NRC. In 266 of these events, licensed material entered the public domain in an uncontrolled manner. Seventy-two of the 266 events were reported by NRC licensees and 194 were reported by Agreement State licensees. In some cases, the material caused radioactive contamination or radiation exposure. Most of these events posed little risk to public health. The NRC is aware of only a few events in which members of the public received measurable radiation doses from the loss of control of licensed material, and no events in which acute health effects to a member of the public are expected.

The 266 events of loss of control of licensed material involved both medical and industrial licensed materials. Examples are (1) radioactive sources used in medical treatments or research and development, (2) gauges used to measure the moisture density in soils and to monitor production processes for quality control in construction and civil engineering, (3) chemical agent monitors/detectors used by the military to detect the presence of chemical warfare agents, and (4) tritium used to illuminate exit signs and mortar-sighting mechanisms in the military.

Any loss of control of material is undesirable. To prevent future incidents, the NRC and Agreement States have issued generic communications to inform licensees about these events and their consequences. In some cases, regulatory changes intended to increase licensees' accountability for generally licensed devices have been developed and are being developed. For example, the NRC revised its Enforcement Policy by increasing the base amount of civil penalties for the loss, abandonment, or Improper transfer or disposal of sources and by emphasizing that base civil penalties should normally be proposed for lost sources or devices. The NRC issued thirteen proposed civil penalty actions during fiscal year 2002 to emphasize the importance of maintaining control of licensed material. The NRC is currently evaluating additional security and control requirements for sources. Further, in response to the events of September 11, 2001, the NRC is conducting a review of security matters concerning materials licensees.

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The following example of loss of control of material is provided for illustration.

Lost and Recovered Portable Gauge

On July 25, 2002, the licensee, Atlantic Drilling Supply, reported the loss and recovery of a Campbell Pacific Nuclear (CPN) moisture/density gauge that contained a 1.85 GBq (50 mCi) americium-241:beryllium-40 source and a 0.37 GBq (10 mCi) Cs-137 source. The gauge was picked up for shipment at the licensee's facility on July 3, 2002, and was being returned to the manufacturer in Martinez, California, for calibration. The gauge was shipped via Conway Southern Express. As of August 5, 2002, the gauge had not reached its destination. The shipment was traced to Jacksonville, Florida, where paperwork indicated shipment to the Conway Southern Express facility in Atlanta, Georgia. No paperwork could be produced indicating that the shipment arrived in Atlanta. The Florida Bureau of Radiological Health conducted a visual and radiological survey at the Conway Southern Express facility in Orlando, Florida. The Georgia Environmental Protection Division conducted a similar survey at the Atlanta facility. The U.S. Department of Transportation was notified. The gauge was found in the shipper's facility in Denver, Colorado, on August 23, 2002. The gauge had arrived with no shipping papers, owner, origin, or destination. It was placed in the lost and found bin until the owner was determined. The gauge was undamaged and had not been opened. The gauge was returned to the licensee on August 23, 2002, and will be sent to CPN for calibration.

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