

POLICY ISSUE INFORMATION

April 14, 2011

SECY-11-0056

FOR: The Commissioners

FROM: Scott W. Moore, Acting Director
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE
PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS
FISCAL YEAR 2010

PURPOSE:

This paper provides the ninth annual report on significant nuclear materials issues and licensee performance trends in the Materials and Waste Programs pursuant to Staff Requirements Memorandum (SRM) SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated February 25, 2003 (ML030560328). This report covers fiscal year (FY) 2010. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2010, the staff evaluated significant nuclear materials issues and performance trends based on aggregated information obtained from operating experience associated with reportable events and generic issues affecting the industry. With the exception of the review of escalated enforcement actions, this evaluation included both U.S. Nuclear Regulatory Commission (NRC) and Agreement State licensees. The staff concluded, from the assessment of the overall performance data, that there are no discernable performance trends or generic issues and that health and safety was protected. For FY 2010, there were two nuclear material

CONTACT: Duane E. White, FSME/MSSA
(301) 415-6272

licensees, Nuclear Fuel Services, Inc. and the U.S. Department of Veteran Affairs, who met the criteria for discussion at the Agency Action Review Meeting (AARM).

BACKGROUND:

On June 28, 2002, the Commission issued SRM M020501 concerning the AARM. In the SRM, the Commission directed the staff to propose a process for providing the Commission with annual updates on significant nuclear materials issues (such as overexposures, medical events or misadministrations, and lost or stolen sources) and on adverse licensee performance.

In response to this SRM, on December 11, 2002, the staff issued SECY-02-0216, providing criteria for determining the nuclear materials licensees to be discussed at the AARM and the process the staff would use to provide the Commission with annual updates on significant nuclear materials issues and adverse licensee performance. On February 25, 2003, the Commission issued an SRM for SECY-02-0216, which approved the staff's proposal to evaluate materials licensees with performance issues for discussion at the AARM, and to provide the Commission with information on the Materials and Waste Programs' performance in an annual report.

On September 16, 2008, the staff issued SECY-08-0135 "Revision of the Criteria for Identifying Nuclear Materials Licensees for Discussion at the Agency Action Review Meeting" (ML082480564), which provided a revision to the criteria provided in Table 1 of SECY-02-0216 for determining nuclear materials licensees that warrant discussion at the AARM. The criteria were revised to provide additional clarity and incorporate NRC's current policies and procedures.

DISCUSSION:

The evaluation of significant adverse performance issues and performance trends are based on aggregated information that includes operating experience associated with reportable events and generic issues affecting the industry. As committed to in SECY-02-0216, the staff has developed a process for providing the Commission with annual updates on significant issues and performance trends that builds on existing processes and systems and has minimal impact on staff resources.

The aggregated information used to evaluate significant adverse performance issues and performance trends was obtained through existing processes and systems and includes the following: Abnormal Occurrence (AO) data; strategic outcomes and performance measures data; data derived through escalated enforcement actions; annual report data based on assessment of events reported to the Nuclear Material Events Database (NMED); generic and/or special event study results; and significant licensee performance issues that were identified based on the criteria described in SECY-08-0135.

The following sections represent an evaluation of the nuclear material events data and significant licensee performance issues followed by overall conclusions of performance in the Materials and Waste Programs.

AO Data

The staff determined that 15 events were identified as AOs during FY 2010. These AOs include eight events at NRC-licensed or regulated facilities and seven events at Agreement State-licensed facilities. Twelve of the 15 AO events were medical events as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, and the remaining 3 events involved radiation exposure to an embryo/fetus. It should also be noted that of the 15 AO events, only 6 of the events occurred in FY 2010. The remaining nine AOs occurred previously and the NRC's evaluation was completed in FY 2010. In addition to these 15 AOs that were identified during FY 2010, the staff has identified an additional 15 events in FY 2006 - FY 2010 that are potentially AOs for which additional information about the event is required. Reasons for the missing information include ongoing, pre-decisional enforcement actions that must be resolved. In other cases, additional time is needed for event follow-up. The staff is working with the Agreement States and licensees to obtain the necessary information, and the events will be included in a future report. A breakdown of the AO events by type of events and jurisdiction of the event (NRC vs. Agreement State) may be found in Enclosure 1 of this paper. No significant performance trends or generic concerns were identified when analyzing the last 10 years of data.

Given the small number of AO events reported as compared to the significantly larger number of total medical treatments and diagnostic procedures performed by medical-use licensees per year (e.g., more than 20 million procedures a year), the staff does not believe that these events represent a generic concern.

The staff's analysis and evaluation found that human error was a main contributor to the root causes of these AO events. The causes for these 15 events include: failure to properly visualize, identify and/or verify the treatment site; malfunction of the medical equipment; errors in set-up of medical equipment; failure to perform a pregnancy test; and receiving false negative pregnancy tests.

Strategic Outcomes and Performance Measures Data

NRC staff focused on verification and validation of data generated by NRC and the Agreement States to determine the impact on strategic outcomes and performance measures, as reported in NRC's "Fiscal Year 2010 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero occurrences, and there were no occurrences reported during FY 2010 that met any of the strategic outcomes. Also, the safety and security performance measure targets were met in FY 2010.

Data Derived Through Escalated Enforcement Actions

For the 2010 calendar year (CY) period (January 1, 2010, through December 31, 2010), NRC issued 88 escalated enforcement actions involving NRC materials licensees (i.e., including fuel cycle licensees). Escalated enforcement actions in the Materials and Waste Programs includes civil penalties and Notices of Violation (NOV) for Severity Levels I, II, and III violations (some of these actions involved multiple violations that were grouped together and issued as one violation), as well as Orders and Demands for Information (DFI). The escalated enforcement actions issued in CY 2010 for the Materials and Waste Programs include 4 Severity Level II

NOVs, which are described in Enclosure 2 of this paper, 71 Severity Level III NOVs, 11 Orders, and 2 DFIs. The 11 Orders consisted of 6 Confirmatory Orders that were issued to confirm commitments associated with Alternative Dispute Resolution (ADR) agreements, 1 Order revoking a license, 1 Order approving a settlement agreement, and 3 individual action Orders (i.e., one of the individual Orders resulted from ADR). Also, for these 88 escalated enforcement actions, 23 of them involved a civil penalty.

For CY 2010, the number of escalated enforcement actions for the Materials and Waste Programs was approximately equivalent to the number of actions issued in CY 2009 (i.e. 89 escalated actions in CY 2009). The number of escalated enforcement actions issued in CY 2010 is consistent with the distribution of escalated enforcement actions in past years. No significant performance trends were identified after review of the escalated enforcement action data.

Assessment of Data Reported to NMED

The NMED contains records of events involving nuclear material reported to NRC by its licensees, Agreement States, and non-licensees. These reported events are sorted by the event-reporting requirements as defined in NRC regulations. The event reports are evaluated to identify any safety significant events and their causes. NMED data is analyzed for the main event types and is presented in an annual summary report, and in this report historical data is aggregated for evaluation of potential trends. It should be noted that for the FY 2010 NMED Annual Report, events related to the fuel cycle process have been added to the report. A copy of the FY 2010 NMED Annual Report is available in Enclosure 3. Copies of previous NMED Annual Reports may be found at <http://nmed.inl.gov/>.

For the purposes of the NMED Annual Report data, it should be noted that a single occurrence/event report may be captured in multiple NMED event categories (e.g., a report may describe a loss of licensed material that also resulted in a radiation overexposure). For the data in the NMED Annual Report and in this section, the term "event" is used to describe an individual event category and not a single occurrence/event report.

In order to account for the potential random fluctuations in the event data from year to year and to assess an average trend of the data, the data from the last 10 FYs are reviewed. For the 10 year period covering October 1, 2000, through September 30, 2010, a total of 5,592 events (2,014 NRC and 3,578 Agreement State events) associated with materials licensees were reported to NRC, compared to 5,261 events that were reported for the previous 10 consecutive year period, covering October 1, 1999, through September 30, 2009. It should be noted that due to the addition of the fuel cycle process events, an additional 386 events were added to the number of total events for the 10 year per period covering FY 2001 through FY 2010. Without the addition of the fuel cycle process events, the total number of events would have been 5,206 events for the latest period.

For the current 10 year period, the review of the overall current and prior event data did not indicate any significant performance trends. The NMED annual report indicated some statistically significant trends related to narrow sections of the data (See Enclosure 3, page 4, Table 1, for a summary of trending analysis). For example, the radiation overexposure ten-year data trend analysis determined that NRC-regulated and Agreement State-regulated events represented statistically significant decreasing trends. However, based on the current analysis

of NMED, enforcement, event coordination and performance metrics, a specific reason was not identified for the statistical trends found in the report.

For FY 2010, 32 of the 421 reportable events were considered more significant and are described in the FY 2010 NMED Annual Report. The breakdown of these significant events was as follows:

- 4 lost/abandoned/stolen radioactive material events;
- 13 medical events;
- 1 radiation overexposure event;
- 4 release of material or contamination events;
- 1 leaking sealed source event;
- 2 equipment failure events;
- 1 transportation event;
- 4 fuel cycle process events; and
- 2 events (i.e., embryo/fetus dose events) that met the “Other” event category.

For the four significant lost/abandoned/stolen radioactive material events, it should be noted that there were four sources (i.e., one source per event) that were classified under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004) as Category 3 sources. All but one of the IAEA classified Category 3 sources were recovered. There were no IAEA Category 1 or 2 sources that were reported lost, abandoned or stolen in FY 2010. A summary of the significant events that took place in FY 2010 may be found on Page IX of the enclosed NMED Annual Report, and a detailed description of the significant events and events of interest may be found in the main body of the report for the specific event categories.

Generic and Special Event Study Results

In CY 2010, the staff performed a study to evaluate fuel cycle events related to Subpart H in 10 CFR Part 70. Subpart H was added to Part 70 in 2000 to impose performance requirements on fuel cycle licensees who process enriched uranium and plutonium, and the regulations require enhanced safety programs and an integrated safety analysis (ISA), and impose new reporting requirements. The purpose of the study was to evaluate operating experience related to the new requirements.

NMED contained records of 70 events reported by these licensees between FY 2005 and 2010. The NMED data indicates that the number of events reported each year has increased slightly in recent years but, a trend analysis of the data determined that the data does not represent a statistically significant trend. A breakdown of these events by number and event cause may be found in Enclosure 4. Based on the information in the NMED records, the study found that the events reported had the following causes:

- Human error was the direct cause of 56 percent of the events,
- Equipment failure was the direct cause of 24 percent of the events,
- Procedure problems were the direct cause of 10 percent of the events, and

- For the remaining 10 percent of the events, the cause of the event was not reported (i.e., 9 percent of events) or the event was caused by an external condition that was outside the control of the licensee (i.e., 1 percent of events).

A majority of the human errors (64 percent) were associated with management deficiencies such as deficient policies, administrative controls, work planning, resource allocation, or supervision.

Appendix A of Part 70 contains the new reporting requirements imposed in 2000. Most of the events related to Subpart H were reported under only 2 of the 10 requirements in Appendix A.

- 44 percent were reported under Part 70, Appendix A, Section (b)(2) – Loss or degradation of an item relied on for safety (IROFS) that results in failure to meet the performance requirements in 70.61.
- 43 percent were reported under Part 70, Appendix A, Section (b)(1) – Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the ISA, and which results in failure to meet the performance requirements in 70.61.

After evaluating the NMED records, which include investigation results and corrective actions, the staff concludes that licensees are using the ISAs and the IROFS to evaluate the safety significance of identified events and new accident scenarios. The conclusions from the evaluations have resulted in improved ISAs and IROFS. Licensees are making corrections to ISAs that fail to analyze, or improperly analyze accident scenarios. The staff believes that the ISAs will continue to improve as more experience is gained. In addition, the staff concludes that efforts to reduce human error and improve management oversight should lead to improved performance. The staff intends to discuss the study results in upcoming meetings with the industry. The staff will continue to focus inspection resources on management oversight, and support industry initiatives to improve human performance, such as recent efforts to improve safety culture.

Licensees Identified with Significant Performance Issues

SECY-08-0135 defines the criteria used to identify licensees with significant performance issues and licensees that warrant the highest level of NRC management attention. The criteria target the most critical issues involving: very serious events (those triggering NRC's strategic level measures); significant licensee issues or events; or licensee performance trends. For FY 2010, there were two nuclear material licensees that met the criteria.

The nuclear material licensees that met the criteria as described in SECY-08-0135 were Nuclear Fuel Services, Inc. and the U.S. Department of Veteran Affairs. The staff's analysis regarding these licensees is contained in Enclosure 5. The staff's analysis outlines the issues and describes the regulatory actions being taken to improve licensee performance.

OVERALL PERFORMANCE CONCLUSIONS:

Based on the review of events data and assessment of key events, the staff concludes that the Materials and Waste Programs are functioning effectively to protect public health and safety. Based on the significant-issues criteria, two licensees were identified as having significant performance issues during FY 2010. NRC staff is addressing the issues surrounding these licensees.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections.

/RA/

Scott W. Moore, Acting Director
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:

1. Annual Trend in Abnormal Occurrence Events from FY 2001-2010
2. Summary of Severity Level I and II Enforcement Actions for CY 2010
3. Nuclear Material Events Database Annual Report FY 2010
4. Fuel Cycle Event Study Breakdown
5. Licensees Identified with Significant Performance Issues

ANNUAL TREND IN ABNORMAL OCCURRENCE EVENTS FROM FISCAL YEAR 2001-2010

Table 1 shows the number of events reported annually that were determined to meet the Abnormal Occurrence (AO) criteria. A total of 105 events were found to meet the AO criteria for the period fiscal year (FY) 2001-2010. Of these 105 events, 39 of the events were by U.S. Nuclear Regulatory Commission (NRC) licensees and 66 of the events were by Agreement State (AS) licensees. It should be noted that the number of Agreement State AOs is lower than expected when compared to the number of NRC AOs considering the Agreement States have 87 percent of the materials licensees. After an analysis of the NRC and Agreement State AO data separately, the data indicated that there was a statistically significant increase in the number of NRC AOs. The staff has not identified the cause of this increasing trend at this time but, will continue to analyze the data and report our findings in a future report.

Approximately 87 percent of the AO events for the last 10 years were medical events. However, the relative higher number of medical events determined to be AOs is not necessarily an indication of relative performance between the medical industry and other industries. One reason why medical events make up a large fraction of AOs is that medical therapy procedures use large sources of radiation in very close proximity to or within the body. Due to the close proximity of the sources, small errors in source location can cause high radiation doses to unintended locations, resulting in unintended doses that exceed the AO criteria. There is no discernable trend in the total number of AO events when data from FY 2001 through 2010 are analyzed.

It is noteworthy that although events involving the loss or theft of material account for about 45 to 50 percent of the number of events reported to NRC each year, there were no loss/stolen source events in the last 10 years that met the AO criteria.

Table 1 - Comparison of the Annual Number of Abnormal Occurrence Events

Year	Radiation Levels Exceed Limit		Medical		Personnel Overexposure		Fuel Cycle Facility		Totals	
	NRC	AS	NRC	AS	NRC	AS	NRC	AS	NRC	AS
2001	0	0	0	0	1	1	0	0	1	1
2002	0	1	1	3	1	3	0	0	2	7
2003	0	0	5*	7	0	2	0	0	5	9
2004	0	0	2	12*	0	1	2	0	4	13
2005	0	0	3	6*	0	0	0	0	3	6
2006	0	0	2*	5*	0	1	1	0	3	6
2007	0	0	5*	6	0	0	0	0	5	6
2008	0	0	5*	5*	0	0	0	0	5	5

Year	Radiation Levels Exceed Limit		Medical		Personnel Overexposure		Fuel Cycle Facility		Totals	
	NRC	AS	NRC	AS	NRC	AS	NRC	AS	NRC	AS
2009	0	0	3	6*	0	0	0	0	3	6
2010	0	0	8*	7*	0	0	0	0	8	7
Totals	0	1	34	57	2	8	3	0	39	66

*Include events involving a dose to embryo/fetus.

SUMMARY OF LEVEL I AND II ENFORCEMENT ACTIONS FOR CALENDAR YEAR 2010

No Severity Level (SL) I violations were issued in calendar year (CY) 2010.

**U.S. Department of Veteran Affairs
Washington, D.C.
EA-09-038
Docket No. 030-34325**

Severity Level II

On March 17, 2010, the U.S. Nuclear Regulatory Commission (NRC) issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$227,500 to the U.S. Department of Veterans Affairs for violations related to activities at the Philadelphia Veterans Affairs Medical Center. The following violations were identified: (1) Two Severity Level (II) II violations of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.41(a)(2) (i.e., one SL II violation issued with civil penalty and without civil penalty) for failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive, resulting in a total of 74 prostate brachytherapy treatments where the administered radiation dose was not in accordance with the written directive; (2) SL II violation of 10 CFR 35.41(b)(2) for failure to have procedures that addressed verifying that the administration was in accordance with the applicable treatment plan and written directive, which resulted in the licensee administering at least 16 prostate brachytherapy treatments without performing post-treatment verifications until a prolonged period of time had passed; (3) SL III violation of 10 CFR 35.41(b)(2) related to the licensee's failure to identify that the treatment plan for a brachytherapy treatment differed from the written directive, resulting in the wrong activity of seeds being ordered and administered; (4) SL III problem involving violations of 10 CFR 35.27(a)(1) and 19.12(a)(4) for failing to instruct individuals about procedures, 10 CFR Part 35 and licensing requirements, and prompt reporting of conditions that resulted in the failure to instruct two medical physicists in the requirements for identifying and reporting medical events (10 CFR 35.2 and 35.3045) and failure to instruct an authorized user physician of his responsibility to report to the licensee any condition that may lead to or cause a violation; (5) SL III violation of 10 CFR 35.3045(c) for failure to report to the NRC Operations Center no later than the next calendar day when the licensee had information that medical events occurred between November 15, 2004, and May 12, 2008; and (6) two SL IV violations.

**Basin Electric Power Cooperative
Wheatland, Wyoming
EA-09-258
Docket No. 030-14682**

Severity Level II

On August 26, 2010, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$24,700 to Basin Electric Power Cooperative. The violations involved: (1) SL II violation of 10 CFR 20.1301(a)(1) for failure to limit radiation exposure to members of the public to less than 100 millirem in a year, resulting in six members of the public received doses in excess of 100 millirem; (2) SL III violation of 10 CFR 20.1902(e) for failure to conspicuously post caution signs with the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER RADIOACTIVE MATERIAL(S)" in areas where nuclear gauges were used; (3) SL III violation of 10 CFR 30.50(b)(4) for failure to notify the NRC within 24 hours after the discovery of an unplanned fire on March 8, 2007, that damaged the integrity of a licensed device; and (4) SL III violation of License Condition 21 of Amendment 10 to NRC Materials License 33-18224-01 for failure to close and lock the nuclear gauge shutters after

Enclosure 2

plant operations had stopped and prior to allowing welders to begin work, resulting in welders exposed to the direct radiation beam from these nuclear gauges.



February 2011

Nuclear Material Events Database

Annual Report

Fiscal Year 2010

Prepared for the U.S. Nuclear Regulatory Commission
by the Idaho National Laboratory (INL/LTD-11-20865)

Enclosure 3

NOTICE

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Nuclear Material Events Database

Annual Report

Fiscal Year 2010

Thomas W. Smith, INL
Robert L. Sant, INL

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**Idaho National Laboratory
Risk, Reliability, and NRC Programs Department
Idaho Falls, Idaho 83415**

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ABSTRACT

This report presents information on trending and analysis of incidents/accidents (events) reported to the Nuclear Regulatory Commission (NRC) that involve radioactive material. The events are reported by NRC licensees, Agreement States, and non-licensees, and are recorded in the NRC's Nuclear Material Events Database (NMED). The reported events are classified into categories based on event reporting requirements defined in Title 10 of the Code of Federal Regulations (CFR). The categories in this report are (1) Lost/Abandoned/Stolen Material, (2) Medical, (3) Radiation Overexposure, (4) Release of Licensed Material or Contamination, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, (8) Fuel Cycle Process, and (9) Other. Events involving irretrievable well-logging sources abandoned in accordance with 10 CFR 39.77 are excluded from this report.

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ACRONYMS

ALI	annual limit on intake
AO	abnormal occurrence
AORC	Alabama Office of Radiation Control
AU	authorized user
BCS	bowl cleaning stations
BRP	Bureau of Radiation Protection
CFR	Code of Federal Regulations
CT	computed tomography
DHE	Department of Health and Environment
DHS	Department of Health Services
DOE	Department of Energy
DOH	Department of Health
DRH	Division of Radiological Health
DSHS	Department of State Health Services
ECD	electron capture detector
EQP	equipment
EXP	radiation overexposure
FBI	Federal Bureau of Investigation
FCP	Fuel Cycle Process
FY	fiscal year
GM	General Motors
HAZMAT	hazardous material
HDR	high dose rate
IAEA	International Atomic Energy Agency
INL	Idaho National Laboratory
IROFS	items relied on for safety
LAS	lost/abandoned/stolen material
LKS	leaking sealed source
LS	least squares
MED	medical
NA	not applicable
NHP	Nevada Highway Patrol
NMED	Nuclear Material Events Database

NO _x	nitrogen oxides
NR	not recovered
NRC	Nuclear Regulatory Commission
OTH	other
RLM	release of licensed material or contamination
RSO	radiation safety officer
SSE	error sum of squares
SSR	regression sum of squares
SST	total sum of the squares
TLD	thermoluminescent dosimeter
TRS	transportation

EXECUTIVE SUMMARY

The Nuclear Regulatory Commission's (NRC) Nuclear Material Events Database contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The reported events are classified based on reporting requirements defined by Title 10 of the Code of Federal Regulations. The event reports are evaluated to identify statistically significant trends and significant events.

The significant events that occurred in Fiscal Year 2010 are summarized below. Note that a single event may be listed in more than one event type category.

Lost/Abandoned/Stolen Radioactive Sources/Material

Four significant events occurred involving the loss of Category 1-3 sources as defined by the *International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. No Category 1 sources, no Category 2 sources, and four Category 3 sources were lost, all but one of which were subsequently recovered. The unrecovered Category 3 source was a radiography source that fell from an oil platform into the Gulf of Mexico. The other events involved a radiography source lost during shipment, a brachytherapy source that fell from a carrier's truck, and a brachytherapy device that was delivered to the wrong location.

A Category 2 source event occurred prior to FY10 that was recently added to NMED. This event involved the loss and recovery of a radiography source during shipment.

Medical Events

Thirteen significant events occurred, all of which were classified as potential Abnormal Occurrences. Five of the events involved doses to the wrong site during high dose rate (HDR) brachytherapy. Four events involved the incorrect placement of brachytherapy seeds. One event involved the administration of I-131 when I-123 was prescribed. The remaining event involved the incorrect placement of brachytherapy sources into an applicator; the sources fell out of the applicator during treatment.

Two significant events classified as potential Abnormal Occurrences occurred prior to FY10 that were recently added to NMED. The events involved doses to the wrong sites during HDR brachytherapy and gamma knife treatments.

Radiation Overexposure Events

One significant event occurred. A radiographer was exposed while trying to install the safety plug on the camera with the source not in the shielded position. As of 11/18/2009, this incident was classified as an International Nuclear Event Scale level 2 event.

Release of Licensed Material or Contamination Events

Four significant events occurred. Two events involved transporting contaminated individuals offsite from commercial nuclear power plants for medical attention. The third event involved contamination at a hospital while packaging old sources for disposal. The fourth contamination event occurred at a laboratory while handling radioactive material.

Leaking Sealed Source Events

One significant event occurred. This event involved contamination at a hospital while packaging a ruptured source for disposal (also classified as a Contamination event).

Equipment Failure Events

Two significant events occurred. The first event involved contamination at a hospital while packaging a ruptured source for disposal (also classified as a Contamination event and Leaking Sealed Source event). The other event involved a Category 3 radiography source that fell from an oil platform into the Gulf of Mexico (also classified as a Loss event).

A significant event occurred prior to FY10 that was recently added to NMED. This event involved an incorrect dose to a patient as a result of a gamma knife equipment failure (also classified as a Medical event).

Transportation Events

One significant event occurred. This event involved an F-18 package with a high dose rate. The vial of F-18 had separated from its shielding during shipment.

Fuel Cycle Process Events

Four significant events occurred. Two events involved violations of criticality controls at a gaseous diffusion plant. The third event involved a potential UF6 cylinder overpressure condition at a nuclear fuel manufacturer. The fourth event involved the loss of a metallurgy laboratory sample containing uranium at a nuclear fuel manufacturer.

Other Events

Two significant events occurred, both of which were classified as potential Abnormal Occurrences. Both events involved fetal doses resulting from treatments administered to pregnant patients.

A significant event classified as a potential Abnormal Occurrence occurred prior to FY10 that was recently added to NMED. This event also involved a fetal dose resulting from a treatment administered to a pregnant patient.

Nuclear Material Events Database Annual Report: Fiscal Year 2011

1. INTRODUCTION

1.1 Overview and Objectives

Nuclear material event reports are evaluated to identify statistically significant trends and significant events. The reported information aids in understanding why the events occurred and in identifying any actions necessary to improve the effectiveness of the nuclear material regulatory program.

A database for tracking nuclear material events was developed by the Nuclear Regulatory Commission (NRC) in 1981. In 1993, using existing material events databases, the NRC developed a new and more comprehensive database for tracking material events. This database, designated the Nuclear Material Events Database (NMED), contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by the Idaho National Laboratory (INL) and contains over 20,000 records of material events submitted to the NRC from approximately January 1990 to present.

The events in this report are classified into the following categories based on event reporting requirements defined by Title 10 of the Code of Federal Regulations (CFR):

- Lost/Abandoned/Stolen Material (LAS),
- Medical (MED),
- Radiation Overexposure (EXP),
- Release of Licensed Material or Contamination (RLM),
- Leaking Sealed Source (LKS),
- Equipment (EQP),
- Transportation (TRS),
- Fuel Cycle Process (FCP), and
- Other (OTH).

Events involving irretrievable well-logging sources abandoned in accordance with 10 CFR 39.77 are excluded from this report. A description of categories addressed in this report and associated screening criteria are presented in Appendix A.

1.2 NMED Data

A single occurrence report may be captured in several NMED event categories. For example, a report may describe a loss of licensed material that also resulted in a radiation overexposure. In such a case, both event categories are recorded in the NMED and identified by the same report number (referred to as an item number in the database). In this report, the term “event” is used to describe an individual event category.

The data presented in this report are limited to reportable events that occurred between October 1, 2000, and September 30, 2010. The data were downloaded from the NMED on January 13, 2010. Because the NMED is a dynamic database that is updated daily, variations in data may be encountered over time. Furthermore, even though many events were reported and entered in the database for operational experience purposes, only those events required to be reported by 10 CFR are addressed in this report.

This report displays annual trend data for each of the event categories for a 10-year period. A trend analysis was performed on each event category to identify the existence or absence of a statistically significant trend. If a statistically significant trend exists, the display indicates the direction and approximate rate of change with a trend line. For the purposes of this report, a statistically significant trend exists if the analysis indicates that the computed fit and slope of a least squares linear model is valid at a 95% confidence level. A primer on the statistical methods employed in the trend analysis is presented in Appendix B.

Note that the trending methodology is not normalized; the trend only considers the number of reported events and does not directly account for external issues such as changes to regulatory requirements or changes in the number of licensees. For example, an increasing trend in the number of medical events could be caused by an increase in the number of medical procedures being performed. Likewise, an event type showing a decreasing trend for NRC licensees and an increasing trend for Agreement State licensees could be caused by States becoming Agreement States (resulting in fewer NRC licensees and more Agreement State licensees). If any external effects on the trending are known, they will be discussed with the trending results.

Reporting guidance for Agreement States is provided in the *Handbook on Nuclear Material Event Reporting in the Agreement States*. The handbook is an appendix to the NRC Office of Federal and State Materials and Environmental Management Programs procedure SA-300, *Reporting Material Events*. Access to NMED is available to the staff of NRC, Agreement State, and Federal agencies at <http://nmed.inl.gov>.

For assistance on searches or other questions, contact Duane White (nmednrc@nrc.gov), (301) 415-6272.

2. ANALYSIS OF NMED DATA

Event reports involving nuclear material submitted to the NRC are reviewed, categorized, and entered into the NMED. Charts are provided to display trends in annual data for the most recent 10-year period (FY01-10).

2.1 All NMED Events

Figure 1 displays the annual number and trend of NMED events that occurred during the 10-year period. The trend analysis determined that the data represent a statistically significant decreasing trend in the number of NRC-regulated events (indicated by the trend line). However, the Total events and Agreement State-regulated events do not represent statistically significant trends (indicated by the absence of trend lines). Therefore, variations within the Total and Agreement State values represent random fluctuation around the average of the data.

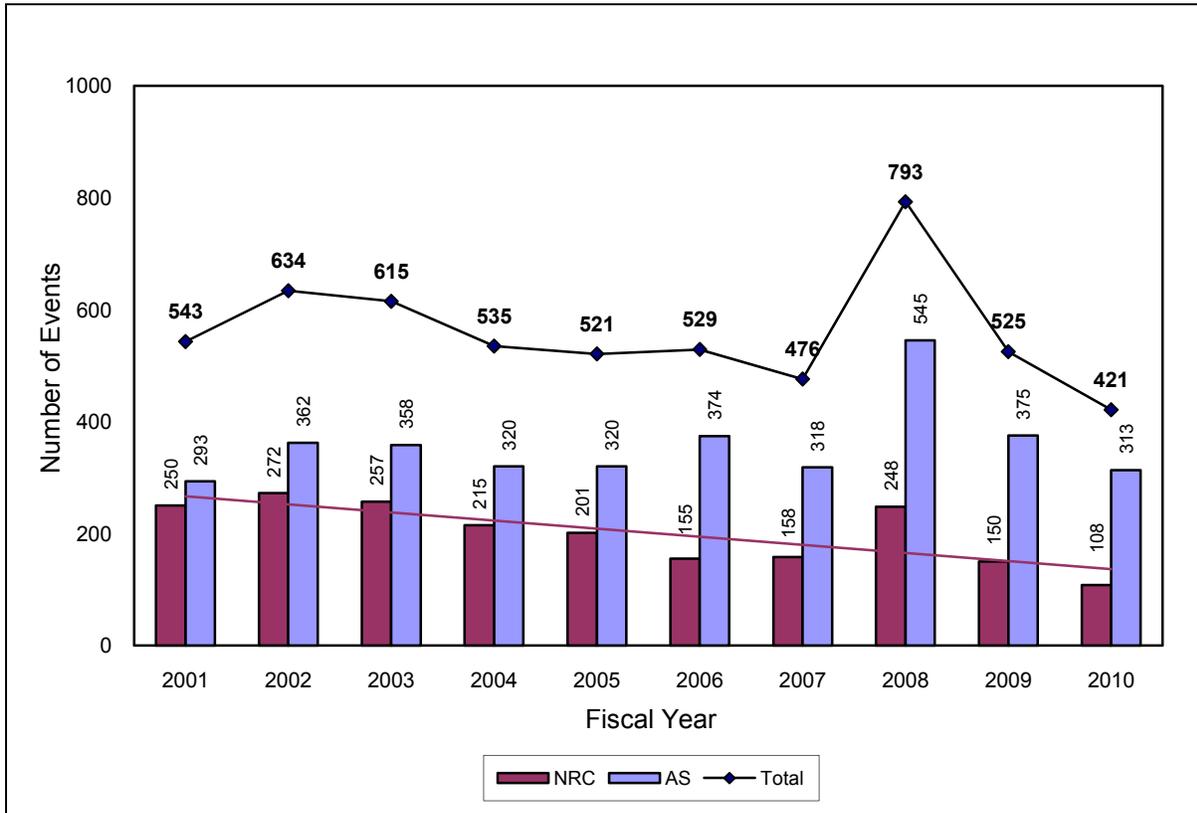


Figure 1. All NMED Events (5,592 total)

The following observations are made regarding the data in Figure 1.

- In FY10, 373 occurrences accounted for 421 events; a single occurrence can be classified in different event categories.
- The FY08 and FY09 data include 272 and 65 events respectively that resulted from Wal-Mart's one-time review of their tritium exit sign inventory. If the Wal-Mart data is excluded, a statistically significant decreasing trend exists in the total remaining events.
- The most recent year's data are typically many records less than their final value when subsequent updates and late reports are received (see Appendix D, Figure D-1).

- The transition of states from NRC to Agreement State jurisdiction could result in increasing trends in Agreement State data and decreasing trends in NRC data.
- The expanded definition of byproduct material became effective November 30, 2007, which should result in an increased number of events. However, no significant effect has yet been seen in NMED data.
- This FY10 report is the first to include events that occurred at fuel cycle facilities (FCP events). Therefore, a comparison of Figure 1 against previous annual reports will show an increase during each year in the NRC-regulated events and the Total events.

Table 1 displays a summary of the trending analysis for all NMED event types included in this report. A more detailed discussion of the trending analysis results can be found in the section of this report devoted to each event type.

Table 1. Summary of Trending Analysis

Event Type	Total	NRC	Agreement State
All NMED Events	-	↘	-
Lost/Abandoned/Stolen Material (LAS)	-	↘	-
Medical (MED)	-	-	-
Radiation Overexposure (EXP)	↘	↘	↘
Release of Licensed Material or Contamination (RLM)	-	-	-
Leaking Sealed Source (LKS)	↘	↘	-
Equipment (EQP)	-	-	-
Transportation (TRS)	-	-	-
Fuel Cycle Process (FCP)	↘	↘	NA
Other (OTH)	NA	NA	NA

Notes:

- ↗ indicates a statistically significant increasing trend.
- ↘ indicates a statistically significant decreasing trend.
- - indicates no statically significant trend.
- NA indicates that the data does not support trending analysis.

2.2 Lost/Abandoned/Stolen Material

2.2.1 Ten-Year Data

Figure 2 displays the annual number and trend of LAS events that occurred during the 10-year period, excluding irretrievable well-logging sources abandoned in accordance with 10 CFR 39.77. The trend analysis determined that the data does not represent statistically significant trends in the Total and Agreement State-regulated events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data. However, the NRC-regulated events represent a statistically significant decreasing trend (indicated by the trend line).

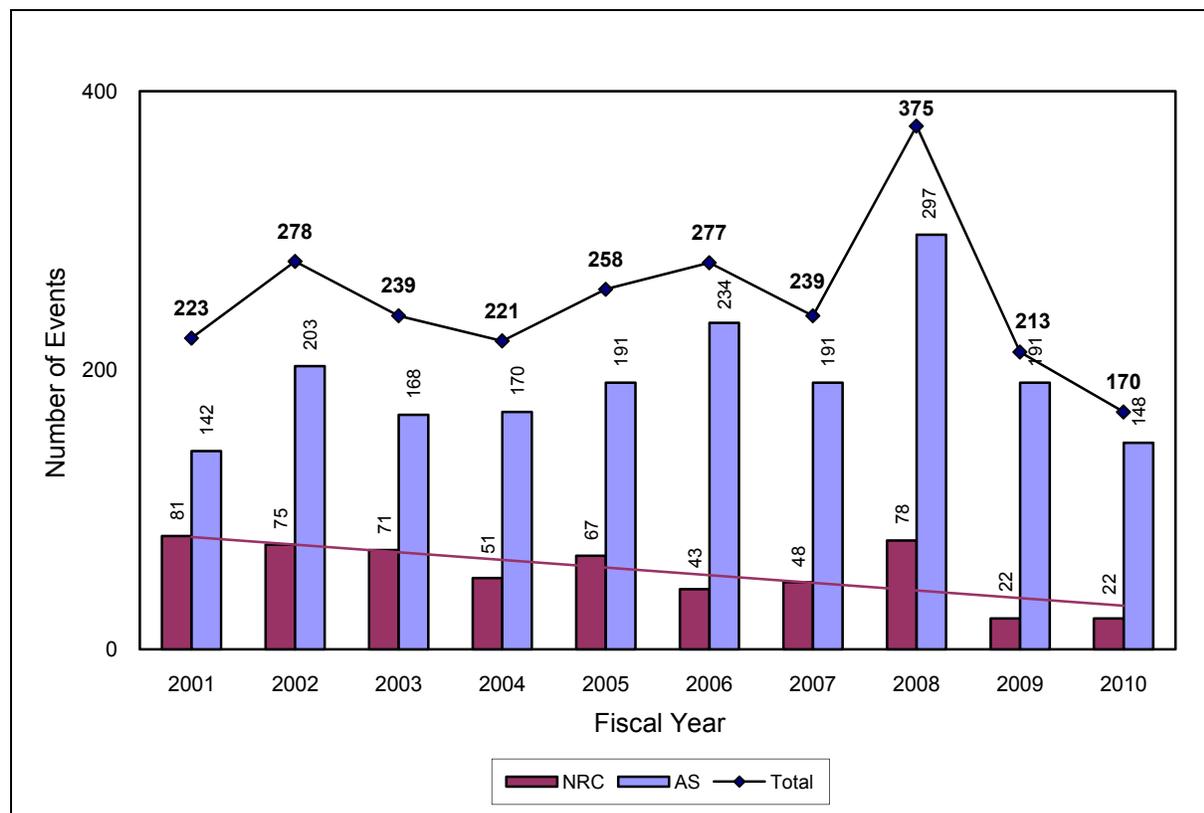


Figure 2. Lost/Abandoned/Stolen Material Events (2,493 total)

The FY08 and 09 data include 142 and 45 LAS events respectively that resulted from Wal-Mart's one-time review of their tritium exit sign inventory. Excluding these events does not result in a statistically significant trend in the total remaining events.

Appendix C contains a list of radionuclides derived from the *International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. These radionuclides are grouped by the amount of radioactivity into five categories that correspond to the relative hazard, with Category 1 being the most hazardous. For this report, Categories 1 through 3 are considered significant.

The 2,493 LAS events that occurred during the ten-year period involved the loss of approximately 4,593 sources. Table 2 displays the number of sources lost during the 10-year period and the number that have not been recovered, grouped by the IAEA category where possible. During the 10-year period, no Category 1 sources, 47 Category 2 sources, and 23 Category 3 sources were lost. All of these sources were recovered, with the exception of two Category 2 and three Category 3 sources.

Table 2. Number of Sources Lost/Abandoned/Stolen (LAS) and Sources Not Recovered (NR)

Category		Fiscal Year										Total
		2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	
1	LAS ⁴	0	0	0	0	0	0	0	0	0	0	0
	NR ⁵	0	0	0	0	0	0	0	0	0	0	0
2	LAS	7	3	5	5	8	4	2	11	2	0	47
	NR	1	0	0	0	1	0	0	0	0	0	2
3	LAS	0	3	0	1	6	4	1	3	1	4	23
	NR	0	0	0	0	2	0	0	0	0	1	3
4	LAS	83	82	87	76	108	95	57	71	49	70	778
	NR	31	30	28	30	34	48	19	37	26	29	312
5	LAS	131	123	137	106	150	108	70	126	73	73	1097
	NR	61	52	59	35	57	42	20	56	21	31	434
< 5	LAS	2	4	2	4	7	0	2	0	2	1	24
	NR	2	2	1	4	4	0	0	0	2	1	16
Activity Not Known ¹	LAS	3	15	1	8	3	7	3	9	5	8	62
	NR	2	6	0	3	0	1	0	0	0	0	12
Nuclide Not Known ²	LAS	1	1	1	0	3	0	0	0	0	0	6
	NR	0	0	1	0	0	0	0	0	0	0	1
Other ³	LAS	151	307	274	248	235	257	264	422	249	149	2556
	NR	92	200	170	169	148	131	134	349	152	104	1649
Total	LAS	378	538	507	448	520	475	399	642	381	305	4593
	NR	189	290	259	241	246	222	173	442	201	166	2429

Notes:

1. The “Activity Not Known” category includes sources containing radionuclides listed in Appendix C for which the activity was not reported. Therefore, the sources were not included in Categories 1 through 5.
2. The “Nuclide Not Known” category includes those sources for which the radionuclide was not reported. Thus, the sources were not included in Categories 1 through 5 or Other.
3. The “Other” category includes sources containing radionuclides not included in Appendix C.
4. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity). The Category 1 through 3 source counts were corrected for the “aggregate” source events.

- Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The Category 1 through 3 “not recovered” source counts were corrected for the “partially recovered” source events.

Tables 3 and 4 provide more detail regarding the 10-year and current year “not-recovered” data highlighted in Table 2 in yellow and green, respectively. Table 3 displays radionuclide data pertaining to the IAEA Category 1 through 3 sources lost during the 10-year period that have not yet been recovered. The Decayed Activity values are conservative estimates in that the values are typically decayed from the loss date instead of the manufacture’s assay date. As a result, the actual decayed activities (based on manufacture’s assay date) are likely less than the estimates. Table 4 is similar to Table 3, but limited to the current year.

Table 3. Summary of IAEA Category 1 through 3 Sources Not Recovered (FY01-10)

Radionuclide	Half Life ¹	Number of Sources Not Recovered ^{2,3}	Total Activity (Ci)	Total Decayed Activity (Ci) ⁴	Aggregate IAEA Category ⁵
Ir-192	73.83 days	5	108	0.40326	4
Total		5	108	0.40326	4

Notes:

- Half-life values from the Chart of the Nuclides, 16th Edition.
- Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity). The source counts were corrected for the “aggregate” source events.
- Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the “partially recovered” source events.
- The source activities were decayed from the event date to 1/13/2011 (data download date).
- The equivalent IAEA Category based on the decayed activity if all of the sources were in a single location (unrealistic worst-case).

Table 4. Summary of IAEA Category 1 through 3 Sources Not Recovered (FY10)

Radionuclide	Half Life ¹	Number of Sources Not Recovered ^{2,3}	Total Activity (Ci)	Total Decayed Activity (Ci) ⁴	Aggregate IAEA Category ⁵
Ir-192	73.83 days	1	7	0.40326	4
Total		1	7	0.40326	4

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity). The source counts were corrected for the “aggregate” source events.
3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the “partially recovered” source events.
4. The source activities were decayed from the event date to 1/13/2011 (data download date).
5. The equivalent IAEA Category based on the decayed activity if all of the sources were in a single location (unrealistic worst-case).

2.2.2 FY10 Data

One hundred seventy LAS events occurred in FY10 involving the loss of approximately 305 sources, 166 of which have not been recovered. Of the 305 lost sources, none were Category 1, none were Category 2, and four were Category 3. All but one of the Category 3 sources were recovered.

Significant Events - Category 1 Source Events

None.

Significant Events - Category 2 Source Events

None.

Significant Events - Category 3 Source Events

Item Number 100125 - A 259 GBq (7 Ci) Ir-192 radiography source was lost on 3/15/2010 while operations were being conducted at night on an oil platform in the Gulf of Mexico. The guide tube was removed from the exposure device in an attempt to return the source to the shielded position within the exposure device. During this attempt, the source was thought to have moved into the exposure device, so the exposure device was secured. However, the next day it was determined that the source was not in the exposure device. After a search failed to locate the source, it was determined that the source must have disconnected from the drive cable and fallen through the grating and into the ocean. The platform was approximately six miles from shore and the depth of the water was about 40 feet. No attempt was made to retrieve the source. The cause of the incident was determined to be mechanical failure. This event was classified as an EQP and LAS event.

Item Number 100130 - A manufacturer of radiography sources and equipment reported that a 296 GBq (8 Ci) Se-75 source was missing from a shipment of six sources received on 3/12/2010. The special form (solid) sources were shipped from Prudoe, England, on 3/9/2010. The manufacturer contacted the shipment carrier to investigate. The shipment was believed to have entered the U.S. in Memphis, Tennessee, via air freight. On 5/3/2010, a lead pig without any identification marks was turned in to the carrier’s overgoods facility at Memphis. The lead pig was surveyed and found to contain radioactive

material. The pig was determined to contain the Se-75 source. The source was eventually received by the manufacturer on 5/27/2010.

Item Number 100250 - A five-gallon container holding a 218.3 GBq (5.9 Ci) Ir-192 brachytherapy source fell off a carrier's truck in Miami, Florida, on 4/15/2010. The City of Miami Fire Department, Metro Police, and FBI responded to the scene. The container was not breached and was returned to the licensee. Further investigation was turned over to the U.S. Department of Transportation.

Item Number 100280 - A brachytherapy device manufacturer reported that a General Motors (GM) plant in Martinsburg, West Virginia, mistakenly received a properly shielded 173.53 GBq (4.69 Ci) Ir-192 source from a common carrier on 5/28/2010. The source was contained in a brachytherapy afterloader. On 5/27/2010, the carrier picked up the source package from an oncology facility in Martinsburg, West Virginia, for delivery to the manufacturer in Burlington, Massachusetts. Sometime on 5/28/2010, the source package was mistakenly delivered to the GM plant in Martinsburg, who notified the source manufacturer's (not the device manufacturer) radiation safety officer (RSO). However, the RSO did not get the name, contact information, or the location of the GM plant, resulting in a delay in retrieving the source. An investigation determined that the carrier had intended to return the source package to the oncology facility due to perceived paperwork problems. On 6/1/2010, the source package was located and arrangements were made to have the carrier retrieve the source package and return it to the oncology facility. Once at the oncology facility, the source package was inspected and showed no evidence of damage or tampering. The cause was determined to be human error on the part of the carrier's driver. Inadequate attention was given to the Bill of Lading and the source package was dropped off at the wrong address.

Events of Interest

Item Number 090772 - Radiation monitor alarms were triggered at a scrap metal processing facility by a load of scrap metal from metal recycling facility on 10/12/2009. The load of scrap was returned to the recycling facility. The Ohio Bureau of Radiation Protection (BRP) dispatched an inspector to the recycling facility on 10/13/2009. A fixed gauge was identified that contained a 7.4 GBq (200 mCi) Cs-137 source. The BRP inspector surveyed the gauge and determined that the shutter was stuck open with an in-beam dose rate of 200 mR/hour at six inches. The shutter mechanism was freed and verified closed by the inspector and a wipe test identified negative results. BRP contacted the gauge manufacturer and learned that the device was initially distributed to an oilfield services company on 9/9/1986. The oilfield services company was contacted and sent a representative to the recycling facility to retrieve the gauge. The inspector determined that the gauge had been inadvertently sent to the recycling facility; the oilfield services company had not attempted to illegally dispose of it. The oilfield services company contacted the gauge manufacturer, who took possession of the gauge and shipped it to their facility on 10/22/2009. This event was classified as an EQP and LAS event.

Item Number 090845 - A steel company reported that a load of scrap metal set off their radiation monitor alarms on 11/17/2009. Maximum radiation levels of 7 to 9 mR/hour were noted on the exterior of the roll-off container. The container was isolated at the facility and on 11/20/2009 an Alabama Office of Radiation Control representative responded to the site. The item was located and identified as a Cs-137 source on the end of a 17 inch rod and an Am-Be source. Maximum radiation levels of 1.5 mSv/hour (150 mrem/hour) were noted at close proximity to the sources. The activity of the sources was estimated to be 0.37 GBq (10 mCi) for the Cs-137 source and 1.85 GBq (50 mCi) for the Am-Be source. The sources were isolated and secured. The sources had no markings to identify make, model, or serial numbers. The Alabama Office of Radiation Control was unable to identify the owner of the sources. The sources were eventually transferred to the DOE Orphan Source and Recovery Program. This event was classified as an EQP and LAS event.

Item Number 100004 - The Nevada Highway Patrol (NHP) reported that a moisture/density gauge containing a 1.85 GBq (50 mCi) Am-Be source and a 0.37 GBq (10 mCi) Cs-137 source fell out of a

material testing company's truck in Las Vegas, Nevada, and was destroyed. Initial radiation instrument readings taken by the NHP revealed 415 uR/hour at 10 feet. It was determined that the source tube had not ruptured. Metro All Regional Multi-Agency Operations and Response was contacted and responded to the scene with additional radiation detection instruments. Their surveys revealed 600 mR/hour at the surface of the gauge case. The gauge pieces were placed in a shipping container and transported to the material testing company's facility. The Nevada Division of Radiological Health (DRH) responded to the facility on 12/29/2009. DRH surveys revealed 70 mR/hour on contact with the shipping container that held the gauge pieces. DRH determined that both sources were recovered, intact, and leak tested satisfactory. Corrective actions included providing HAZMAT training to the technician involved. This event was classified as an EQP and LAS event.

Item Number 100119 - A nuclear fuel manufacturer reported the loss of a metallurgy laboratory sample that contained approximately 0.67 grams of uranium, of which 0.65 grams (51.8 kBq or 1.4 uCi) was U-235. The sample was determined missing from its prescribed location on 3/9/2010. A search was immediately initiated, but as of 3/12/2010 it had not been located. There is no indication of intentional theft or diversion. The sample was last accounted for on 10/26/2009. This event was caused by the lack of a formal system for handling samples for purposes other than metallurgical analysis. Corrective actions included procedural and equipment changes. This event was classified as an FCP and LAS event.

Item Number 100223 - A hospital reported the loss and recovery of a package that contained a 74 GBq (2 Ci; as of 4/30/2010) Mo-99/Tc-99m generator and three Tl-201 sources totaling 2.76 GBq (74.5 mCi; as of 5/5/2010). The package was delivered to the hospital on 5/1/2010. An unauthorized person (conciierge) signed for the package and stored it under the conciierge counter (a controlled, but unrestricted, area). The dose rate at the closest conciierge workstation was 20.6 uSv/hr (2.06 mrem/hr), while the dose rate at the closest surface of the uncontrolled area (in the walkway outside of the conciierge desk) was 185.6 uSv/hr (18.56 mrem/hr). On the evening of 5/1/2010, the health physicist searched for the generator, which was supposed to have been delivered earlier in the day. The package was found on the morning of 5/3/2010, approximately 44 hours after delivery. The package was moved to a proper location and dose calculations were performed for any individuals who may have been in the vicinity of the package while it was improperly stored. No doses exceeding limits were identified. This event was caused by the failure of the conciierge to follow procedures for the receipt of radioactive material. To prevent recurrence, the hospital modified procedures and reiterated their policy outlining who is authorized to sign for packages. This event was classified as an LAS and OTH event.

Item Number 100270 - An oilfield services company reported that a well logging tool was placed in a truck while the 55.5 GBq (1.5 Ci) Cs-137 source was still in the tool on 5/21/2010. The truck was located in the company's shop. The source had been removed from storage to perform calibrations on the logging tool. After calibrations were performed, the logging tool was powered down, disconnected from the wireline, and loaded into the logging truck. When in the tool, the source is highly collimated. The tool and source were left in the truck for approximately 24 hours, potentially exposing two well logging supervisors, a district manager, and one well logging assistant. While performing post-calibration tasks, a worker noticed high gamma ray background readings on a survey meter. He began searching the shop and noted high radiation readings as he approached the logging truck that contained the tool and source. Radiation levels were approximately 5.5 mR/hour adjacent to the truck. The dosimeters for the two supervisors, the assistant, one spare located in the office, one control, and an employee's dosimeter (which had been left on a desk) were sent to Landauer for analysis. One well logging supervisor and the district manager were not wearing their dosimeters during the incident. The incident was reconstructed and surveys performed to aid in identifying the possibility of excess personnel exposure. Incident investigation uncovered many procedural issues, including failure to document the removal of radioactive material from storage, failure to properly secure storage areas, failure to properly return radioactive material to storage, and failure to establish a radiation area during calibration procedures. Personnel actions were taken for one of the individuals involved for not following procedures. In addition, the

supervisor was reprimanded for not wearing a dosimeter while on duty and failure to notify management of an improperly secured storage area. All facility employees were reminded of radiation procedures. Based on event reconstruction and available dosimeter readings, it is believed that none of the four employees received in excess of 0.18 mSv (18 mrem) total effective dose equivalent. This event was classified as an LAS and OTH event.

Item Number 100274 - A metal processing facility reported that a load of scrap metal alarmed their radiation monitors on 5/21/2010, prior to a charge being loaded into their furnace. On 5/24/2010, an employee saw part of a radiation symbol in the off-loaded metal scrap and radiation surveys revealed high radiation levels. A health physics company was contacted and responded to the site. Production was stopped while the three charge buckets were checked, along with other areas, for radiation. A thickness gauge was located that contained a 7.4 GBq (200 mCi) Am-241 source. The gauge revealed a dose rate of 150 mR/hour on contact. The flap on the shutter mechanism was broken off. Health physics personnel wrapped the gauge in lead, labeled it with a radioactive material sign, and stored it in a secured room at the site. It was determined that the device had been sold to a corporation in January 1976. The gauge was sent to the gauge manufacturer for proper disposal. This event was classified as an EQP and LAS event.

Item Number 100397 - A patient received radiation exposure to an unintended area during a cervical cancer brachytherapy treatment on 7/9/2010. The patient was prescribed 3,500 cGy (rad) to the uterus. The treatment was performed using two 1.64 GBq (44.2 mCi) Cs-137 sources. The physician failed to correctly place the sources in the applicator and one source fell onto the patient's buttocks. The second source was missing from the patient and later recovered from the trash before it left the facility, when it set off their radiation monitor alarms. The hospital estimated that the maximum dose received by the unintended site (buttocks) was 1,050 cGy (rad). No reddening of the skin has been noticed. The hospital stated that 89% of the medical directive was administered to the intended site and no medical impact to the patient is anticipated. The patient's physician and the patient were notified of the event. Corrective actions included revising procedures that involve brachytherapy applicators, updating the Radiation Safety Guidelines Policy, and providing additional training to staff. The hospital is also investigating replacement costs of a new applicator. This event was classified as an LAS and MED event.

Item Number 100398 - A steel manufacturing company reported that a load of scrap metal set off their radiation monitor alarms on 8/2/2010. The manufacturer isolated and secured the load of scrap. Alabama Office of Radiation Control (AORC) personnel responded to the site on 8/3/2010. The source of radiation was an item approximately six inches wide by two inches deep by two inches high. There were no identifying marks on the item and it appeared to have been compacted. Exposure rates were approximately 330 mR/hour at about four inches from the item. No removable activity was identified on the item or around its location. The item was returned to the scrap facility, who conducted a follow-up investigation of the incident on 8/12/2010. The radionuclide was identified as Cs-137. Radiation surveys revealed maximum levels of 1.7 R/hour at six inches and 440 mR/hour at one foot. The activity was estimated to be approximately 4.63 GBq (125 mCi). The shielding for the source was determined to have been dismantled in a shredder. Very conservative calculations by AORC estimated that no one received greater than 50 mrem. This event was classified as an EQP and LAS event.

Item Number 100417 - A scrap processing facility reported that a load of scrap metal set off their radiation monitor alarms on 1/19/2010. A device was isolated from the load and stored in a secure location. A Wisconsin Department of Health (DOH) inspector visited the site on 6/9/2010. The device was identified as a dew pointer. A survey identified 110 mR/hour on the backside of the device. Wipe samples revealed no removable contamination. The scrap facility stated that the device's top cover was missing when it was received. The radioactive material labels and markings were also missing from the device's external casing. The dew pointer was double bagged, tagged, and placed back into secure storage. The NRC Radioactive Sealed Sources and Devices Registry states that the dew pointer contains a Ra-226 source with a maximum activity of 0.26 MBq (7 uCi). The DOH tried contact the manufacturer

in an attempt to identify the original owner, but the manufacturer is no longer in business. The manufacturer's distribution records were transferred to another company, but they did not have records on the original owner of the device. This event was classified as an EQP and LAS event.

Item Number 100438 - The Pennsylvania Department of Environmental Protection discovered the improper tracking of six thickness gauges, each containing a 37 GBq (1 Ci) Am-241 source. During an inspection in July 2010, six gauges were accounted for; four onsite and two recently returned to a gauge manufacturer. One of the four onsite gauges was found with an open shutter. The facility has had three different owners over the years, two of which are now out of business. The current owner was not a steel manufacturer and was unaware that the radioactive sources were on their property. The cause of the incident was determined to be improper transfer of generally licensed sources and ineffective regulatory control. This event was classified as an EQP and LAS event.

Item Number 100502 - During a routine health and safety inspection on 10/7/2010, the Iowa Department of Public Health (DOH) identified that an explosion occurred at a radioactive source manufacturing facility on 12/3/2009. An authorized user (AU) was quenching a mixture containing 14.8 GBq (400 mCi) of C-14 at the time of the explosion. The AU showered and was taken to the emergency room. The AU had several bioassays performed prior to returning to work. The manufacturer decontaminated the area of concern within the laboratory. Decontamination was completed on 12/4/2009. Between 10 and 20 mCi was recovered, with the remainder of the material being lost. Corrective actions included personnel receiving additional training and improved supervision. In addition, new equipment was obtained. This event was classified as an EQP, LAS, and RLM event.

Item Number 100529 - On 4/30/2010, a licensee reported a radioactive material contamination event that resulted in the improper disposal of radioactive material to normal trash. The contamination event occurred on 4/13 and 4/14/2010 and involved a reference source containing approximately 2.2 milligrams of Pu metal. The reference source was analyzed using a secondary ion mass spectrometer (SIMS), which employed a beam of oxygen ions impacting the reference source to "sputter off" Pu ions from the surface for analysis in the mass spectrometer. The licensee determined that 8.1 micrograms (55.5 kBq or 1.5 uCi) of the Pu reference source was "sputtered off" during the SIMS analysis. Most of this material was deposited on a collection plate within the SIMS vacuum chamber, which was subsequently cleaned using a variety of methods. However, ineffective contamination surveys prior to cleaning failed to identify the presence of contamination, so the cleaning procedures were performed under the assumption that no contamination was present. Contamination was later discovered on the work table and in the laboratory sink. Items used during the cleaning process were disposed of in the normal trash, which had already been removed from the facility and sent to an incinerator. Analysis of a urine sample collected from the individual involved in this event showed no detectable activity. While investigating this event, the licensee determined that a similar event may have occurred in July and August, 2004. Conservative calculations assuming that the entire 8.1 micrograms (55.5 kBq or 1.5 uCi) was incinerated indicate minimal dose to the maximally exposed individual. Corrective actions include halting the use of alpha-emitting radionuclides pending review of the risks presented by their use. This review resulted in procedure modification and personnel training. This event was classified as an LAS and RLM event.

2.2.3 Events Recently Added to NMED That Occurred Prior to FY10

Twenty LAS events were recently added to NMED that occurred prior to the current fiscal year and have not been included in any previous annual report. One of these events involved a Category 2 source. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Category 1 Source Events

None.

Significant Events - Category 2 Source Events

Item Number 100415 - A radioactive source manufacturer reported the loss and recovery of a 3.7 TBq (100 Ci) Ir-192 radiography source. The manufacturer shipped the source to a radiography company on 9/15/2006. The shipment was due to arrive on 9/18/2006 and was reported as overdue. It was last scanned by the carrier on 9/19/2006 in Providence, Rhode Island. The shipment was delivered to the radiography company on 9/21/2006.

Significant Events - Category 3 Source Events

None.

Events of Interest

Item Number 100315 - During an inspection by the Kansas Department of Health and Environment (DHE) of a hospital on 2/14/2007, the loss of a 1.258 GBq (34 mCi) Cs-137 brachytherapy source was identified. The source was lost for approximately 45 hours before being found in the sheets in the laundry room by the RSO on 12/1/2006. The RSO had not made a determination of exposure to the patient based on conservative and worst case scenarios, and the incident was not reported to DHE. It was determined that on the day the applicator was removed from the patient, one source was missing. Two physicists searched for the source using a GM counter. The source was recovered from the bottom of a large bin where bags of linen accumulate in the laundry capture room. The physician authorized user had removed the sources from the applicator, and then the applicator from the patient. Both were returned to the radiation oncology to be placed back into the sealed source safe. It was at that time that the source was discovered to be missing. It was determined that the source never reached its destination in the patient and that it most likely fell into the bed linens during insertion. The exposure rate from the source would have been approximately 1.2 mrem/hour at three meters. It was suggested that linen be left in the patient's room during their stay to guard against recurrence.

2.3 Medical

2.3.1 Ten-Year Data

Figure 3 displays the annual number and trend of MED events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data.

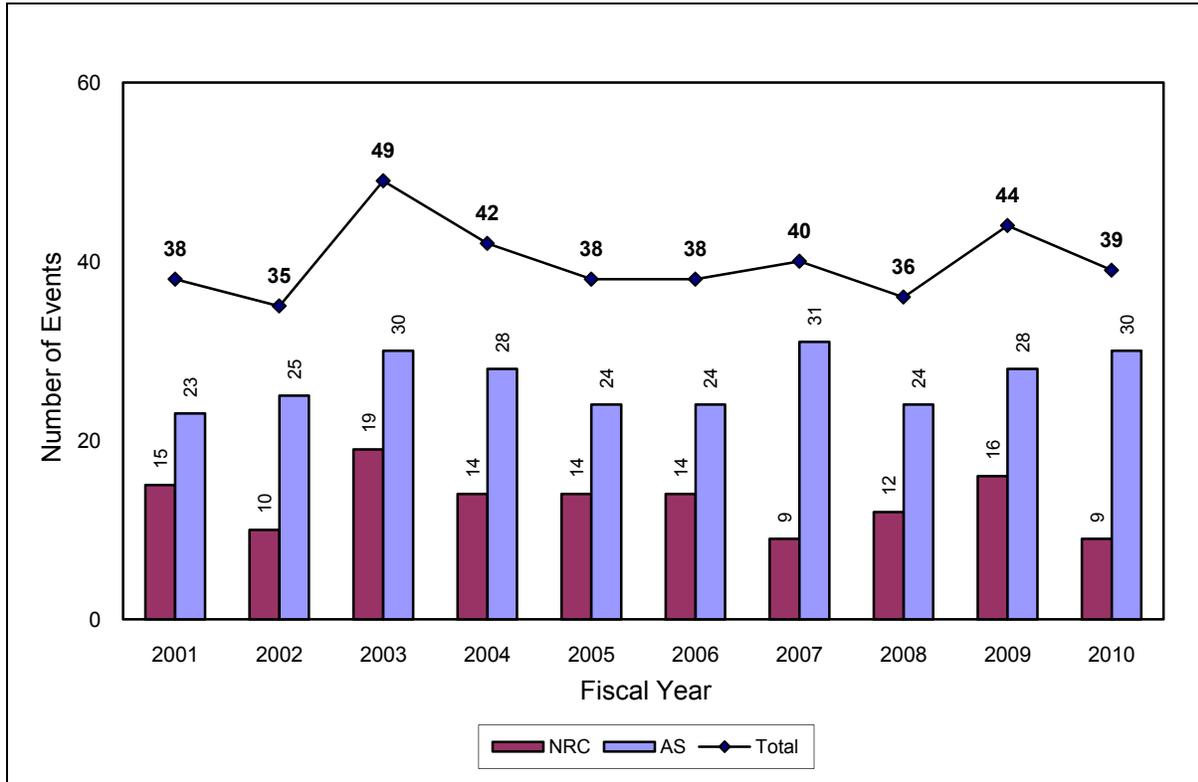


Figure 3. Medical Events (399 total)

Table 5 lists the number of MED events that were classified as Abnormal Occurrences (AOs) in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Table 5 also includes potential AOs (recent events where the AO determination process has not been completed). For this report, MED events classified as AOs (or potential AOs) are considered significant.

Table 5. Medical AO Events

	Fiscal Year										Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	
Events	2	6	10	12	7	8	11	10	15	13	94

Notes:

1. Events are marked as potential AOs until they undergo the NRC's formal AO determination process. Potential AOs are included in this table. The final AO determination results are published annually in NUREG-0090, *Report to Congress on Abnormal Occurrences*.

2. The AOs in this table are medical events that were reported in accordance to 10 CFR 35.3045. This table does not include embryo/fetus or nursing child AOs reported in accordance with 10 CFR 35.3047.

2.3.2 FY10 Data

Thirty-nine MED events occurred in FY10, 13 of which were classified as significant events.

Significant Events - AOs or Potential AOs

Item Number 100074 - Two patients received doses to the wrong sites during breast cancer treatments. The procedure involved a high dose rate (HDR) unit that contained a 361.1 GBq (9.76 Ci) Ir-192 source during the first patient's treatment and 320.4 GBq (8.66 Ci) Ir-192 source during the second patient's treatment. Both patients were prescribed to receive 340 cGy/fraction for 10 fractions. It was determined on 2/14/2010 that the source was positioned approximately 2 to 2.5 cm proximal to the correct patient treatment sites. The first patient's treatment had been completed in January 2010 before the error was identified. For that patient approximately 25% of the planned volume received the prescribed dose and another 25% of the planned volume received 25% or less than the prescribed dose. Also, a large volume outside the prescribed treatment volume exceeded the prescribed dose. The maximum proximal skin dose was approximately 220% greater than the prescribed dose. The second patient received eight of ten fractions prior to the discovery of the error; the last two fractions were delivered correctly. The second patient received at least 50% of the prescribed dose to about 50% of the correct treatment volume. Some areas of the planned volume received greater than 700% of the prescribed dose. There were also several areas not prescribed treatment that received 300 to 400% greater than anticipated. The proximal skin received about 125% more dose than prescribed. Both patients and their doctors were notified of the event. The Florida Bureau of Radiation Control investigated the incident. The mistakes were believed to be caused by inputting the wrong parameters into the program (human error). Corrective actions included improving the review of paperwork and data prior to the start of patient treatment.

Item Number 100082 - A measurement error resulted in a medical event during an HDR brachytherapy treatment to a patient's left breast. The procedure involved an HDR unit containing a 247.49 GBq (6.689 Ci) Ir-192 source. The procedure utilized a multi-lumen catheter device and involved 10 treatments between 1/18/2010 and 1/22/2010. The intent was to deliver 3,400 cGy (rad) to the left breast. On 2/22/2010, the patient complained of skin reddening and tenderness on the external left breast, distal to the catheter insertion site. It was determined that an incorrect measurement resulted in placement of the radioactive source 10 cm proximal to the intended position, delivering the prescribed dose to an unintended site. During pre-treatment simulation, the physicist used a dummy source wire to measure the distance to the tips of the catheters at 115.2 cm. There were two representatives from the manufacturer present at that time. The measured distance was entered into the plan as the position of the first dwell position of the source for each catheter. The physicist was informed of the patient's skin reaction and immediately began an investigation. The physicist determined that the actual distance to the tips of the catheters was 125.2 cm. The patient received an average dose of 1,700 cGy (rad) to approximately 100 cc of the unintended breast tissue. About 7.5 cc of the skin and underlying tissue received a maximum dose of 6,800 cGy (rad). Approximately 35 cc of the intended site received an average dose of 340 cGy (rad), or 10% of the total prescribed dose. The patient was notified on 2/25/2010. This event was caused by the use of a damaged source positioning simulator tool. Corrective actions included removing the damaged tool from service, obtaining a new tool, developing and posting a reference table of source to catheter tip distances, procedure revisions to require a double-check of all patient measurements, and personnel training. The NRC contacted a medical consultant to review this event, who stated that the patient experienced acute/sub-acute radiodermatitis. He concluded that the patient could experience fat necrosis, the dose to the unintended breast tissue is probably unlikely to result in any significant or unusual adverse effect, the affected skin may not heal and could ulcerate, and that local tumor recurrence could occur if additional intervention is not performed.

Item Number 100085 - A medical event occurred involving a patient treated for prostate cancer. The treatment included implanting 65 I-125 brachytherapy seeds containing a total activity of 0.814 GBq (22 mCi) in the patient's prostate for a prescribed therapeutic radiation dose of 14,500 cGy (rad). The prostate gland only received approximately 500 cGy (rad). The seeds were implanted on 1/21/2010 using real time dosimetry under ultrasonic guidance. On 2/23/2010, a 30-day post implant scan that showed that the implanted seeds, although in an appropriate pattern, were placed outside of the intended target. The hospital's oncology group determined that an additional quality assurance review was warranted. The Pennsylvania Bureau of Radiation Protection performed a reactive inspection during the week of 3/1/2010. Initially, a malfunction of the ultrasound unit was suspected. That unit was re-evaluated and was determined to be working properly. The cause was determined to be human error. An unintended dose to the penile bulb of approximately 16,100 cGy (rad) was received, where no dose was anticipated. The radiation oncology department suspended prostate brachytherapy treatments. Corrective actions included changes to the prostate brachytherapy protocol to incorporate an additional step to ensure the urologist and radiation oncologist clearly identifies the prostate gland and the surrounding anatomy. The treatment will be cancelled if the prostate gland and surrounding anatomy cannot be visualized adequately.

Item Number 100118 - A patient received more dose than prescribed during the second of 14 high dose rate (HDR) fraction treatments to the ear on 3/11/2010. The patient was prescribed 250 cGy (rad) to the ear for each fraction using an HDR surface applicator with a 210.9 GBq (5.7 Ci) Ir-192 source. However, the therapist accidentally pushed the "auto radiography" button rather than the "treatment" button, which delivered approximately nine times the intended dose or 2,250 cGy (rad). The patient and doctor were notified of the incident. Corrective actions taken by the clinic included deactivating the autoradiograph function and providing training to technicians concerning the incident.

Item Number 100148 - A patient received two fractions of a high dose rate (HDR) afterloader treatment to the wrong location. The patient was prescribed four fractions of 400 cGy (rad) for a biliary HDR treatment. The HDR unit contained a 329.49 GBq (8.905 Ci) Ir-192 source. The catheter had been placed and imaged. A dummy source was pushed into the catheter until it met resistance, which was assumed to be the end of the catheter. In fact, the resistance was actually a tight bend approximately 17 cm short of the end of the catheter. This incorrect distance was used for the treatment distance and the patient was subsequently treated. Prior to treatment the following day, a dummy source was again inserted. That dummy source extended beyond the programmed distance. An x-ray revealed that the end of the catheter was beyond the initial treatment location. For the first two fractions, the HDR source was 17 cm from its intended location. This resulted in the tumor receiving only 30% of the prescribed fractional dose and an unintended location (duodenum) receiving 1,000 cGy (rad). The patient was informed of the incident on 3/24/2010. Corrective actions included implementing a new procedure that requires that prior to administering the first fraction on each biliary HDR patient, an image be taken with the measurement cable in place. An additional fraction was completed to provide a total tumor dose that was within 90% of the prescribed dose.

Item Number 100219 - A patient treated for adenocarcinoma of the prostate gland received less than 50% of the prescribed V100 dose during a brachytherapy implant performed on 3/12/2010. The patient also received dose to an unintended site. The patient was implanted with 95 I-125 brachytherapy seeds that contained an activity of 11.91 MBq/seed (322 uCi/seed). The prescribed dose was 14,500 cGy (rad). The radiation oncologist, with the assistance of the urologist, inserted the needles through the appropriate holes in the needle template. During the procedure, the oncologist used ultrasound to guide the needle placement. However, the oncologist and ultrasound technologist had difficulty visualizing the balloon location (indicating the prostate base) clearly on the sagittal view of the ultrasound while the seeds were being dispensed from the needles. It is believed that the patient may have moved during the procedure, which may have caused the balloon and ultimately the base plane to shift. A variance was suspected by the oncologist after reviewing the post implant seed count x-ray. The patient was asked to return for an

early post-implant computed tomography CT scan on 3/22/2010 to confirm the implanted seed locations. Using those images, a treatment plan was constructed using the treatment planning system's post-plan software. Based on that plan, it was estimated that the entire implanted volume was shifted approximately 3 cm inferiorly, resulting in a D90 dose of 1,288 cGy (rad). The patient was informed and supplemental treatment was recommended. Corrective actions included a change in procedures such that the needles will be inserted into the prostate prior to acquiring the planning images.

Item Number 100294 - A patient treated for endometrial carcinoma of the vaginal cuff received skin burns on her thighs. The patient was prescribed to receive three fractions of 700 cGy (rad) each at a distance of 0.5 cm from the surface of the applicator. The treatment involved an HDR remote afterloader with a 129.735 GBq (3.50634 Ci) Ir-192 source. The dose to the skin of the thighs occurred during the third fraction performed on 5/4/2010. The patient started noticing two dark spots on each thigh on 5/11/2010. She notified the hospital on 5/18/2010 of the two spots that were somewhat painful and returned to the facility on 5/19/2010. The prescribing physician did not diagnose the spots as radiation erythema. The patient was asked to return again on 5/24/2010. At that time, the physician identified two circular areas with a diameter of approximately 1 cm. The spots were determined to be radiation erythema on 5/26/2010. The cause was believed to be that the patient moved in such a way that the catheter moved and/or workers may have moved the catheter while trying to better align the stretcher with the treatment device. The estimated exposure received by the patient during the treatment is 3,025 cGy (rad) shallow dose to the thigh, 409 cGy (rad) deep dose at 2.5 cm to the thigh, and 6.2 cGy (rad) to the prescribed region. Corrective actions included procedure modifications to assure that the catheter is correctly positioned prior to the start of treatment. In addition, a special in-service will be held to address the procedure updates.

Item Number 100314 - A patient undergoing high dose rate (HDR) treatment for ovarian cancer received 1,900 cGy (rad) to an unintended area on 6/3/2010. The intended area was prescribed 720 cGy (rad), but only received 500 cGy (rad). The HDR unit contained a 310.8 GBq (8.4 Ci) Ir-192 brachytherapy source. The area to be treated was incorrectly entered into the HDR afterloader computer. The error was discovered during the second fraction of treatment on 6/15/2010. The cause of the event was human error. The patient and attending physician were notified of the error on 6/16/2010. Corrective actions included procedure modifications.

Item Number 100357 - A medical services provider reported the preliminary identification of nine medical events involving permanent implants of I-125 seeds for prostate brachytherapy where the total dose delivered differed from the prescribed dose by 20% or more, or an unintended organ received more than intended. During a recent inspection, the Wisconsin Department of Health Services (DHS) determined that the provider was not reviewing prostate brachytherapy cases against the medical event criteria. The provider evaluated 275 prostate implants performed since August 2003. The review included an assessment of whether implants involved doses to an organ or tissue above 50 cGy (rad) and 50% more than the expected dose. The provider notified the affected patients and referring physicians. The reported medical events involved two locations of use. One facility identified three under doses of 25.2, 24.8, and 23.5%, and one overdose of 21.4%. The other facility identified one under dose of 22.8% and one overdose of 21%. Three additional medical events involved overdoses to the urethra of 59.7, 61.3, and 51.6%. DHS investigated the medical events. The underdoses were generally caused by needle and seed placements that did not match the locations specified in the treatment plans. One prostate overdose was caused by an entry error in the planning process, when the dosimetrist used the standard isodose lines for a 16,000 cGy (rad) therapy for a patient prescribed a boost treatment of 12,000 cGy (rad). The implants that resulted in overdoses to the urethra were caused by needles that deviated from their intended tracks after insertion into the prostate, causing the seeds to be deposited closer to the urethra than planned. Corrective actions included generating a new procedure to increase ultrasound visualization during prostate implants and providing new training to personnel. In addition, the provider

determined that they were not always able to evaluate doses to unintended organs because the post implant CT scan did not extend to a patient's rectum or urethra.

Item Number 100388 - A patient prescribed to receive 7.4 MBq (200 uCi) of I-123 for a diagnostic uptake scan, was administered 148 MBq (4 mCi) of I-131 for a whole body scan on 4/21/2010. The administration resulted in a dose of approximately 3,108 cGy (rad) to the patient's intact thyroid tissue, rather than an estimated 7 cGy (rad) from the I-123 administration. The patient's physician gave her a written prescription slip for the I-123 scan. However, the physician's office faxed an order to the hospital for an I-131 scan. The patient allegedly presented the correct written prescription slip to admitting. The receptionist allegedly refused the written prescription, because she thought the hospital already had the correct procedure in their records. On 4/23/2010, the whole body scan was performed. At that time, the nuclear medicine technologist noticed there was something wrong when the scan indicated the thyroid was intact. The referring physician and patient were notified. The cause of the incident was a result of human error and failure to follow procedures. Training and written procedures were in place, but the nuclear medicine technologist failed to follow the written procedures. Corrective actions included modifying procedures and re-educating the nuclear medicine technologists. Additionally, a pathology report is now required for all thyroid cancer patients before an I-131 dose is administered. Thyroid interview and patient assessment and history sheets were developed for use. The nuclear medicine technologists received training on 6/8/2010. The physicians were also re-educated on 6/9/2010.

Item Number 100397 - A patient received radiation exposure to an unintended area during a cervical cancer brachytherapy treatment on 7/9/2010. The patient was prescribed 3,500 cGy (rad) to the uterus. The treatment was performed using two 1.64 GBq (44.2 mCi) Cs-137 sources. The physician failed to correctly place the sources in the applicator and one source fell onto the patient's buttocks. The second source was missing from the patient and later recovered from the trash before it left the facility, when it set off their radiation monitor alarms. The hospital estimated that the maximum dose received by the unintended site (buttocks) was 1,050 cGy (rad). No reddening of the skin has been noticed. The hospital stated that 89% of the medical directive was administered to the intended site and no medical impact to the patient is anticipated. The patient's physician and the patient were notified of the event. Corrective actions included revising procedures that involve brachytherapy applicators, updating the Radiation Safety Guidelines Policy, and providing additional training to staff. The hospital is also investigating replacement costs of a new applicator. This event was classified as an LAS and MED event.

Item Number 100448 - A patient was implanted with I-125 brachytherapy seeds in the anus for a palliative procedure on 8/30/2010. Two days later, a follow-up CT scan revealed that the implants had been inserted 4 cm superior to the intended location, which would lead to less dose at the target location. The intended dose was 9,000 cGy (rad) to the anus. The patient was scheduled to be implanted again after completion of the imaging study. The reason for the error is believed to be twofold; the tumor had progressed markedly since the original planning and the decision was made to correct the plan for the additional growth based on palpation indications, and the 10-cm mark on the needle may have been mistaken for the 5-cm mark. Both the patient and physician were informed. Doses to normal tissue from the implants at the end of the treatment plan were 375 cGy (rad) to the bladder instead of the prescribed dose of 7 cGy (rad), 2,517 cGy (rad) to the seminal vesicles instead of the prescribed 538 cGy (rad), 420 cGy (rad) to the prostate instead of the prescribed 624 cGy (rad), and 316 cGy (rad) to the rectum instead of the prescribed 4,518 cGy (rad).

Item Number 100457 - A licensee reported that 11 medical events occurred at a medical center. The medical events involved I-125 permanent prostate seed implant brachytherapy and occurred between 2/16/2005 and 8/4/2008. The medical events were identified during follow-up of 10 previously discovered events (see NMED Item 080606). Following up on those 10 medical event reports, the licensee initiated a comprehensive external review and reanalysis of post-treatment dose parameters for all prostate seed implants performed at the medical center. Upon evaluation of update dose information generated by external review, medical center staff discovered the 11 additional events on 9/8/2010. Ten

of the 11 events were based on updated D90 final values for the planned treatment site being 80% or less than the prescribed dose. One of the 11 events was based on absorbed dose to tissue other than the treatment site exceeding the expected dose by 50% or more. The referring physicians and patients were notified. This event was caused by suboptimal seed placement due to inadequate procedures. No significant deterministic effect to the patients is expected. The brachytherapy program at the medical center was suspended in September 2008 and terminated in August 2009.

Events of Interest

Item Number 100071 - A hospital reported a medical event that resulted in a 90% underdose during an HDR afterloader treatment on 2/10/2010. The HDR contained a 407 GBq (11 Ci) Ir-192 source. The incident was two treatment fraction underdoses delivered on the same day to the same patient that differed from the prescribed dose by more than 50% per fraction. The prescription was for two treatments of 400 cGy (rad) per fraction per day for two days and one final 400 cGy (rad) fraction on the third day. Two fractions of 40 cGy (rad) were delivered on the first day of treatment. The event was caused by an equipment software failure. The prescribing physician and equipment manufacturer were notified. The equipment manufacturer found that the software issue was reproducible and may be classified as a potential patient safety issue. The suspect portion of software will not be used again until the program is debugged and documented to be correct. The suspect portion of the software had not been used in the past by the hospital, so no previous patients were affected. The equipment manufacturer published a customer information bulletin describing the problem. The event was classified as an EQP and MED event.

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs

Doses to an embryo/fetus or nursing child are reportable per 10 CFR 35.3047. By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as an "Other" event. However, it is appropriate to also discuss these events in this section. Two such events occurred in FY10, both of which are classified as potential AOs.

Item Number 100245 - A pregnant patient was administered 1.11 GBq (30 mCi) of I-131 on 3/16/2010. A blood serum pregnancy test was performed prior to the administration and results were negative. On 4/26/2010, the patient took a home urine pregnancy test that revealed positive results. Pregnancy was confirmed using a blood serum pregnancy test on 4/27/2010. The patient's physician estimated that conception occurred on 3/13/2010. The fetal dose was estimated to be approximately 8 cSv (rem). The patient was notified. The Colorado Department of Health investigated the incident. A second medical physicist reviewed the incident and estimated the fetal whole body dose to be between 5.3 and 9.2 cSv (rem). The hospital stated that all procedures were followed to prevent this incident. The blood serum test does not detect a pregnancy until 7 to 12 days post conception. The hospital will ask additional questions during the screening process of potentially pregnant patients.

Item Number 100400 - A pregnant patient was administered 5.73 GBq (154.9 mCi) of I-131 for thyroid ablation on 6/7/2010. Prior to the administration, the patient received a blood serum pregnancy test to check for pregnancy and the results were negative. On 7/8/2010, the patient returned for a follow-up visit and informed the doctor that she was pregnant. An ultrasound estimated that the date of conception was 6/1/2010. A dose assessment conservatively estimated the fetal dose to be 41.27 cGy (rad). Due to the age of the fetus, there was no thyroid present and no acute effect to the fetus is expected. The patient was informed of these results on 8/11/2010. Corrective actions included updating the patient consent form to explain that the pregnancy test may not show a positive result until 7 to 10 days after conception, and reinforcing with staff the need to inform patients of the potential for false negative results from the pregnancy test and advise the patient to refrain from actions that may lead to pregnancy. The NRC contracted a medical consultant to review this event.

2.3.3 Events Recently Added to NMED That Occurred Prior to FY10

Twenty MED events and one embryo/fetal dose event were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Two of the MED events and the embryo/fetal dose event were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - AOs or Potential AOs

Item Number 090466 - A cancer treatment facility reported an equipment malfunction involving an HDR unit that resulted in a medical event. The incident occurred on 4/14/2009 during a patient prostate treatment. The aluminum connector to needle 13 detached from the plastic guide tube. The HDR was connected to the plastic guide tube, the plastic guide tube was attached (glued) to the aluminum connector, and the aluminum connector screwed into the needles that were implanted in the patient. As a result, the 185 GBq (5 Ci) Ir-192 source wire failed to enter the needle and hung about six inches past the disconnected guide tube in open air. The source wire was supposed to be in needle 13 for 32 seconds. The source wire retracted normally after the incident. The event did not interfere with the remaining treatment needles. The dose differed by approximately 180 cGy (rad) to a small volume of the prostate in the vicinity of needle 13. The total dose to the prostate differed from the prescribed dose by less than 5%. The incident also resulted in as much as 1,250 cGy (rad) to a small area of skin on the patient's inner thigh. However, several subsequent inspections of the patient have not identified any skin reactions. The attending physician does not believe there was any clinically significant effect to the patient. The root causes of the failure of the adhesive that attached the aluminum connector to the plastic extension adaptor was sterilization of the extension adaptor (the manufacturer's written product information cautions that sterilization may cause adhesive failure) and reuse of extension adaptors (the manufacturer's written product information recommends that they are for single use only). Corrective actions included procedure modification, including (1) requiring the staff to sign the patient quality assurance list when they check the applicators, transfer guide tubes, and aluminum connectors; (2) inspecting the guide tube catheters daily and examining the aluminum connectors prior to patient use; and (3) revising the refresher training to include new procedures for staff prior to patient treatment. This event was classified as an EQP and MED event.

Item Number 090659 - A hospital reported that an equipment malfunction involving a gamma knife unit occurred on 8/5/2009 and resulted in a patient receiving an incorrect dose. According to the NRC Registry of Radioactive Sealed Sources and Devices, this unit contains 201 Co-60 sources with a total maximum activity of 244.2 TBq (6,600 Ci). Two patients were scheduled for treatment on that day. While treating the first patient, the automatic positioning system reported positioning error codes to the treatment console and the operators called the manufacturer for help. The hospital was told to undock the patient, reinitialize the positioning system, and then complete the treatment. The error occurred again during the second patient's treatment and the manufacturer service representative person was called to inspect the unit. The service representative arrived after the completion of treatment to the second patient. It was noted that while trying to drive the positioning system back to its nominal position, one of the axis indicators was off by 4.5 mm. It was determined that the shift happened during patient treatment. The patient was prescribed to receive 1,800 cGy (rad) at the 50% isodose line for six lesions in the brain. It was concluded that the intended treatment sites received less than 80% of the prescribed dose and unintended sites received greater than 50 cGy (rad) and greater than 50% of the intended dose. A medical consultant concurred with the hospital's assessment that the untreated area could be retreated and that no clinically significant side-effects from radiation damage to the unintended areas were expected. An NRC investigation determined that the dose error was caused by inadequate procedures that did not require a physical verification of the automatic position system coordinates against the electronic coordinates prior to treatment, and did not specify how personnel should respond to unexpected treatment console errors.

Corrective actions included personnel training and procedure modification. This event was classified as an EQP and MED event.

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs

Item Number 100319 - A pregnant patient was administered 3.81 GBq (102.9 mCi) of I-131 as a treatment for reoccurring cancer associated with a previous thyroidectomy conducted in 2006. The treatment was administered on 5/1/2007 and the patient was 25 to 27 weeks pregnant. The patient had received I-131 following the thyroidectomy in 2006 and was treated a second time with I-131 on 5/1/2007. The doctor stated that when he asked the patient if she was pregnant, she replied that she was not. No independent test was conducted. The doctor was contacted on 6/11/2007 by the physician's obstetrician, who advised that she was 32 weeks pregnant. Calculations were performed by the Illinois Emergency Management Agency resulted in an estimated dose to the fetus of 86 cGy (rad). The child was delivered after a full term pregnancy and is receiving thyroid hormone therapy.

2.4 Radiation Overexposure

2.4.1 Ten-Year Data

Figure 4 displays the annual number and trend of EXP events that occurred during the 10-year period. The trend analysis determined that the Total, NRC-regulated, and Agreement State-regulated events represent statistically significant decreasing trends (indicated by the trend lines).

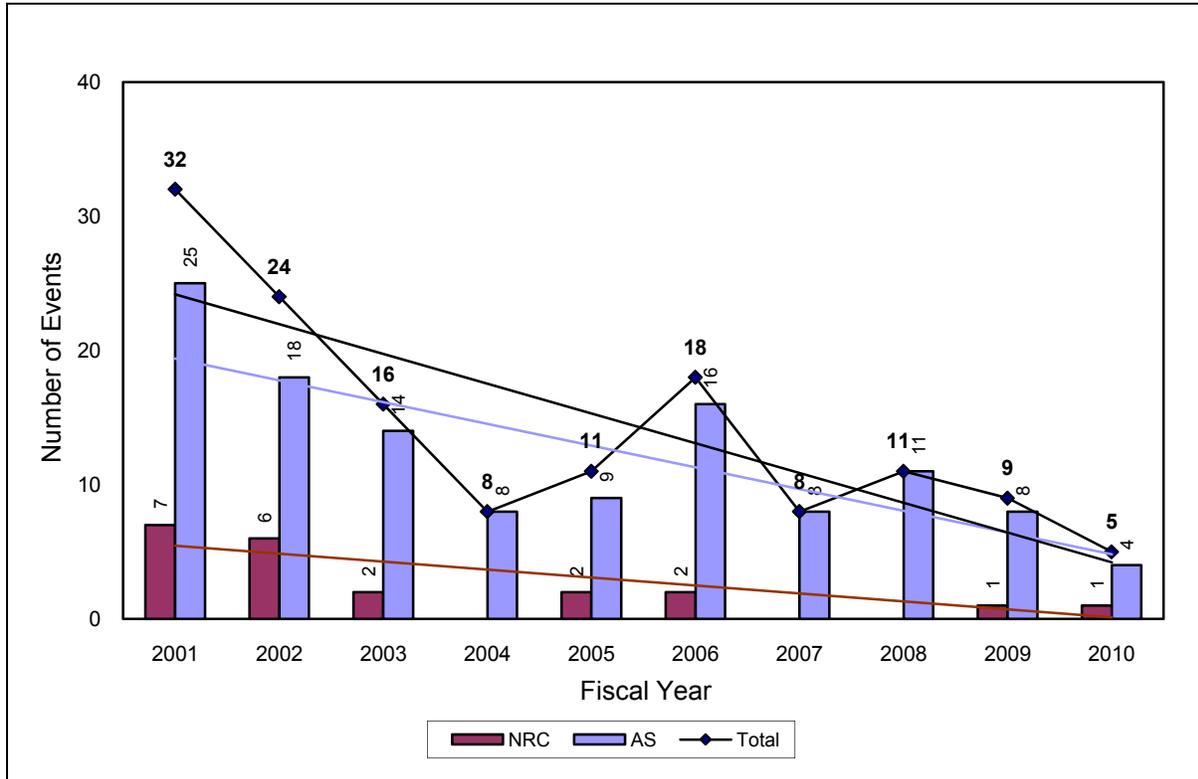


Figure 4. Radiation Overexposure Events (142 total)

The significance of individual EXP events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, those events requiring immediate or 24-hour reporting are considered significant.

Table 6 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 6. EXP Events Classified by CFR Reporting Requirement

CFR Reporting Requirement	Fiscal Year										Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	
Immediate	2	1	2	1	0	1	1	0	0	0	8
24-Hour	1	0	1	1	1	3	1	3	1	1	13
30-Day	29	23	13	6	10	14	6	8	8	4	121
Total	32	24	16	8	11	18	8	11	9	5	142

2.4.2 FY10 Data

Five EXP events occurred in FY10, one of which was classified as a significant event.

Significant Events - Immediate Reports

None.

Significant Events - Within 24-Hour Reports

Item Number 090837 - While performing radiography on a pressure vessel on 11/12/2009, the radiographers mistakenly believed that they had cranked the 2.92 TBq (79 Ci) Ir-192 source back into the camera after a shot. One of the radiographers went to the camera without a survey meter to remove the source guide tube. He was trying to install the safety plug on the camera when he realized that the source was not in the shielded position. Instead of roping off the area and contacting the RSO per procedure, the radiographers returned the source to the camera themselves and failed to report the incident to the RSO until the next day. Their pocket dosimeters were off-scale and their personnel dosimeters were sent to the dosimetry vendor for emergency processing. One of the radiographers had a November dose of 5.57 cSv (rem), for an annual dose of 6.67 cSv (rem). The other radiographer had a November dose of 0.45 cSv (rem), for an annual dose of 1.00 cSv (rem). The Louisiana Department of Environmental Quality performed an investigation into this event. Corrective actions included terminating the employment of the two radiographers involved, providing a two-day safety refresher training for the remainder of the radiographers, and performing more frequent field audits of their crews. In addition, all radiography equipment was inspected for proper operation. As of 11/18/2009, this incident was classified as an International Nuclear Event Scale level 2 event.

Events of Interest

Item Number 100209 - A hospital reported a radiation overexposure to a member of the public. A patient received temporary implants of Cs-137 and Ir-192 seeds on 4/16/2010. The patient's visitor (fiancé) was instructed that he could stay no longer than two hours with the patient in a 24-hour period. He was also instructed to stay behind the bedside shield during those visitations. However, the fiancé spent two consecutive nights in the patient's room. The fiancé stated that he slept in the same bed with the patient both nights. The Ohio Department of Health investigated the incident. Calculations revealed that the fiancé received 1.25 cSv (rem). Corrective actions taken by the hospital included instituting major procedural changes and conducting training for medical staff involved with brachytherapy treatments. As of 4/23/2010, this incident was classified as an International Nuclear Event Scale level 2 event.

2.4.3 Events Recently Added to NMED That Occurred Prior to FY10

Two EXP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Neither of the events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate or 24-Hour Reporting

None.

Events of Interest

Item Number 100399 - A brachytherapy seed manufacturer reported that an employee received a whole body dose of 6.1 cSv (rem) and an extremity exposure to the right hand of 51.881 cSv (rem) in December 2008. The employee work involves producing I-125 and Pd-103 brachytherapy seeds. The incident was discovered during a scheduled State of Florida audit conducted on 7/27/2010. Corrective actions included implementing the use of leaded gloves, increased shielding, and the review of the radiation protection manual and procedures. As of 8/6/2010, this incident was classified as an International Nuclear Event Scale level 2 event.

2.5 Release of Licensed Material or Contamination

2.5.1 Ten-Year Data

Figure 5 displays the annual number and trend of RLM events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data.

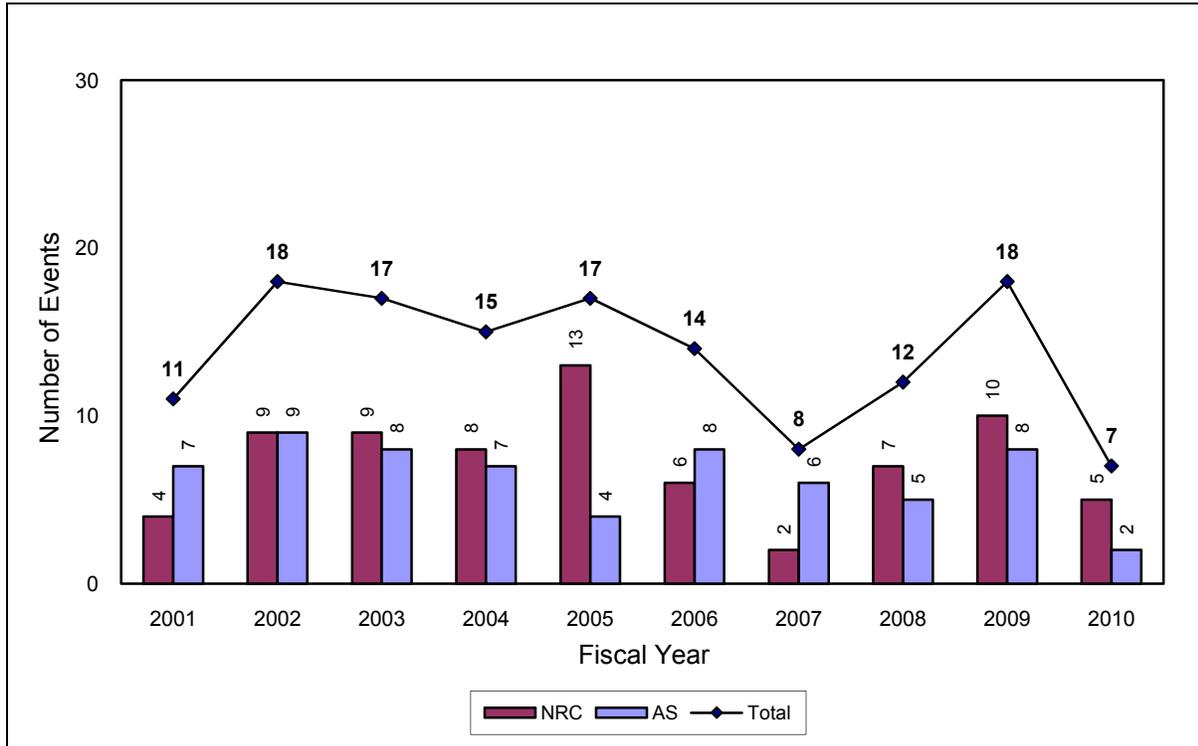


Figure 5. Release of Licensed Material or Contamination Events (137 total)

The significance of individual RLM events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, those events requiring immediate or 24-hour reporting are considered significant.

Table 7 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 7. RLM Events Classified by CFR Reporting Requirement

CFR Reporting Requirement	Fiscal Year										Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	
Immediate	1	0	0	2	0	0	0	2	1	1	7
24-Hour	9	15	16	13	17	12	8	8	12	3	113
30-Day	1	3	1	0	0	2	0	2	5	3	17
Total	11	18	17	15	17	14	8	12	18	7	137

2.5.2 FY10 Data

Seven RLM events occurred in FY10, four of which were classified as significant events.

Significant Events - Immediate Reports

None.

Significant Events - Within 24-Hour Reports

Item Number 090854 - A commercial nuclear power plant reported that a radioactively contaminated individual traveled to a hospital for treatment on 12/1/2009. The machinist was working on a reactor coolant pump seal and contaminated his left hand index finger on 11/26/2009. The net contamination level was 1,500 cpm. Upon exit, the individual set off the personnel monitor alarms and decontamination was attempted. Decontamination for the next two shifts included wrapping the individual's hand, waiting two hours, rechecking, and repeating two hours later. However, decontamination was unsuccessful. The individual was conditionally released and allowed to leave the site with his hand wrapped. On 12/1/2009, power plant health physics personnel met the individual at the hospital for further treatment.

Item Number 090878 - A radioactive source disposal company reported a leaking Cs-137 brachytherapy source that contained an activity between 0.37 and 1.30 GBq (10 and 35 mCi). On 12/09/2009, company personnel were at a hospital to package several old sources for disposal. The following day, the packages were transported to the company's facility. On 12/11/2009, an employee identified radioactive contamination on his clothing. On 12/13/2009, it was determined that the contamination came from a leaking Cs-137 brachytherapy source that had ruptured at the hospital during the packaging process. A health physics consultant performed radiation surveys at the hospital, which identified that contamination was limited to the oncology department, along with a small amount of contamination on one employee's car floor mat and home door mat. The South Carolina Department of Health (DOH) responded and performed radiation surveys. The highest reading identified by DOH was 50 mR/hour at the nurse's station, which was on the other side of the oncology suite from where the source rupture occurred. Readings of 100 mR/hour and higher were reported by the source disposal company, who decontaminated the suite from 12/13 to 12/20/2009. Patient treatments were suspended on 12/14 and 12/15/2009. Corrective actions included modifying procedures, providing additional training to personnel, and terminating the employment of personnel. This event was classified as an EQP, LKS, and RLM event.

Item Number 100160 - A commercial nuclear power plant reported that a contaminated individual was transported offsite for medical attention on 4/5/2010. The individual had been in the containment building complaining of chest pain. Offsite medical was contacted and the individual was transported via ambulance to a hospital. Radiation Protection personnel accompanied the individual to the hospital and determined that the individual was radioactively contaminated at a level of 3,500 corrected cpm on his left ankle. The individual was successfully decontaminated.

Item Number 100502 - During a routine health and safety inspection on 10/7/2010, the Iowa Department of Public Health (DOH) identified that an explosion occurred at a radioactive source manufacturing facility on 12/3/2009. An authorized user (AU) was quenching a mixture containing 14.8 GBq (400 mCi)

of C-14 at the time of the explosion. The AU showered and was taken to the emergency room. The AU had several bioassays performed prior to returning to work. The manufacturer decontaminated the area of concern within the laboratory. Decontamination was completed on 12/4/2009. Between 10 and 20 mCi was recovered, with the remainder of the material being lost. Corrective actions included personnel receiving additional training and improved supervision. In addition, new equipment was obtained. This event was classified as an EQP, LAS, and RLM event.

Events of Interest

Item Number 100529 - On 4/30/2010, a licensee reported a radioactive material contamination event that resulted in the improper disposal of radioactive material to normal trash. The contamination event occurred on 4/13 and 4/14/2010 and involved a reference source containing approximately 2.2 milligrams of Pu metal. The reference source was analyzed using a secondary ion mass spectrometer (SIMS), which employed a beam of oxygen ions impacting the reference source to “sputter off” Pu ions from the surface for analysis in the mass spectrometer. The licensee determined that 8.1 micrograms (55.5 kBq or 1.5 uCi) of the Pu reference source was “sputtered off” during the SIMS analysis. Most of this material was deposited on a collection plate within the SIMS vacuum chamber, which was subsequently cleaned using a variety of methods. However, ineffective contamination surveys prior to cleaning failed to identify the presence of contamination, so the cleaning procedures were performed under the assumption that no contamination was present. Contamination was later discovered on the work table and in the laboratory sink. Items used during the cleaning process were disposed of in the normal trash, which had already been removed from the facility and sent to an incinerator. Analysis of a urine sample collected from the individual involved in this event showed no detectable activity. While investigating this event, the licensee determined that a similar event may have occurred in July and August, 2004. Conservative calculations assuming that the entire 8.1 micrograms (55.5 kBq or 1.5 uCi) was incinerated indicate minimal dose to the maximally exposed individual. Corrective actions include halting the use of alpha-emitting radionuclides pending review of the risks presented by their use. This review resulted in procedure modification and personnel training. This event was classified as an LAS and RLM event.

2.5.3 Events Recently Added to NMED That Occurred Prior to FY10

Two RLM events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Neither of the events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate or 24-Hour Reporting

None.

Events of Interest

Item Number 090696 - A Texas radioactive waste disposal company identified a radiologically contaminated area on 8/28/2009. The contamination was discovered while performing radiological surveys in response to a shipping event. Access to that area of their facility was not normally controlled for radiological reasons, but was isolated after discovering the contamination. The company had previously shipped an empty 30-gallon transport container to a Pennsylvania university on 8/20/2009. Upon receipt (8/25/2009), contamination was noted on the lid with another spot on the pallet and another on the banding holding the drum to the pallet. A survey identified 659,000 dpm alpha/100 cm² (fixed plus removable) on the container. The carrier’s truck was not contaminated. Surveys of the Texas facility identified extensive contamination. The radionuclide was identified as Cm-244 with 346.14 GBq (9.355 Ci) contained in the transport container and 0.533 MBq (14.4 uCi) on various surfaces. On 3/18/2010, decontamination of the Texas facility was completed. On 4/7/2010, a Texas Department of State Health Services inspector performed a check survey of the facility. One slightly elevated area of fixed contamination was identified. That area was decontaminated while the inspector was present. This event was classified as an RLM and TRS event.

2.6 Leaking Sealed Sources

2.6.1 Ten-Year Data

Figure 6 displays the annual number and trend of LKS events that occurred during the 10-year period. An event reporting anomaly associated with a single electron capture detector (ECD) manufacturer occurred from Fiscal Year 2000 through early 2005, which notably increased the number of LKS events. The anomalous events were not significant and involved leaking ECD sources (Ni-63 foil sources) that had been returned to the manufacturer for refurbishment. The manufacturer discontinued refurbishing ECDs and now disposes of the returned sources without leak testing. To show this affect, Figure 6 displays the anomalous events as yellow shaded bars. The trend analysis determined that the Agreement State-regulated events do not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data. However, the Total and NRC-regulated events (excluding the anomalous data) represent a statistically significant decreasing trend (indicated by the trend line).

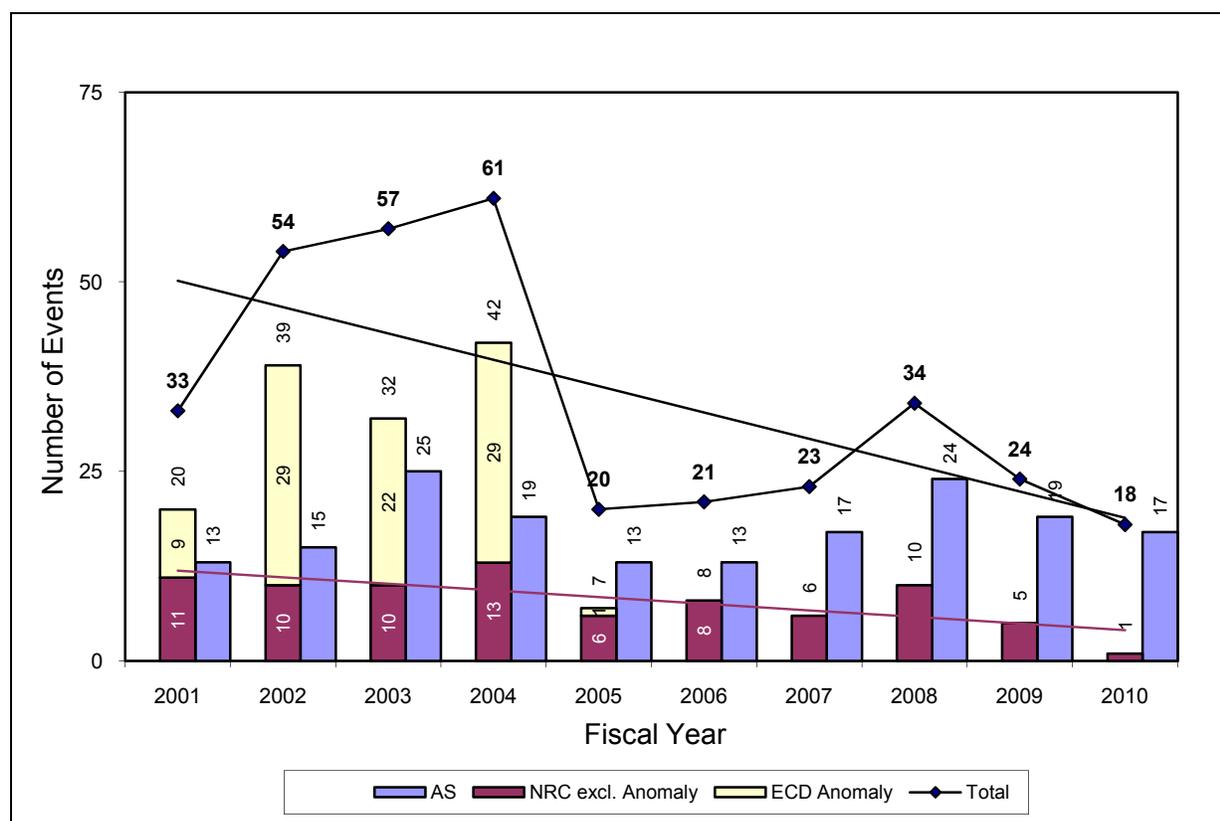


Figure 6. Leaking Sealed Source Events (345 total)

It is not possible to discern the significance of LKS events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9). Thus, significance of these events is determined using a qualitative review of the potential event consequences.

2.6.2 FY10 Data

Eighteen LKS events occurred in FY10, one of which was classified as a significant event.

Significant Events

Item Number 090878 - A radioactive source disposal company reported a leaking Cs-137 brachytherapy source that contained an activity between 0.37 and 1.30 GBq (10 and 35 mCi). On 12/09/2009, company personnel were at a hospital to package several old sources for disposal. The following day, the packages

were transported to the company's facility. On 12/11/2009, an employee identified radioactive contamination on his clothing. On 12/13/2009, it was determined that the contamination came from a leaking Cs-137 brachytherapy source that had ruptured at the hospital during the packaging process. A health physics consultant performed radiation surveys at the hospital, which identified that contamination was limited to the oncology department, along with a small amount of contamination on one employee's car floor mat and home door mat. The South Carolina Department of Health (DOH) responded and performed radiation surveys. The highest reading identified by DOH was 50 mR/hour at the nurse's station, which was on the other side of the oncology suite from where the source rupture occurred. Readings of 100 mR/hour and higher were reported by the source disposal company, who decontaminated the suite from 12/13 to 12/20/2009. Patient treatments were suspended on 12/14 and 12/15/2009. Corrective actions included modifying procedures, providing additional training to personnel, and terminating the employment of personnel. This event was classified as an EQP, LKS, and RLM event.

Events of Interest

None.

2.6.3 Events Recently Added to NMED That Occurred Prior to FY10

Five LKS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Neither of the events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events

None.

Events of Interest

Item Number 080169 - A licensee reported that two patients were implanted with one or more leaking brachytherapy seeds containing I-125 at a medical center. Each seed contained a nominal activity of 11.1 MBq (300 uCi). Three patients were scheduled for transperineal permanent prostate seed implants on 3/14/2008 with a prescribed dose of 14,500 cGy (rad). Three separate packages of seeds in preloaded needles were received. Surveys showed no surface contamination or contamination outside the inner sterile containers. After 12 of 106 seeds were implanted in the first patient, a survey showed a small amount of contamination on the inside of the sterile packaging. This implantation procedure was stopped and a survey showed contamination on the tips of three of the four needles that had been used, the greatest being 5,000 cpm (420 Bq [0.01135 uCi] assuming a 20% efficiency). A deviation from the pre-implantation treatment plan was authorized by signature of the authorized user and was documented on the written directive. The patient was administered stable iodine to block his thyroid and the seed vendor was notified. To determine if the remaining patients would be implanted, the remaining two packages of seeds were opened to survey the interiors of the sterile packaging. When no contamination was found, the implant procedure was performed on the second patient. The patient was implanted with the prescribed 92 seeds on 3/14/2008, for a total activity of 1.02 GBq (27.6 mCi). At the end of that procedure, surveys of the used needles revealed 1,000 cpm (83 Bq [0.00224 uCi] assuming a 20% efficiency). The seed vendor was again notified. Urine bioassays of the first and second patients showed evidence of I-125 excretion, with a total excretion by 3/25/2008 of 5,735 and 3.7 MBq (155 and 0.1 uCi), respectively. Based on urine and thyroid bioassays, one or more seeds were determined to be leaking. The implant procedure for the third patient was cancelled. It was determined that damage to the seeds did not likely occur during shipping, handling, or implantation. The licensee tracked possible patient doses by thyroid counts and urine bioassay with final results indicating the doses to organs and effective dose equivalents to the patients were less than the criteria for a medical event. Results indicated maximum thyroid activity was 0.11 MBq (3 uCi). The calculated thyroid dose ranges were between 2 and 15 cGy (rad) for the first patient and between 10 and 45 cGy (rad) for the second patient. Corrective actions included procedure modifications and a change in the seed vendor. The seed manufacturer identified a

problem with welding fixtures, with a slight distortion in the welding and a potential for a microscopic pore not being completely sealed in the welding process. It was determined that the problem was isolated. This event was classified as an EQP and LKS event.

Item Number 080237 - A patient was implanted on 4/16/2008 with a damaged and leaking Pd-103 seed with an activity of 55.5 MBq (1.5 mCi). The prostate treatment prescribed implanting 187 seeds into the patient. During the procedure, it was noted that one of the seeds was sheared off with only 5% of the seed remaining in the cartridge. The piece was identified as leaking and it was assumed that the other part of the seed was injected into the patient. The hospital believes that a malfunction in the applicator caused the seed to be out of alignment when the cartridge was inserted or removed. The cartridges were disposed of as biomedical waste immediately after the surgery. The applicator was taken out of service and returned to the manufacturer for evaluation. The patient was prescribed to receive 12,400 cGy (rad) and received that dose. The Oklahoma Department of Environmental Quality determined that the incident was not a reportable medical event.

2.7 Equipment

2.7.1 Ten-Year Data

Figure 7 displays the annual number and trend of EQP events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data.

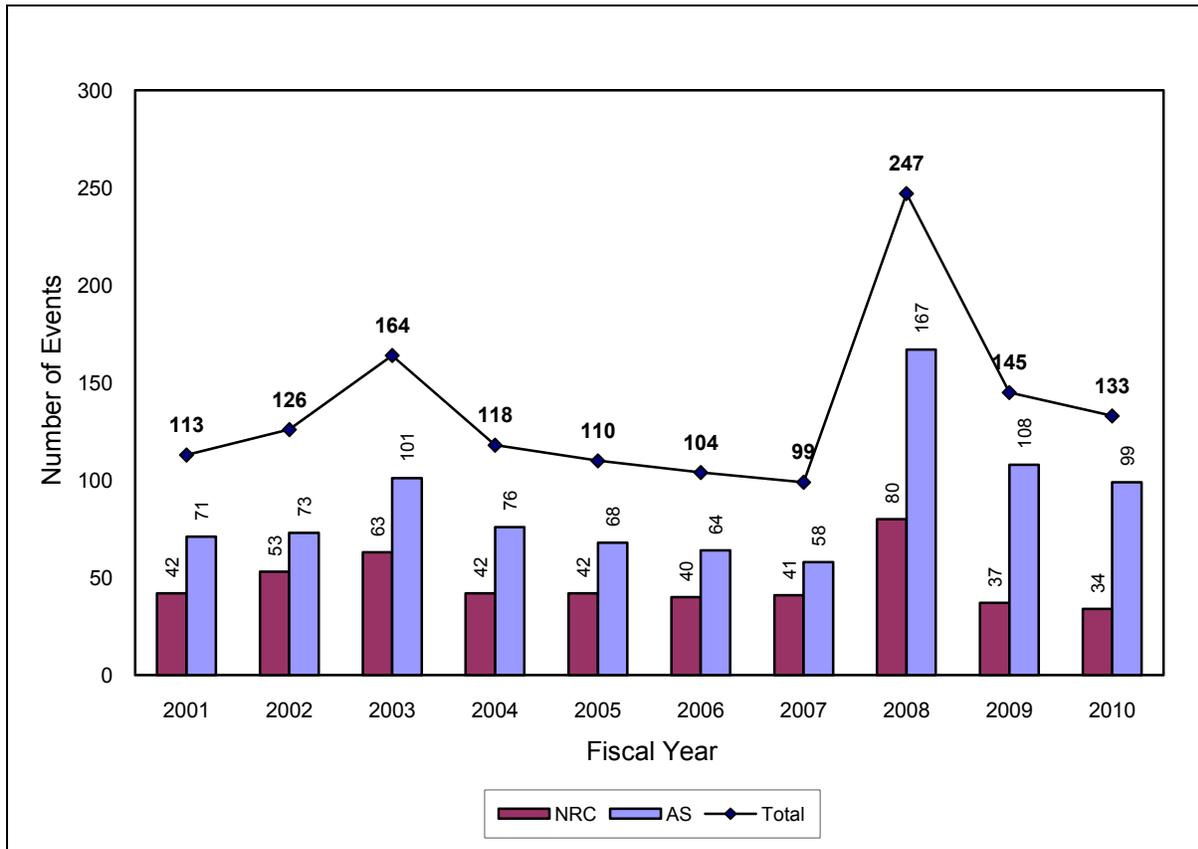


Figure 7. Equipment Events (1,359 total)

The FY08 and 09 data include 130 and 20 EQP events, respectively, which resulted from Wal-Mart's one-time review of their tritium exit sign inventory. Excluding these events does not result in a statistically significant trend in the total remaining events.

It is not possible to discern the significance of EQP events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9). Thus, significance of these events is determined using a qualitative review of the potential event consequences.

2.7.2 FY10 Data

One hundred thirty-three EQP events occurred in FY10, two of which were classified as significant events.

Significant Events

Item Number 090878 - A radioactive source disposal company reported a leaking Cs-137 brachytherapy source that contained an activity between 0.37 and 1.30 GBq (10 and 35 mCi). On 12/09/2009, company personnel were at a hospital to package several old sources for disposal. The following day, the packages were transported to the company's facility. On 12/11/2009, an employee identified radioactive

contamination on his clothing. On 12/13/2009, it was determined that the contamination came from a leaking Cs-137 brachytherapy source that had ruptured at the hospital during the packaging process. A health physics consultant performed radiation surveys at the hospital, which identified that contamination was limited to the oncology department, along with a small amount of contamination on one employee's car floor mat and home door mat. The South Carolina Department of Health (DOH) responded and performed radiation surveys. The highest reading identified by DOH was 50 mR/hour at the nurse's station, which was on the other side of the oncology suite from where the source rupture occurred. Readings of 100 mR/hour and higher were reported by the source disposal company, who decontaminated the suite from 12/13 to 12/20/2009. Patient treatments were suspended on 12/14 and 12/15/2009. Corrective actions included modifying procedures, providing additional training to personnel, and terminating the employment of personnel. This event was classified as an EQP, LKS, and RLM event.

Item Number 100125 - A 259 GBq (7 Ci) Ir-192 radiography source was lost on 3/15/2010 while operations were being conducted at night on an oil platform in the Gulf of Mexico. The guide tube was removed from the exposure device in an attempt to return the source to the shielded position within the exposure device. During this attempt, the source was thought to have moved into the exposure device, so the exposure device was secured. However, the next day it was determined that the source was not in the exposure device. After a search failed to locate the source, it was determined that the source must have disconnected from the drive cable and fallen through the grating and into the ocean. The platform was approximately six miles from shore and the depth of the water was about 40 feet. No attempt was made to retrieve the source. The cause of the incident was determined to be mechanical failure. This event was classified as an EQP and LAS event.

Events of Interest

Item Number 090772 - Radiation monitor alarms were triggered at a scrap metal processing facility by a load of scrap metal from metal recycling facility on 10/12/2009. The load of scrap was returned to the recycling facility. The Ohio Bureau of Radiation Protection (BRP) dispatched an inspector to the recycling facility on 10/13/2009. A fixed gauge was identified that contained a 7.4 GBq (200 mCi) Cs-137 source. The BRP inspector surveyed the gauge and determined that the shutter was stuck open with an in-beam dose rate of 200 mR/hour at six inches. The shutter mechanism was freed and verified closed by the inspector and a wipe test identified negative results. BRP contacted the gauge manufacturer and learned that the device was initially distributed to an oilfield services company on 9/9/1986. The oilfield services company was contacted and sent a representative to the recycling facility to retrieve the gauge. The inspector determined that the gauge had been inadvertently sent to the recycling facility; the oilfield services company had not attempted to illegally dispose of it. The oilfield services company contacted the gauge manufacturer, who took possession of the gauge and shipped it to their facility on 10/22/2009. This event was classified as an EQP and LAS event.

Item Number 100004 - The Nevada Highway Patrol (NHP) reported that a moisture/density gauge containing a 1.85 GBq (50 mCi) Am-Be source and a 0.37 GBq (10 mCi) Cs-137 source fell out of a material testing company's truck in Las Vegas, Nevada, and was destroyed. Initial radiation instrument readings taken by the NHP revealed 415 uR/hour at 10 feet. It was determined that the source tube had not ruptured. Metro All Regional Multi-Agency Operations and Response (ARMOR) was contacted and responded to the scene with additional radiation detection instruments. ARMOR surveys revealed 600 mR/hour at the surface of the gauge case. The gauge pieces were placed in a shipping container and transported to the material testing company's facility. The Nevada Division of Radiological Health (DRH) responded to the facility on 12/29/2009. DRH surveys revealed 70 mR/hour on contact with the shipping container that held the gauge pieces. DRH determined that both sources were recovered, intact, and leak tested satisfactory. Corrective actions included providing HAZMAT training to the technician involved. This event was classified as an EQP and LAS event.

Item Number 100025 - A radioactive source manufacturer reported a 10 CFR 21 defect involving a radiography source assembly. A customer had received a source assembly and reported problems with

the assembly connection on 10/21/2009. The unit was returned to the manufacturer and an evaluation was performed on the extent of the defect. It was determined that the female connector sleeve was the problem. The male connection would not seat in the sleeve of the connector and would not lock in. That could give the user a false impression that the source is connected to the drive cable when there is only a partial connection. The manufacturer conducted a 100% search of a lot of 1,567 assemblies in stock and found five to be defective. They sent out a notice dated 1/11/2010 to all their radiography customers describing the disconnect issue. There are 236 source assemblies in the field with 29 different licensees.

Item Number 100061 - A public utility company reported that two employees removed a fixed gauge from a mounted position on 11/12/2009 with the source shutter in the open position. The gauge was mounted on a pipe to measure scrubber slurry flow and contained a 1.85 GBq (50 mCi) Cs-137 source, which was manufactured in April 2002. The detector was not working correctly and needed to be repaired. The shutter was locked after the gauge was taken down. The employees that removed the gauge did not notify anyone of the open shutter until 1/29/2010. The RSO stated that exposure estimates for the employees involved were approximately 9 and 250 uSv (0.9 and 25 mrem). The two employees did not exceed the exposure limits for members of the public. The cause of the incident was considered to be human error. Corrective actions included a clarification of procedures for working on fixed gauges, incorporating fixed gauges into the lock out/tag out program, and providing additional training to all facility staff and personnel who work on gauges. This event was classified as an EQP and OTH event.

Item Number 100071 - A hospital reported a medical event that resulted in a 90% underdose during an HDR afterloader treatment on 2/10/2010. The HDR contained a 407 GBq (11 Ci) Ir-192 source. The incident was two treatment fraction underdoses delivered on the same day to the same patient that differed from the prescribed dose by more than 50% per fraction. The prescription was for two treatments of 400 cGy (rad) per fraction per day for two days and one final 400 cGy (rad) fraction on the third day. Two fractions of 40 cGy (rad) were delivered on the first day of treatment. The event was caused by an equipment software failure. The prescribing physician and equipment manufacturer were notified. The equipment manufacturer found that the software issue was reproducible and may be classified as a potential patient safety issue. The suspect portion of software will not be used again until the program is debugged and documented to be correct. The suspect portion of the software had not been used in the past by the hospital, so no previous patients were affected. The equipment manufacturer published a customer information bulletin describing the problem. The event was classified as an EQP and MED event.

Item Number 100086 - A radiography company reported a potential radiation overexposure to a radiographer and a contractor (aerial lift bucket operator). The incident occurred on 2/26/2010 during radiography of elevated piping of a pumping station. The radiographers were using an exposure device that contained a 3.18 TBq (85.9 Ci) Ir-192 source. The radiographer and contractor were in an aerial lift bucket and had just completed a radiography shot on some overhead piping. The assistant radiographer had supposedly retracted the source into the exposure device, applied positive pressure to the control assembly, and surveyed the area underneath the device with no detection of radiation. The radiographer and lift operator approached the device guide tube to setup for the next shot. The radiographer removed the exposed film cassettes and placed the cassettes for the next exposure. He then removed the collimator from under a bungee cord used to hold the collimator in place and adjusted it for the next exposure. He then walked behind the exposure device to push the lock mechanism to permit the next shot. At that time, the radiographer noticed that the lock slide was not in the secured position. He yelled to the assistant radiographer to re-perform the source retraction process. Because the radiographer had his alarming rate meter under his clothing and there was significant ambient noise, the radiographer did not immediately hear his rate meter alarming as they approached the radiography camera guide tube. When the radiographer heard his alarming rate meter, he checked his pocket dosimeter and it was off-scale. The assistant attempted to retract the source into the fully shielded position without success. The assistant then cranked the source into the exposed position four revolutions and retracted the source. Radiation

surveys were performed to confirm retraction and the radiographer also performed visual confirmation that the automatic lock was engaged. The radiographer's thermoluminescent dosimeter (TLD) was sent for immediate processing. Results revealed an exposure of 4.22 mSv (422 mrem) for the period of 2/1/2010 to 2/26/2010. A reenactment and dose calculations performed by a Nebraska Division of Radioactive Materials inspector revealed that the radiographer received a dose of 2.75 mSv (275 mrem) from the incident. The dose calculations to the lift bucket operator (member of the public) revealed an exposure of 0.898 uSv (89.8 mrem). Causes of the event were a defective lock mechanism and failure to follow procedures. Corrective actions included returning the radiography equipment to the manufacturer for examination and providing training to personnel. The involved radiography crew was suspended indefinitely until they can prove their ability to follow procedures, at which time they will be retrained.

Item Number 100349 - Based on an onsite inspection by the Virginia Radioactive Materials Program on 7/9/2010 of an engineered materials manufacturer, two thickness gauges were identified with their shutters in the open position. The investigation was conducted as a result of a missing gauge (NMED Item 100348). Radiation surveys of the storage location indicated 0.2 mSv/hour (20 mrem/hour). Further investigation identified that the two gauges had springs that were not properly working. Both shutters were moved to the closed position and taped to ensure they remained closed. A lock was placed on the storage cabinet for security purposes. The manufacturer is working with a licensed broker for proper disposal of the remaining five gauges. This event was classified as an EQP and OTH event.

Item Number 100417 - A scrap processing facility reported that a load of scrap metal set off their radiation monitor alarms on 1/19/2010. A device was isolated from the load and stored in a secure location. A Wisconsin Department of Health (DOH) inspector visited the site on 6/9/2010. The device was identified as a dew pointer. A survey identified 110 mR/hour on the backside of the device. Wipe samples revealed no removable contamination. The scrap facility stated that the device's top cover was missing when it was received. The radioactive material labels and markings were also missing from the device's external casing. The dew pointer was double bagged, tagged, and placed back into secure storage. The NRC Radioactive Sealed Sources and Devices Registry states that the dew pointer contains a Ra-226 source with a maximum activity of 0.26 MBq (7 uCi). The DOH tried contact the manufacturer in an attempt to identify the original owner, but the manufacturer is no longer in business. The manufacturer's distribution records were transferred to another company, but they did not have records on the original owner of the device. This event was classified as an EQP and LAS event.

Item Number 100483 - A hospital reported that a gamma knife experienced a fatal error and terminated treatment to a patient on 9/27/2010. The gamma knife contained 511.49 TBq (13,824 Ci) of Co-60 sources. The gamma knife safety system functioned as designed, moving the patient out of the unit, and closing the shielding doors. The patient was safely removed from the treatment room. The patient was prescribed to receive 1,400 cGy (rad) to the brain, but only received 71.5 cGy (rad). The patient was informed of the error on the same day. The problem was diagnosed as a faulty computer on the unit. The computer was replaced and fully tested on 9/28/2010. The patient received the remainder of the treatment on 9/28/2010. This event was classified as an EQP and MED event.

Item Number 100492 - A hospital reported that a patient only received 5% of the prescribed dose during a gamma knife procedure performed on 9/30/2010. The RSO stated that while conducting a single fraction exposure to the patient, the computer screen froze. The patient was immediately removed from the gamma knife unit, which contained Co-60 sources with a total activity of 102.34 TBq (2,766 Ci). The patient was prescribed to receive 2,000 cGy (rad) to one location and 1,500 cGy (rad) to a second location, both to be delivered simultaneously. The referring physician and patient were notified of the event. The service provider for the gamma knife responded and replaced the control unit. The manufacturer stated that the event occurred due to a computer programming problem. The timer that froze is used to display the total run time of the treatment and does not control any part of the treatment. They also stated that the treatment would have run normally had the technician not stopped it and the

patient would have received the prescribed dose. The manufacturer is resolving the problem in their latest upgrade to the system. This event was classified as an EQP and MED event.

Item Number 100502 - During a routine health and safety inspection on 10/7/2010, the Iowa Department of Public Health (DOH) identified that an explosion occurred at a radioactive source manufacturing facility on 12/3/2009. An authorized user (AU) was quenching a mixture containing 14.8 GBq (400 mCi) of C-14 at the time of the explosion. The AU showered and was taken to the emergency room. The AU had several bioassays performed prior to returning to work. The manufacturer decontaminated the area of concern within the laboratory. Decontamination was completed on 12/4/2009. Between 10 and 20 mCi was recovered, with the remainder of the material being lost. Corrective actions included personnel receiving additional training and improved supervision. In addition, new equipment was obtained. This event was classified as an EQP, LAS, and RLM event.

2.7.3 Events Recently Added to NMED That Occurred Prior to FY10

Eleven EQP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. One of these events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events

Item Number 090659 - A hospital reported that an equipment malfunction involving a gamma knife unit occurred on 8/5/2009 and resulted in a patient receiving an incorrect dose. According to the NRC Registry of Radioactive Sealed Sources and Devices, this unit contains 201 Co-60 sources with a total maximum activity of 244.2 TBq (6,600 Ci). Two patients were scheduled for treatment on that day. While treating the first patient, the automatic positioning system reported positioning error codes to the treatment console and the operators called the manufacturer for help. The hospital was told to undock the patient, reinitialize the positioning system, and then complete the treatment. The error occurred again during the second patient's treatment and the manufacturer service representative person was called to inspect the unit. The service representative arrived after the completion of treatment to the second patient. It was noted that while trying to drive the positioning system back to its nominal position, one of the axis indicators was off by 4.5 mm. It was determined that the shift happened during patient treatment. The patient was prescribed to receive 1,800 cGy (rad) at the 50% isodose line for six lesions in the brain. It was concluded that the intended treatment sites received less than 80% of the prescribed dose and unintended sites received greater than 50 cGy (rad) and greater than 50% of the intended dose. A medical consultant concurred with the hospital's assessment that the untreated area could be retreated and that no clinically significant side-effects from radiation damage to the unintended areas were expected. An NRC investigation determined that the dose error was caused by inadequate procedures that did not require a physical verification of the automatic position system coordinates against the electronic coordinates prior to treatment, and did not specify how personnel should respond to unexpected treatment console errors. Corrective actions included personnel training and procedure modification. This event was classified as an EQP and MED event.

Events of Interest

Item Number 080169 - A licensee reported that two patients were implanted with one or more leaking brachytherapy seeds containing I-125 at a medical center. Each seed contained a nominal activity of 11.1 MBq (300 uCi). Three patients were scheduled for transperineal permanent prostate seed implants on 3/14/2008 with a prescribed dose of 14,500 cGy (rad). Three separate packages of seeds in preloaded needles were received. Surveys showed no surface contamination or contamination outside the inner sterile containers. After 12 of 106 seeds were implanted in the first patient, a survey showed a small amount of contamination on the inside of the sterile packaging. This implantation procedure was stopped and a survey showed contamination on the tips of three of the four needles that had been used, the greatest being 5,000 cpm (420 Bq [0.01135 uCi] assuming a 20% efficiency). A deviation from the pre-

implantation treatment plan was authorized by signature of the authorized user and was documented on the written directive. The patient was administered stable iodine to block his thyroid and the seed vendor was notified. To determine if the remaining patients would be implanted, the remaining two packages of seeds were opened to survey the interiors of the sterile packaging. When no contamination was found, the implant procedure was performed on the second patient. The patient was implanted with the prescribed 92 seeds on 3/14/2008, for a total activity of 1.02 GBq (27.6 mCi). At the end of that procedure, surveys of the used needles revealed 1,000 cpm (83 Bq [0.00224 uCi] assuming a 20% efficiency). The seed vendor was again notified. Urine bioassays of the first and second patients showed evidence of I-125 excretion, with a total excretion by 3/25/2008 of 5,735 and 3.7 MBq (155 and 0.1 uCi), respectively. Based on urine and thyroid bioassays, one or more seeds were determined to be leaking. The implant procedure for the third patient was cancelled. It was determined that damage to the seeds did not likely occur during shipping, handling, or implantation. The licensee tracked possible patient doses by thyroid counts and urine bioassay with final results indicating the doses to organs and effective dose equivalents to the patients were less than the criteria for a medical event. Results indicated maximum thyroid activity was 0.11 MBq (3 uCi). The calculated thyroid dose ranges were between 2 and 15 cGy (rad) for the first patient and between 10 and 45 cGy (rad) for the second patient. Corrective actions included procedure modifications and a change in the seed vendor. The seed manufacturer identified a problem with welding fixtures, with a slight distortion in the welding and a potential for a microscopic pore not being completely sealed in the welding process. It was determined that the problem was isolated. This event was classified as an EQP and LKS event.

Item Number 080237 - A patient was implanted on 4/16/2008 with a damaged and leaking Pd-103 seed with an activity of 55.5 MBq (1.5 mCi). The prostate treatment prescribed implanting 187 seeds into the patient. During the procedure, it was noted that one of the seeds was sheared off with only 5% of the seed remaining in the cartridge. The piece was identified as leaking and it was assumed that the other part of the seed was injected into the patient. The hospital believes that a malfunction in the applicator caused the seed to be out of alignment when the cartridge was inserted or removed. The cartridges were disposed of as biomedical waste immediately after the surgery. The applicator was taken out of service and returned to the manufacturer for evaluation. The patient was prescribed to receive 12,400 cGy (rad) and received that dose. The Oklahoma Department of Environmental Quality determined that the incident was not a reportable medical event.

Item Number 090736 - A hospital reported that a patient undergoing mammosite brachytherapy on 9/21/2009 received a dose greater than prescribed during one treatment fraction. The 355.2 GBq (9.6 Ci) Ir-192 source failed to retract during the eighth treatment fraction. The administering physician retrieved the source from the patient and placed it back into the HDR unit. Evaluation revealed that the patient received approximately 37.7% more dose during that fraction. The patient was prescribed a dose of 3,400 cGy (rad) through the course of 10 fractions. The hospital decided to forgo the ninth and tenth fractions, which resulted in the patient receiving 17% less dose than prescribed during the entire treatment. The medical aspect of the incident was retracted on 1/27/2010. The Texas Department of Health Services performed an investigation on 9/29/2009. The HDR manufacturer inspected the equipment and determined that the transfer guide tube, which connects to the applicator, had bunched at the point where it entered the HDR unit. That bunching caused the source wire to bind as it moved between dwell positions, and subsequently caused the source to become stuck in the guide tube. The service engineer cut out the bunched portion of the guide tube and completed a source exchange.

Item Number 100196 - A hospital reported a treatment planning software problem that occurred during a patient's high dose rate (HDR) brachytherapy procedure on 1/26/2009. The patient was prescribed to receive 700 cGy (rad) in two fractions to the central endobronchial cavity using the HDR unit. The incident involved a 145.97 GBq (3.945 Ci) Ir-192 source. Plans generated from planar images required scaling of the actual image and specification of the magnification of the projected image. The images were scaled correctly, and based on experience with other treatment planning algorithms, that would have

set the magnification. In August 2009, after the software was upgraded, it was discovered that there was a separate portion of the planning system that set the magnification. The planning magnification value was inherently set to within 2% of the actual value for non-endobronchial patients and was a clinically insignificant difference. However, it represented an 11% variation in spatial coordinates for an endobronchial patient planned with planar images. That resulted in a shift of the distribution center of 6 mm and variation of the distribution of 4 mm on the longitudinal ends. There was little, if any, variation in the radial width of the dose delivered. The issue was determined to be the lack of training for clients from the vendor about this particular modality, as well as the apparent fact that when the clients called the vendor, the vendors themselves appeared unaware of the potential problem and the lack of training for clients. For this patient, the distal portion of one of the treatment catheters was cross digitized with the second catheter during the input process. That led to the misrepresentation of the actual single catheter's geometric position and source dwell positions. Upon final analysis, it was determined that the delivered dose distribution was within 1 to 1.5 mm radial width in the central 6.5 cm of the target. The delivered dose on the distal 1.5 cm of the target was narrowed by 2 to 3 mm radially and extended by approximately 5 mm. The dose to the proximal 1 cm of the target was also radially decreased by the same amount. Additionally, the geometric displacement caused the source dwell positions proximal to the target and delivered a prescription dose to a cylindrical volume of approximately 5 to 6 mm radius and 3.5 to 4 cm in length. That volume was not intended to receive HDR treatment and resulted in approximately an additional 6% of the total dose. Corrective actions included procedure modifications requiring the use of CT data for patients that are treated without rigid applicators, using three planar images for planning since any misregistration of the catheters will be immediately noticed, and comparing additional image verification of the dwell positions to the plan prior to initiation of treatment.

2.8 Transportation

2.8.1 Ten-Year Data

Figure 8 displays the annual number and trend of TRS events that occurred during the 10-year period. The trend analysis determined that the data do not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data.

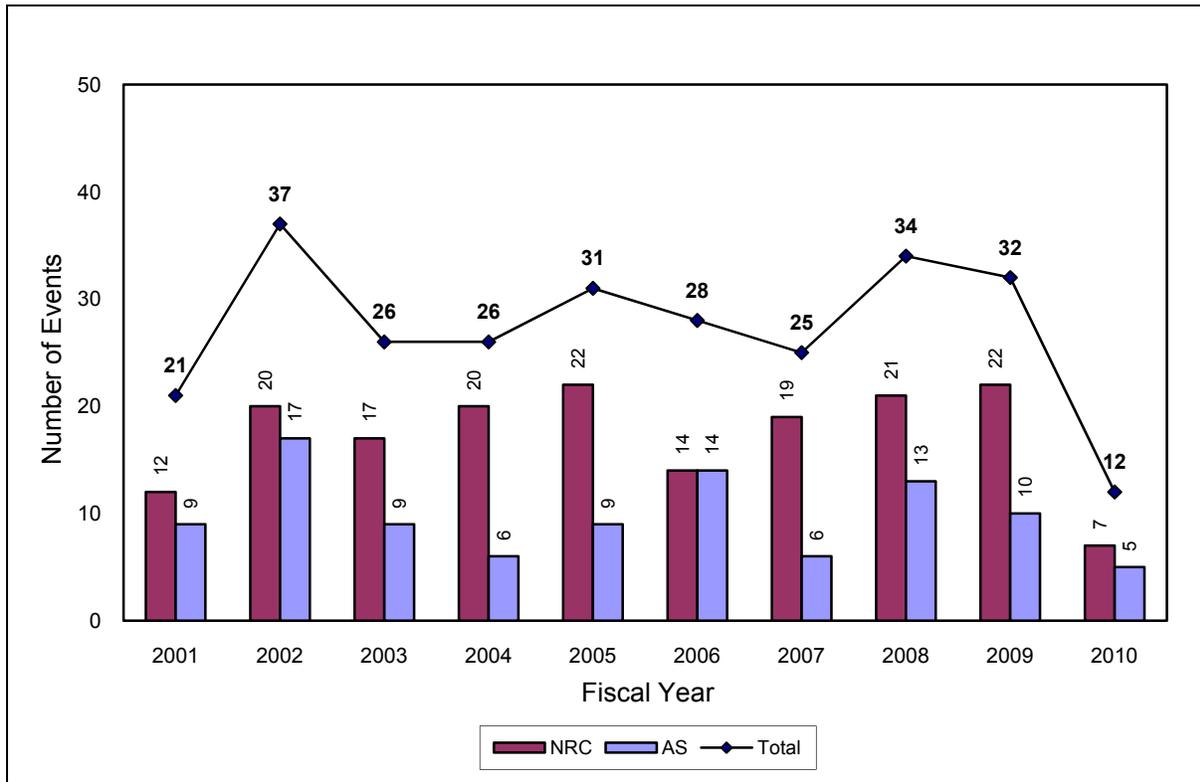


Figure 8. Transportation Events (272 total)

It is not possible to discern the significance of TRS events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9). Thus, significance of these events is determined using a qualitative review of the potential event consequences.

2.8.2 FY10 Data

Twelve TRS events occurred in FY10, one of which was classified as a significant event.

Significant Events

Item Number 100384 - A medical imaging facility received a package containing 18.28 GBq (494 mCi) of F-18 with a dose rate of 0.47 mSv/hour (47 mrem/hour) at one meter. The dose rate on contact exceeded the measuring capabilities of their survey instrument. The service manager opened the package and determined that the vial of F-18 had separated from its shielding. The vial was removed from the package and taken to an appropriate storage location. The F-18 production facility was notified of the incident. The Texas Department of State Health Services (DSHS) conducted an inspection at both facilities. Both facilities provided conflicting information concerning the layout of the shielding for the vial. It was determined that the package had been damaged, but it was not determined when or where. DSHS also determined that the vial could not separate from the package shielding if the package was used as designed, unless the package was opened. DSHS could not determine how the vial could have

separated from the shielding due to conflicting information. Corrective actions included procedure modifications and personnel retraining.

Events of Interest

Item Number 100128 - A radiopharmacy received a package containing 29.97 GBq (810 mCi) of F-18 on 3/11/2010 with a surface radiation reading of 100 mR/hour and 300,000 cpm (estimated 1,500,000 dpm) of removable contamination. The removable contamination was identified on the outer handle of the Yellow II, Type A container. The delivery vehicle and driver's (a pharmacy employee) left hand were also contaminated. The pharmacy estimated the driver's highest exposure to be 4.05 cSv (rem) to the left hand. The driver's whole body badge was sent for immediate processing and did not identify any abnormal dose to the whole body. The New Jersey Department of Environmental Protection conducted an investigation of the facility that provided the F-18 on 5/25/2010. It is believed that the cause of the event was a staff member handling the package with contaminated gloves after it had been prepared for shipment. The activity of the contamination on the package was estimated to have been 0.046 MBq (1.25 uCi). Corrective actions included a training session for all employees on 3/18/2010. Training covered the proper procedures for detecting contamination, decontaminating, and avoiding cross contamination.

Item Number 100244 - A healthcare company received a Mo-99/Tc-99m generator with a contact radiation reading of 310 mR/hour. The generator was manufactured on 4/22/2010 and delivered on 4/23/2010. The manufacturer investigated the incident, but did not find any evidence of a problem with the generator in their records. The manufacturer received the generator back from the customer on 5/10/2010 and performed tests and inspections on the unit. They found no evidence of any defect or condition that could have cause the high radiation reading. The radiation levels measured on 5/10/2010 were decayed back to the manufacture date and indicated that the radiation level should have been 140 mR/hour, not 310 mR/hour. The production facility stated that there are only two scenarios to explain the high readings; migration of Tc-99m to an unshielded section of the fluid path while the generator was in transit, or that the reading of 310 mR/hour was in error. The first scenario would involve an as yet unknown failure mode since all required fittings and plugs were in place at the time of inspection of the returned generator. Based on the reported measurements of the returned generator, it appears that the labeled transportation index value was correct. The customer's transportation index measurements agreed with the labeled value.

2.8.3 Events Recently Added to NMED That Occurred Prior to FY10

Five TRS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Neither of these events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events

None.

Events of Interest

Item Number 090696 - A Texas radioactive waste disposal company identified a radiologically contaminated area on 8/28/2009. The contamination was discovered while performing radiological surveys in response to a shipping event. Access to that area of their facility was not normally controlled for radiological reasons, but was isolated after discovering the contamination. The company had previously shipped an empty 30-gallon transport container to a Pennsylvania university on 8/20/2009. Upon receipt (8/25/2009), contamination was noted on the lid with another spot on the pallet and another on the banding holding the drum to the pallet. A survey identified 659,000 dpm alpha/100 cm² (fixed plus removable) on the container. The carrier's truck was not contaminated. Surveys of the Texas facility identified extensive contamination. The radionuclide was identified as Cm-244 with 346.14 GBq (9.355 Ci) contained in the transport container and 0.533 MBq (14.4 uCi) on various surfaces. On

3/18/2010, decontamination of the Texas facility was completed. On 4/7/2010, a Texas Department of State Health Services inspector performed a check survey of the facility. One slightly elevated area of fixed contamination was identified. That area was decontaminated while the inspector was present. This event was classified as an RLM and TRS event.

2.9 Fuel Cycle Process

2.9.1 Ten-Year Data

Figure 9 displays the annual number and trend of FCP events that occurred during the 10-year period. Because all fuel cycle facilities are regulated by the NRC, Figure 9 does not display separate values for Agreement State and NRC-regulated events; only the Total number of events is shown. The trend analysis determined that the data represent a statistically significant decreasing trend in the total number of events (indicated by the trend line).

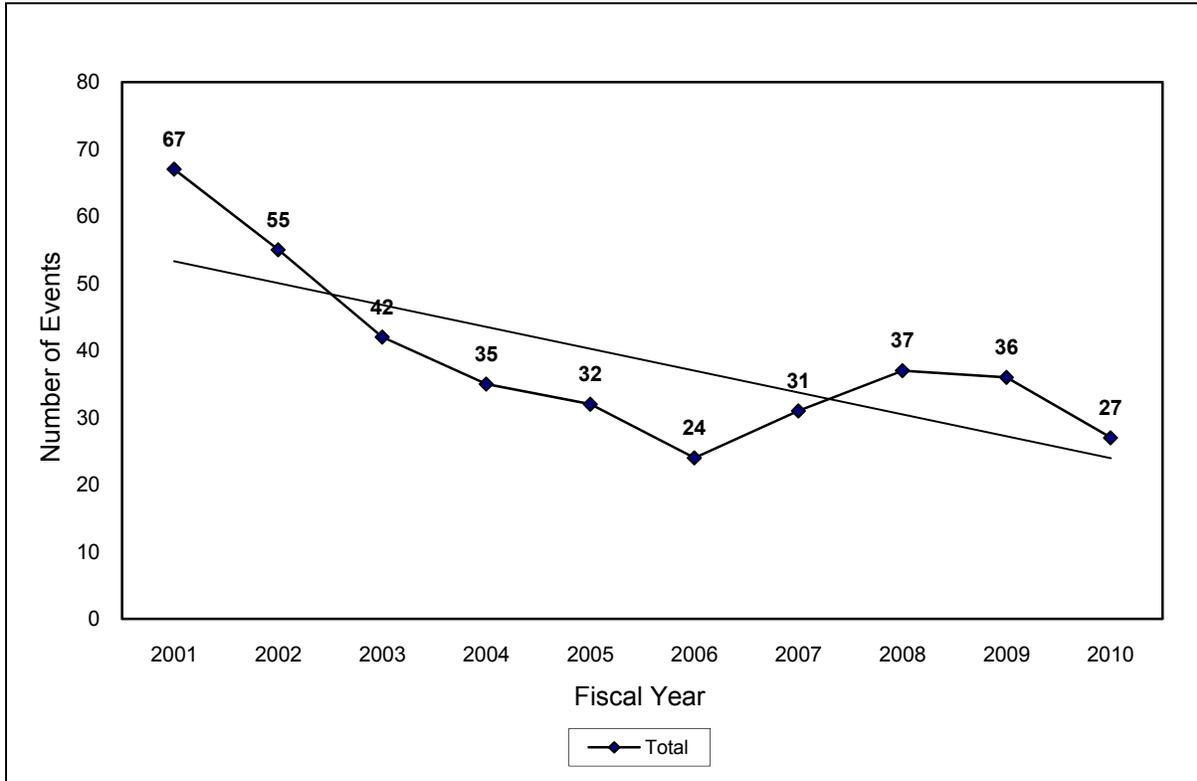


Figure 9. Fuel Cycle Process Events (386 total)

The significance of individual FCP events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, those events requiring immediate reporting are considered significant.

Table 8 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If more than one reporting requirement applied to an event, the event is counted in only the most restrictive category.

Table 8. FCP Events Classified by CFR Reporting Requirement

CFR Reporting Requirement	Fiscal Year										
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	Total
Immediate	38	37	23	24	13	7	6	9	7	4	168
24-Hour	25	13	18	11	19	16	25	26	28	22	203
30-Day	2	1	0	0	0	1	0	2	1	1	8
60-Day	2	4	1	0	0	0	0	0	0	0	7
Total	67	55	42	35	32	24	31	37	36	27	386

2.9.2 FY10 Data

Twenty-seven FCP events occurred in FY10, four of which were classified as significant events.

Significant Events - Immediate Reports

Item Number 090830 - A gaseous diffusion plant reported a violation of criticality safety controls when piping containing an unknown mass of uranium was discovered without water-proof covers on 11/12/2009. The 16-inch abandoned cell piping is from the cell recycle line that was replaced in the mid-1970s. The safety significance of this event is low because the piping was not exposed to a liquid moderator (the cell housing containing the piping does not have fire suppression) and there was no indication that the piping contained greater than a safe mass of uranium. Corrective actions include procedure modification.

Item Number 100039 - Due to a fire in a process glove box on 11/13/2009 (NMED Item 090838), a nuclear fuel manufacturer analyzed stored UF6 cylinders for the presence of fluorine gas. On 1/20/2010, the manufacturer reported that calculations indicated that the theoretical pressure in some of the UF6 cylinders exceeded the service pressure of 200 psi, with some exceeding the hydrostatic test pressure of 400 psi. This situation presented a potential risk associated with the stored cylinders and in future handling and processing of the cylinders. Immediate steps were taken to post an exclusion zone around the cylinder storage areas and provide enhanced fire safety support until a thorough hazards analysis could be completed. The initial hazards analysis concluded that the storage situation was stable and that a catastrophic cylinder failure was not credible. On 3/18/2010, the manufacturer reported that an extensive review determined that the likelihood of a release from the cylinders was low and the consequences to workers, the public, and the environment was also low. Therefore, the additional compensatory actions implemented since 1/20/2010 were discontinued. The probable cause of this event was insufficient information related to potential UF6 cylinder pressurization and the presence of fluorine gas within the cylinders prior to receipt and storage. Corrective actions include establishing protocols to ensure that material characterization is adequate.

Item Number 100119 - A nuclear fuel manufacturer reported the loss of a metallurgy laboratory sample that contained approximately 0.67 grams of uranium, of which 0.65 grams (51.8 kBq or 1.4 uCi) was U-235. The sample was determined missing from its prescribed location on 3/9/2010. A search was immediately initiated, but as of 3/12/2010 it had not been located. There was no indication of intentional theft or diversion. The sample was last accounted for on 10/26/2009. This event was caused by the lack of a formal system for handling samples for purposes other than metallurgical analysis. Corrective actions included procedural and equipment changes. This event was classified as an FCP and LAS event.

Item Number 100360 - A gaseous diffusion plant reported that cracks were discovered in a spray booth containment pan. The spray booth is used to clean and decontaminate equipment and the resulting wash solution, containing up to 5% enriched material, is transferred to safe geometry storage tanks. A large part of the floor is covered with a one-inch deep stainless steel floor pan, which is a safety related item and is credited as part of the double contingency arrangement. The cracks in the pan would allow

solution to leak to the floor, thus defeating the double contingency arrangement and allowing the solution to accumulating in or create an unsafe geometry/volume. The cracks were characterized as through-wall and approximately nine inches long. The pan is flush to the concrete floor and the manufacturer does not believe that any material accumulated under the pan. A preliminary inspection of the pan did not reveal any indication of voiding under the pan. The manufacturer has not determined if the pan will be lifted to inspect underneath. The cause of the cracking is still under investigation.

Events of Interest

Item Number 090788 - A fuel manufacturer reported an incident where the nitrogen oxides (NO_x) generation rate was higher than expected on 10/13/2009. On 10/12/2009, the manufacturer finalized procedure changes to allow chemical processing of small particles of high-enriched uranium scrap material (fines) in the Uranium-Aluminum (U-Al) centrifugal bowl cleaning stations (BCS). On 10/13/2009, they began using BCS to dissolve U-Al fines. The fines were loaded into strainer baskets and placed directly into the bowls to be dissolved with nitric acid. After the dissolution process began, the operator noticed that the temperature of the system was increasing and that NO_x (in the form of a brown cloud) was beginning to form inside BCS storage columns. The heaters were shutdown and the pump was jogged to control pressure. The upper NO_x detector alarmed at approximately 20 minutes into the event, and the building was evacuated. The heated gases deformed a section of the wet off-gas piping system for the BCS and the nitric acid knockout column. Personnel entered the building in self-contained breathing equipment to validate shutdown conditions and remote monitoring was performed of NO_x levels. Based on that data and remote NO_x detector readings, NO_x levels inside the building (outside of containment) were not significant. Laboratory analysis of similar U-Al fines was conducted from 10/14 through 10/16/2009. It behaved in the laboratory in the same manner as that observed during the operational event. Based on the laboratory testing, a NO_x generator rate specific for the material was estimated. Engineering calculations determined that the NO_x generation for the fines was significantly higher than the previously analyzed NO_x generation for the U-Al ingots. The previous NO_x evaluation for the U-Al BCS resulted in an "intermediate occupational consequence". Using the generation rate specific for U-Al fines resulted in a "high occupational consequence". On 10/19/2009, based on the revised NO_x generation rate, it was determined that insufficient items relied on for safety (IROFS) were in place and that the performance criteria of 10 CFR 70.61 were not met. Radiological hazards included high-enriched uranium at approximately 1,000 grams (710 gram of U-235). Chemical hazards included approximately 1.85 pounds of NO_x gas. No actual exposures to workers or the public were recorded. IROFS BPF-43 was in place and functioned correctly during the event. The NRC dispatched an augmented inspection team to the facility to inspect and assess circumstances associated with the event. This team concluded that the event was caused by the lack of management oversight, the lack of a questioning attitude, production pressure, and poor communication. Corrective actions included procedure revision and personnel training.

Item Number 090838 - A nuclear fuel manufacturer reported that a fire occurred in a process glove box on 11/14/2009. Operators were preparing a UF₆ cylinder for sublimation. The cylinder contained 11.4 kg of highly enriched uranium and was put into the process on 11/12/2009. During a valve alignment procedure on 11/13/2009, a glowing ember was observed in an argon supply line connected to the cylinder. The argon supply line was not damaged; however, it was replaced to ensure the integrity of the system. On 11/14/2009, personnel successfully leak tested the cylinder and were venting the cylinder to relieve pressure. As personnel opened the cylinder valve slightly, a heated high-pressure release, resulting in a thermal reaction, occurred inside the process containment. The thermal reaction resulted in an observable flame and the stainless steel braided Teflon-lined hose glowed red. The hose failed in four locations, with the Teflon liner partially consumed. Reaction residues were deposited inside the containment. Other than the hose, there was no significant damage to any process equipment. No loss of containment or process ventilation impairment occurred. The area was secured, a firewatch was posted, and surveys were performed. All sublimation stations were taken out of service pending an investigation. This event was likely caused by a buildup of fluorine gas under pressure inside the aged cylinder. The

hose failure likely resulted from a weakness at several locations where the hose had been kinked. Proposed corrective actions include material changes for the process piping, installation of a trap to safely control any reactions from cylinder contents, procedure/policy modification, and improved configuration management.

Item Number 100046 - A nuclear fuel manufacturer reported a spill of approximately 200 gallons of uranium-bearing ammoniated (5 to 7%) waste water, which overflowed from a quarantine tank into a diked area on 1/24/2010. The waste water contained approximately 20 ppm uranium. Operators received a high level alarm and responded by shutting down the process in accordance with the operational procedures, with the overflow occurring for approximately six minutes. Health Physics staff responded within minutes and determined that ammonia concentrations in the immediate area of the dike were as high as 256 ppm. Readings in adjacent areas were approximately 150 ppm, which is the intermediate consequence level. Non-essential personnel were evacuated and essential personnel were instructed to don respirators with ammonia cartridges. The event was the result of a pump failure in the tank discharge line. Cleanup of the area was completed and, with normal plant ventilation running, the ammonia concentrations returned to less than 25 ppm within approximately two hours. The failed pump was reset and returned to service. No workers required medical attention. The NRC dispatched a Special Inspection Team to review the circumstances associated with the event. The inspection identified issues with manufacturer's identification of and response to this event.

Item Number 100136 - A nuclear fuel manufacturer reported that one of the administrative requirements for double contingency was violated on 3/22/2010. An operator noticed that a waste collection bag had torn away from its receptacle as is designed when the mass of the waste exceeds the specified threshold. The operator lifted the bag and found it to be heavier than normal. While sorting the contents, the operator found two vacuum cleaner bags that contained 8.7 kg of UO₂, which is less than the criticality safety limit. As a result, no unsafe condition existed. The material was transferred into a favorable geometry 3-gallon container. In addition, an operational stand down was performed to inform operators of the issue. An NRC inspection determined that the root cause was correctly determined and adequate corrective actions were taken.

Item Number 100168 - During an NRC inspection beginning on 2/22/2010, it was determined that a nuclear fuel manufacturer experienced the failure of a safe geometry IROFS that resulted in the spill of approximately 7 kg of uranium powder into an unfavorable geometry enclosure on 1/26/2010. During the incident, a safe geometry feed tube that connects the feeder station and the slugger failed to perform its intended safety function when it became misaligned from its source.

Item Number 100303 - A nuclear fuel manufacturer reported an unanalyzed accumulation of fissile solution in a glovebox in a high-level dissolver enclosure. On 6/11/2010, maintenance was being performed on the glovebox enclosure. Part of the maintenance activities included spraying water on the interior surfaces of the enclosure to reduce contamination. A small quantity of water leaked into an adjoining pass-through glovebox, which also had loose contamination on its interior surfaces. As a result, approximately one liter of solution with a concentration of approximately 26 grams of U-235/liter accumulated on the bottom of the pass-through glovebox. The trough dissolver system was shutdown pending an investigation. Testing determined that the water had leaked through degraded glovebox door seals. A total of 111.65 grams (8.93 MBq or 241.3 uCi) of U-235 solids were ultimately removed. Although the mass of uranium within the accumulated solution was much less than the minimum amount required for criticality, the solution was more than a minor safety concern because of the failure to analyze the accident sequence and control the accumulation of fissile material in an unsafe geometry glovebox. This resulted in the failure to establish IROFS to prevent a nuclear criticality accident in the glovebox. Corrective actions included performing a nuclear criticality safety evaluation, repairing the degraded door seals, and procedure revision.

Item Number 100405 - A nuclear fuel manufacturer reported that during normal operation of a slugger press, a tube connecting the feed hood to the press became disconnected. After starting the vibrating feeder, an operator discovered the feed tube was slightly misaligned and some uranium powder had spilled into the hood. The operator immediately used the emergency stop button and the equipment was shutdown. A total of 6.9 kg of uranium powder was removed from the hood. An investigation determined that a clamp on the feed tube came loose, allowing the tube to separate from the fit up device. The two controlled parameters for criticality safety for the equipment are moderation and geometry. When the tube became misaligned, one geometry-related IROFS became unavailable to perform its intended safety function. Additional IROFS on geometry and moderation remained available to perform their intended safety functions and were not challenged. Therefore, no unsafe condition existed. The manufacturer's initial review determined that the event was not reportable. However, during an inspection on 2/22 through 2/26/2010, the NRC evaluated the event and determined that during the period when the tube was misaligned, one IROFS was not available to perform its intended safety function. Corrective actions included modification of the feed tube clamps.

Item Number 100455 - A nuclear fuel manufacturer reported the loss of a criticality safety control during normal operation of a slugger feed hood on 9/10/2010. After starting the vibratory feeder, a small amount of uranium powder leaked from the vibratory feeder into the hood. The base of the hood was equipped with a photo-sensor that detected the powder accumulation and automatically shutdown the vibratory feeder to stop the leak. A total of 2.2 kg of uranium powder was removed from the hood. An investigation determined that a clamp on the flexible feed tube between the powder hopper and the vibratory feeder was improperly reinstalled following an equipment cleanout. With the clamp improperly installed, the geometry-related IROFS was in a degraded state. Additional IROFS for moderation remained available to perform their intended safety functions and were not challenged. Geometry control was maintained by the photo sensor interlock; however, that IROFS was not credited for the accident sequence in the Integrated Safety Analysis. This event was caused by inadequate procedures for reassembling the vibratory feeder and flexible connections following equipment cleanouts. Corrective actions included procedure modification and personnel training.

2.9.3 Events Recently Added to NMED That Occurred Prior to FY10

Note that this section is not applicable for FCP events as this is the first annual report to include this data.

2.10 Other

2.10.1 Ten-Year Data

Figure 10 displays the annual number of OTH events that occurred during the 10-year period. Because OTH events do not fit a defined criterion that ensures consistency within the data, trending analysis is not performed on this data.

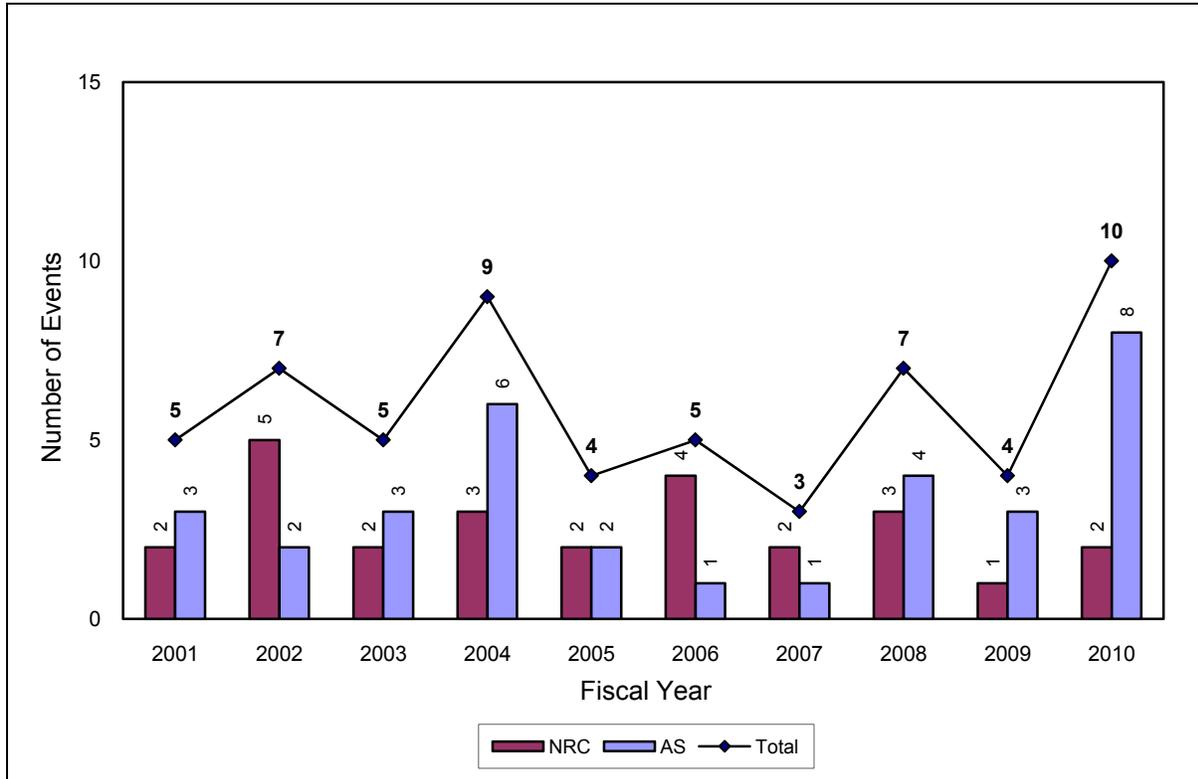


Figure 10. Other Events (59 total)

It is not possible to discern the significance of OTH events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9). Thus, significance of these events is determined using a qualitative review of the potential event consequences.

2.10.2 FY09 Data

Ten OTH events occurred in FY10, two of which were classified as significant events.

Significant Events

Item Number 100245 - A pregnant patient was administered 1.11 GBq (30 mCi) of I-131 on 3/16/2010. A blood serum pregnancy test was performed prior to the administration and results were negative. On 4/26/2010, the patient took a home urine pregnancy test that revealed positive results. Pregnancy was confirmed using a blood serum pregnancy test on 4/27/2010. The patient's physician estimated that conception occurred on 3/13/2010. The fetal dose was estimated to be approximately 8 cSv (rem). The patient was notified. The Colorado Department of Health investigated the incident. A second medical physicist reviewed the incident and estimated the fetal whole body dose to be between 5.3 and 9.2 cSv (rem). The hospital stated that all procedures were followed to prevent this incident. A blood serum test does not detect a pregnancy until 7 to 12 days post conception. The hospital will ask additional questions during the screening process of potentially pregnant patients.

Item Number 100400 - A pregnant patient was administered 5.73 GBq (154.9 mCi) of I-131 for thyroid ablation on 6/7/2010. Prior to the administration, the patient received a blood serum pregnancy test to check for pregnancy and the results were negative. On 7/8/2010, the patient returned for a follow-up visit and informed the doctor that she was pregnant. An ultrasound estimated that the date of conception was 6/1/2010. A dose assessment conservatively estimated the fetal dose to be 41.27 cGy (rad). Due to the age of the fetus, there was no thyroid present and no acute effect to the fetus is expected. The patient was informed of these results on 8/11/2010. Corrective actions included updating the patient consent form to explain that the pregnancy test may not show a positive result until 7 to 10 days after conception, and reinforcing with staff the need to inform patients of the potential for false negative results from the pregnancy test and advise the patient to refrain from actions that may lead to pregnancy. The NRC contracted a medical consultant to review this event.

Events of Interest

Item Number 100055 - Two members of the public were exposed to a 2 TBq (54 Ci) Ir-192 source during radiography operations on 11/15/2009. Radiography operations were being performed at a facility in Ingleside, Texas. The crew setup the radiation boundaries and walked the area with facility personnel to ensure that no individuals were working in the area. An announcement was made over the company intercom system for all workers to stay clear of the radiography area. The radiographers conducted two exposures that were seven minutes long. Three minutes into the third exposure, a radiographer noticed an individual exiting a portable trailer inside the barricades, approximately 15 feet from the source. The radiographer immediately retracted the source into the exposure device. An investigation determined that two individuals had been located inside the trailer during radiography operations. Engine noise prevented the two from hearing the announcement to leave the area. A recreation of the event determined that the individuals received exposures of 150 and 250 uSv (15 and 25 mrem). Both individuals were exposed to greater than 2 mR in any hour. Corrective actions included procedure modifications and obtaining new equipment.

Item Number 100223 - A hospital reported the loss and recovery of a package that contained a 74 GBq (2 Ci; as of 4/30/2010) Mo-99/Tc-99m generator and three Tl-201 sources totaling 2.76 GBq (74.5 mCi; as of 5/5/2010). The package was delivered to the hospital on 5/1/2010. An unauthorized person (conciierge) signed for the package and stored it under the conciierge counter (a controlled, but unrestricted, area). The dose rate at the closest conciierge workstation was 20.6 uSv/hr (2.06 mrem/hr), while the dose rate at the closest surface of the uncontrolled area (in the walkway outside of the conciierge desk) was 185.6 uSv/hr (18.56 mrem/hr). On the evening of 5/1/2010, the health physicist searched for the generator, which was supposed to have been delivered earlier in the day. The package was found on the morning of 5/3/2010, approximately 44 hours after delivery. The package was moved to a proper location and dose calculations were performed for any individuals who may have been in the vicinity of the package while it was improperly stored. No doses exceeding limits were identified. This event was caused by the failure of the conciierge to follow procedures for the receipt of radioactive material. To prevent recurrence, the hospital modified procedures and reiterated their policy outlining who is authorized to sign for packages. This event was classified as an LAS and OTH event.

Item Number 100270 - An oilfield services company reported that a well logging tool was placed in a truck while the 55.5 GBq (1.5 Ci) Cs-137 source was still in the tool on 5/21/2010. The truck was located in the company's shop. The source had been removed from storage to perform calibrations on the logging tool. After calibrations were performed, the logging tool was powered down, disconnected from the wireline, and loaded into the logging truck. When in the tool, the source is highly collimated. The tool and source were left in the truck for approximately 24 hours, potentially exposing two well logging supervisors, a district manager, and one well logging assistant. While performing post-calibration tasks, a worker noticed high gamma ray background readings on a survey meter. He began searching the shop and noted high radiation readings as he approached the logging truck that contained the tool and source. Radiation levels were approximately 5.5 mR/hour adjacent to the truck. The dosimeters for the two

supervisors, the assistant, one spare located in the office, one control, and an employee's dosimeter (which had been left on a desk) were sent to Landauer for analysis. One well logging supervisor and the district manager were not wearing their dosimeters during the incident. The incident was reconstructed and surveys performed to aid in identifying the possibility of excess personnel exposure. Incident investigation uncovered many procedural issues, including failure to document the removal of radioactive material from storage, failure to properly secure storage areas, failure to properly return radioactive material to storage, and failure to establish a radiation area during calibration procedures. Personnel actions were taken for one of the individuals involved for not following procedures. In addition, the supervisor was reprimanded for not wearing a dosimeter while on duty and failure to notify management of an improperly secured storage area. All facility employees were reminded of radiation procedures. Based on event reconstruction and available dosimeter readings, it is believed that none of the four employees received in excess of 0.18 mSv (18 mrem) total effective dose equivalent. This event was classified as an LAS and OTH event.

Item Number 100349 - Based on an onsite inspection by the Virginia Radioactive Materials Program on 7/9/2010 of an engineered materials manufacturer, two thickness gauges were identified with their shutters in the open position. The investigation was conducted as a result of a missing gauge (NMED Item 100348). Radiation surveys of the storage location indicated 0.2 mSv/hour (20 mrem/hour). Further investigation identified that the two gauges had springs that were not properly working. Both shutters were moved to the closed position and taped to ensure they remained closed. A lock was placed on the storage cabinet for security purposes. The manufacturer is working with a licensed broker for proper disposal of the remaining five gauges. This event was classified as an EQP and OTH event.

Item Number 100460 - A petroleum corporation reported that two individuals were exposed to greater than 20 uSv (2 mrem) in any hour while removing and handling a fixed nuclear gauge on 8/4/2010. The gauge contained a 3.7 GBq (100 mCi) Cs-137 source. Maintenance activities consisting of concrete floor repair and replacement were being performed in the area. During the maintenance, the concrete floor, which the gauge mounting bracket was secured to, was removed for repair, thereby removing the gauge from its original mounted location. The gauge was not damaged and the shutter was locked in the closed position. The area was barricaded to prevent unauthorized access, radiation surveys of the area were conducted, a leak test was conducted on the gauge, and the gauge was moved to a secure location. The exposures calculated for the individuals were 0.1 and 0.31 mSv (10 and 31 mrem) deep dose equivalent. Corrective actions included modifying procedures and providing safety training.

Item Number 100524 - A member of the public was exposed to greater than 20 uSv (2 mrem) in any hour on 9/23/2010. The individual entered the restricted area during radiography operations. The radiography exposure device contained a 1.41 TBq (38 Ci) Ir-192 source. The individual was placing film on the tank being radiographed using a man-lift and then retreating behind the 20 uSv (2 mrem) line. The radiographers would then crank the source out to conduct the shot. On one particular shot, the individual misunderstood a communication from the radiographer and ascended to the tank to replace the film while the source was still extended. Dose calculations determined the individual received 0.18 mSv (18 mrem).

Item Number 100061 - A public utility company reported that two employees removed a fixed gauge from a mounted position on 11/12/2009 with the source shutter in the open position. The gauge was mounted on a pipe to measure scrubber slurry flow and contained a 1.85 GBq (50 mCi) Cs-137 source, which was manufactured in April 2002. The detector was not working correctly and needed to be repaired. The shutter was locked after the gauge was taken down. The employees that removed the gauge did not notify anyone of the open shutter until 1/29/2010. The RSO stated that exposure estimates for the employees involved were approximately 9 and 250 uSv (0.9 and 25 mrem). The two employees did not exceed the exposure limits for members of the public. The cause of the incident was considered to be human error. Corrective actions included a clarification of procedures for working on fixed gauges, incorporating fixed gauges into the lock out/tag out program, and providing additional training to all facility staff and personnel who work on gauges. This event was classified as an EQP and OTH event.

2.10.3 Events Recently Added to NMED That Occurred Prior to FY10

Two OTH events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. One of the MED events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - AOs or Potential AOs

Item Number 100319 - A pregnant patient was administered 3.81 GBq (102.9 mCi) of I-131 as a treatment for reoccurring cancer associated with a previous thyroidectomy conducted in 2006. The treatment was administered on 5/1/2007 and the patient was 25 to 27 weeks pregnant. The patient had received I-131 following the thyroidectomy in 2006 and was treated a second time with I-131 on 5/1/2007. The doctor stated that when he asked the patient if she was pregnant, she replied that she was not. No independent test was conducted. The doctor was contacted on 6/11/2007 by the physician's obstetrician, who advised that she was 32 weeks pregnant. Calculations were performed by the Illinois Emergency Management Agency resulted in an estimated dose to the fetus of 86 cGy (rad). The child was delivered after a full term pregnancy and is receiving thyroid hormone therapy.

Appendix A

Event Type Descriptions and Criteria

Appendix A Event Type Descriptions and Criteria

The NMED events covered by this report are divided into the following categories based on the event reporting requirements defined in 10 CFR. Note that the tables in this appendix do not contain the full text of the applicable CFRs.

Lost/Abandoned/Stolen Material (LAS)

The LAS event category includes those events where licensed radioactive material is lost or found, abandoned or discovered, and stolen or recovered. The radioactive material involved can be sealed or unsealed material, specifically or generally licensed, exempt or non-exempt quantities, involve a licensee or a non-licensee, and can be found anywhere.

NMED LAS reportable events are those that meet the reporting requirements of 10 CFR Part 20.2201. Events that do not meet the 20.2201 reporting requirement thresholds are captured as not-reportable LAS events. Additionally, LAS events involving non-AEA material are entered into NMED as not-reportable events.

All reportable LAS events will be coded as one of the following reporting requirements. For events involving more than one source, the decision of $10 \times$ or $1,000 \times$ the 10 CFR Part 20 Appendix C quantity is based on the aggregate quantity of licensed material.

Table A-1. Primary LAS Reporting Requirements

Primary LAS Reporting Requirements	Reporting Requirement Summary
20.2201(a)(1)(i)	Aggregate activity $\geq 1,000 \times$ 10 CFR Part 20 Appendix C quantity.
20.2201(a)(1)(ii)	Aggregate activity > 10 and $< 1,000 \times$ 10 CFR Part 20 Appendix C quantity.

The following additional (secondary) CFRs will be added as applicable.

Table A-2. Secondary LAS Reporting Requirements

Secondary LAS Reporting Requirements	Reporting Requirement Summary
30.55(c)	Theft/diversion of 10 Ci (or 100 Ci per year) of H-3 (not generally licensed).
39.77(b)	Loss/theft of well logging sources.
40.64(c)(1)	Theft/diversion of 15 lbs (or 150 lbs per year) of source material (uranium or thorium).
73.71(a)(1)	Lost shipment of any SNM.
73.App G(l)(a)(1)	Actual or attempted theft or unlawful diversion of SNM.
74.11(a)	Loss, theft or unlawful diversion (actual or attempted) of SNM or the unauthorized production of enriched uranium.
76.120(a)(2)	Loss, other than normal operating loss, of special nuclear material.
76.120(a)(3)	Actual or attempted theft or unlawful diversion of special nuclear material.
150.16(b)(1)	Actual or attempted theft or unlawful diversion of SNM.
150.17(c)(1)	Attempted theft or unlawful diversion of more than 6.8 kg (15 lb) of Uranium or Thorium at any one time or more than 68 kg (150 lb) in any one calendar year.
150.19	Theft/diversion of 10 Ci (or 100 Ci per year) of H-3 (not generally licensed). Note: This requirement is just like 30.55(c), but applies to Agreement States and offshore waters.

Medical (MED)

MED events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-3. MED Reporting Requirements

MED Reporting Requirements	Reporting Requirement Summary
35.3045(a)(1)(i)	Total dose delivered that differs from the prescribed dose by 20% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(1)(ii)	Total dosage delivered differs from prescribed by 20% or more or falls outside the prescribed range; and results in a dose that differs from prescribed by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(1)(iii)	Fractionated dose delivered that differs from the prescribed dose for a single fraction by 50% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(2)(i)	Administration of a wrong radioactive drug containing byproduct material that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE.
35.3045(a)(2)(ii)	Administration of a radioactive drug containing byproduct material by the wrong route of administration that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(2)(iii)	Administration of a dose or dosage to the wrong individual or human research subject that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(2)(iv)	Administration of a dose or dosage delivered by the wrong mode of treatment that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(2)(v)	Leaking sealed source that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(3)	Dose to the skin, organ, or tissue, other than the treatment site, that exceeds the prescribed dose by 0.5 Sv (50 rem) and 50% or more (excluding permanently implanted seeds that migrated from the treatment site).
35.3045(b)	Event resulting from patient intervention in which the administration of byproduct material or radiation from byproduct material results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Events are not considered MED events if they involve:

- Only a linear accelerator,
- Doses administered in accordance with a written directive (even if the directive is in error), or
- Patient intervention.

Events are considered MED events if, for example, a linear accelerator is used for therapy by mistake instead of a teletherapy unit or a teletherapy unit instead of a linear accelerator.

For purposes of determining whether to categorize an event as MED or EXP, MED events occur to patients only (i.e., those being administered a medical procedure). For example, if a patient receives too much dose during a procedure, the event would be categorized as MED rather than EXP. However, radiation exposure received from a cause other than the patient's medical procedure may be categorized as EXP.

Radiation Overexposure (EXP)

EXP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-4. EXP Reporting Requirements

EXP Reporting Requirements	Reporting Requirement Summary
20.2202(a)(1)(i)	An individual received a total effective dose equivalent of 25 rem (0.25 Sv) or more.
20.2202(a)(1)(ii)	An individual received a lens dose equivalent of 75 rem (0.75 Sv) or more.
20.2202(a)(1)(iii)	An individual received a shallow-dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more.
20.2202(b)(1)(i)	Loss of control of material causing or threatening to cause an individual to receive a total effective dose equivalent exceeding 5 rem (0.05 Sv) in a period of 24 hours.
20.2202(b)(1)(ii)	Loss of control of material causing or threatening to cause an individual to receive an eye dose equivalent exceeding 15 rem (0.15 Sv) in a period of 24 hours.
20.2202(b)(1)(iii)	Loss of control of material causing or threatening to cause an individual to receive a shallow-dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv) in a period of 24 hours.
20.2203(a)(2)(i)	Doses in excess of the occupational dose limits for adults in 20.1201.
20.2203(a)(2)(ii)	Doses in excess of the occupational dose limits for a minor in 20.1207.
20.2203(a)(2)(iii)	Doses in excess of the limits for an embryo/fetus of a declared pregnant woman in 20.1208.
20.2203(a)(2)(iv)	Doses in excess of the limits for an individual member of the public in 20.1301.
20.2203(a)(2)(v)	Doses in excess of any applicable limit in the license.
20.2203(a)(2)(vi)	Doses in excess of the ALARA constraints for air emissions established under 20.1101(d).

The EXP event category includes all regulatory overexposures of radiation workers or exposures of members of the public to radiation. The overexposure can be external or internal and can be whole body, extremity, skin, lens of the eye, or internal dose. When the overexposure involves multiple individuals or an individual with multiple overexposure types (such as whole body and extremity), the different types of overexposures are entered separately. Note that dosimeters record exposure if improperly stored near a radiation source and, depending on the type of dosimeter, may react as though they are in a radiation field when exposed to heat or humidity. It is NRC policy to classify only those events that positively involve a personnel overexposure, and not just a dosimeter exposure, as reportable EXP events. For example, either the licensee does not contest the personnel overexposure, or in cases where the licensee does contest the overexposure, the State or NRC determines the event to be personnel overexposure.

EXP limits do not apply to patients receiving medical procedures.

Release of Licensed Material or Contamination (RLM)

RLM events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-5. RLM Reporting Requirements

RLM Reporting Requirements	Reporting Requirement Summary
20.2202(a)(2)	Release of radioactive material, inside or outside of a restricted area, so that had an individual been present for 24 hours, the individual could have received an intake 5 times the ALI.
20.2202(b)(2)	Release of material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of 1 ALI.
20.2203(a)(3)(i)	Radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the license.
20.2203(a)(3)(ii)	Radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times any applicable limit set forth in Part 20 or in the license – NMED metric.
20.2203(a)(4)	Levels of radiation or releases of radioactive material in excess of the standards in 40 CFR Part 190, or of license conditions related to those standards.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(1) 40.60(b)(1) 70.50(b)(1) 76.120(c)(1)	Unplanned contamination event.
30.50(b)(3) 40.60(b)(3) 70.50(b)(3) 76.120(c)(3)	Event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
50.72(b)(3)(xii) 72.75(c)(3)	Event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

The RLM event category includes two types of events. The first type is a radioactive release to air or water exceeding the 10 CFR Part 20 Appendix B annual limit on intake (ALI). The second type of RLM event involves contamination events such as a radioactive spill outside of work areas, removable contamination found on equipment, or material tracked around a laboratory such that additional radiological control measures had to be implemented. This category does not include spills inside of laboratory hoods, radiopharmaceutical dose preparation areas, or hot cells where radioactive work routinely requires cleanup or changing of absorbent paper after the performance of a task. Should there be multiple release types (e.g., surface, air, water, or person) or areas of contamination associated with the release, this information is entered individually.

Leaking Sealed Source (LKS)

LKS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-6. LKS Reporting Requirements

LKS Reporting Requirements	Type of Source
31.5(c)(5)	Generally licensed
34.27(d)	Radiography
35.67(e)	Medical
39.35(d)(1)	Well logging (leaking)
39.77(a)	Well logging (ruptured)
30.50(b)(2)	All other sources

The NRC requires that most sealed sources be periodically leak tested to verify that the material is still sealed and that the source is still considered safe to use without contamination controls, including protective clothing or gloves. Sources are generally exempt from leak testing under the following conditions [see 10 CFR Part 31.5(c)(2), 34.27(c), 35.67(f), and 39.35(e)]:

- Sources containing only gaseous radioactive material (like H-3, Kr-85, etc.),
- Sources containing licensed material with a half-life of 30 days or less,
- Sources containing $\leq 100 \mu\text{Ci}$ of other beta and/or gamma emitting material,
- Sources containing $\leq 10 \mu\text{Ci}$ of alpha emitting material,
- Sources held in storage in the original shipping container prior to initial installation,
- Seeds of Ir-192 encased in nylon ribbon, or
- Sources in storage and not in use (must be leak tested prior to use or transfer).

A source is considered leaking if a leak test can detect greater than $0.005 \mu\text{Ci}$ of removable radioactive material. The leaking source is then removed from service, disposed of or returned to the manufacturer for repair, and a report is sent to the NRC or Agreement State with the details of the leaking source.

For regulatory reporting purposes, a leaking source is generally considered a failed device under 10 CFR Part 30. Therefore, in most cases an LKS event is also coded as an EQP event. An exception is the Ni-63 foil source, which is coded as only an LKS event.

Equipment (EQP)

EQP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-7. EQP Reporting Requirements

EQP Reporting Requirements	Reporting Requirement Summary
21.21(d)(1)(i)	A failure to comply or a defect affecting the construction or operation of a facility or an activity that is subject to licensing requirements.
21.21(d)(1)(ii)	A failure to comply or a defect affecting a basic component that is supplied for a facility or an activity that is subject to licensing requirements.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(2) 40.60(b)(2) 70.50(b)(2) 72.75(d)(1) 76.120(c)(2)	Equipment is disabled or fails to function as designed.
30.50(b)(4) 40.60(b)(4) 70.50(b)(4) 76.120(c)(4)	Unplanned fire or explosion that damages any licensed material or any device, container, or equipment containing licensed material.
31.5(c)(5)	Actual or indicated failure to shielding, the on-off mechanism or indicator, or upon the detection 0.005 uCi or more of removable radioactive material.
34.101(a)(1)	Unintentional disconnection of the radiographic source assembly from the control cable.
34.101(a)(2)	Inability to retract and secure the radiographic source assembly to its fully shielded position.
34.101(a)(3)	Failure of any radiographic component (critical to the safe operation of the device) to properly perform its intended function.
36.83(a)(1)	An irradiator source stuck in an unshielded position.
36.83(a)(2)	Fire or explosion in an irradiator radiation room.
36.83(a)(3)	Damage to the irradiator source racks.
36.83(a)(4)	Failure of the irradiator cable or drive mechanism used to move the source racks.
36.83(a)(5)	Inoperability of the irradiator access control system.
36.83(a)(6)	Detection of irradiator source by the product exit monitor.
36.83(a)(7)	Detection of irradiator radioactive contamination attributable to licensed radioactive material.
36.83(a)(8)	Structural damage to the irradiator pool liner or walls.
36.83(a)(9)	Abnormal water loss or leakage from the irradiator source storage pool.
36.83(a)(10)	Irradiator pool water conductivity exceeding 100 microsiemens per centimeter.
39.77(a)	Ruptured well logging sealed source.
72.75(c)(1)	Defect in any spent fuel, HLW, or reactor-related GTCC waste storage structure, system, or component that is important to safety.
72.75(c)(2)	Significant reduction in the effectiveness of any spent fuel, HLW, or reactor-related GTCC waste storage confinement system during use.
72.242(d)	Design or fabrication deficiency for any spent fuel storage cask delivered to a licensee which affects the ability of components important to safety to perform their safety function.

The EQP event category includes all types of radiological equipment problems, including generally licensed device problems covered in 10 CFR Part 31; radiography equipment problems covered in 10 CFR Part 34; irradiator problems covered in 10 CFR Part 36; well logging problems covered in 10 CFR Part 39, and other types of equipment covered in 10 CFR Part 30, 40, 70, and 76. EQP events are defined as the failure of, or a defect in, any piece of equipment that either contains licensed radioactive materials as an integral part, or whose function is to interact with such materials.

Transportation (TRS)

TRS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-8. TRS Reporting Requirements

TRS Reporting Requirements	Reporting Requirement Summary
20.1906(d)(1)	Transported package exceeds removable surface contamination limits.
20.1906(d)(1)	Transported package exceeds external radiation limits.
71.5	Transportation of licensed material.
71.95(a)(1)	Significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use.
71.95(a)(2)	Defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.
71.95(a)(3)	Conditions of approval in the Certificate of Compliance were not observed in making a shipment.
71.95(b)	Conditions in the Certificate of Compliance were not followed during a shipment.

Fuel Cycle Process

The FCP event type is used two ways. One usage is identical to the other event types in that it is used to code events involving FCP reporting requirements. However, it is also used to denote any type of event occurring at (or involving) a fuel cycle process facility. Therefore, reporting requirements other than those listed below can be used with the FCP event type. In this case, the event will be coded with multiple event types.

For those events involving only the FCP event type, the events are determined and coded per the 10 CFR reporting requirements, NRC Bulletin, and S.E.A. requirement listed below.

Table A-9. FCP Reporting Requirements

TRIS Reporting Requirements	Reporting Requirement Summary
70.52(a)	Inadvertent nuclear criticality.
70.App A(a)(1)	Inadvertent nuclear criticality.
70.App A(a)(2)	Acute intake by an individual of 30 mg or greater of uranium in a soluble form.
70.App A(a)(3)	Acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in 70.61(b)(4).
70.App A(a)(4)(i)	Event or condition such that no IROFSs remain available and reliable to perform the safety function IAW 70.61(b) and 70.61(c).
70.App A(a)(4)(ii)	Event or condition such that no IROFSs remain available and reliable to prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).
70.App A(a)(5)	Loss of controls such that only one IROFS has been available and reliable (for longer than the past eight hours) to prevent a nuclear criticality accident.
70.App A(b)(1)	Event or condition that results in the facility being in a state not analyzed, improperly analyzed, or different from that analyzed, and results in failure to meet the performance requirements of 70.61.
70.App A(b)(2)	Loss or degradation of IROFSs that results in failure to meet the performance requirement of 70.61.
70.App A(b)(3)	Acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of 70.61(c)(4).
70.App A(b)(4)	Natural phenomenon or external event, including fires internal and external to the facility, that affected or may have affected the safety function, availability, or reliability of one or more IROFSs.
70.App A(b)(5)(i)	Occurrence of an event or process deviation that was considered in the ISA and was dismissed due to its likelihood.
70.App A(b)(5)(ii)	Occurrence of an event or process deviation that was considered in the ISA, categorized as unlikely, and whose associated unmitigated consequences would have exceeded those in 70.61(b) had the IROFSs not performed their safety function(s).
72.74(a)	Accidental criticality or any loss of special nuclear material.
76.120(a)(1)	Criticality event.
76.120(a)(4)	Emergency condition that has been declared an alert or site area emergency.
NRCB 91-01	<p>Loss of criticality safety controls, including:</p> <ol style="list-style-type: none"> 1. The complete loss of a controlled parameter. This criteria includes the loss or inoperability of the criticality alarm system. 2. The substantial degradation of a controlled parameter. This criteria can be used for a malfunction of the criticality alarm system, similar to criteria 1, listed above. 3. Failure of a controlled parameter previously identified by the Commission or the licensee's criticality safety specialists as requiring reporting upon failure. 4. Determining that a criticality safety analysis was deficient in evaluating actual plant conditions and necessary controlled parameters were not established. 5. An unusual event or condition for which the severity and remedy are not readily determined. (Note: This criteria would include any major hazardous chemical releases that occur at the facility.)
S.E.A	Safety equipment actuation.

Other (OTH)

The OTH event category includes the following types of events:

1. Doses to an embryo/fetus or nursing child reportable per 10 CFR Part 35.3047. Note that these events are not MED events (reportable per 10 CFR Part 35.3045).
2. Exposure rates in an unrestricted area in excess of 2 mR/hr, but no individual received a dose in excess of limits (if a dose in excess of limits is received, the event is an EXP event).
3. Reportable events that do not specifically fit into one of the previous event types.
4. Events not reportable to the NRC but included in the NMED program for informational purposes.

For items 1 and 2 above, OTH events are determined and coded per the 10 CFR reporting requirements listed below. Due to the nature of items 3 and 4 above, other reporting requirements may also be used.

Table A-10. OTH Reporting Requirements

OTH Reporting Requirements	Reporting Requirement Summary
35.3047(a)	Dose to an embryo/fetus greater than 50 mSv (5 rem) DE from administration of byproduct material or radiation from byproduct material to a pregnant individual unless specifically approved, in advance, by the authorized user.
35.3047(b)(1)	Dose to a nursing child greater than 50 mSv (5 rem) TEDE resulting from an administration of byproduct material to a breast-feeding individual.
35.3047(b)(2)	Dose to a nursing child resulting in unintended permanent functional damage to an organ or physiological system, as determined by a physician, resulting from an administration of byproduct material to a breast-feeding individual.
20.2203(a)(2)(iv)	Exposure rates in an unrestricted area in excess of 2 mR/hr, but no dose received in excess of limits.

Appendix B
Statistical Trending Methodology

Appendix B Statistical Trending Methodology

General

The following is a general discussion of statistical trending techniques.

A common approach to the statistical analysis of trend is based on regression methods. In particular, it is often the case that a relationship exists between the values assumed by a pair of variables. For example, if x is time (in years), and y is the rate of events per year, then we could use regression methods to study whether there is a relationship between time and event rate.

Regardless of the application, it is standard practice to refer to x as the independent variable and y as the dependent variable. Another common term for the dependent variable is “response variable,” and the terms covariant and explanatory variable are sometimes used for the independent variable. Also, it is typical with regression modeling that the independent variable can be measured with little or no error, but the dependent variable involves a random error. Consequently, even if there is a deterministic functional relationship between the two variables, when data pairs $(x_1, y_1), (x_2, y_2), \dots, (x_n, y_n)$ are plotted, the points will not coincide exactly with the function, but instead will tend to be scattered. Such a plot is called a scatter diagram, and shows the variation in the data. The plots in this report are bar charts containing the same information.

Fitting a Straight Line to Data

Consider a linear function

$$f(x) = \alpha + \beta x \tag{B-1}$$

where α and β are unknown parameters. A common model is that y is the sum of a linear function of the form (1) and a random error term, e . Standard results on estimation and inference about the parameters of the model assume that e is a normally distributed random variable with mean 0 and constant (but unknown) variance, σ^2 . These assumptions mean that:

- Each y_i is an observed value of a random quantity that is normally distributed [with mean $f(x_i)$], and
- All the observations y_i are of variables with a common variance, σ^2 .

The y_i are also assumed to be observations of random quantities that are independent of each other.

Under these conditions, the usual approach to estimating the unknown parameters α and β is the method of least squares (LS). In this method, α and β are selected so that the sum of the squares of the vertical distances between the data points and the fitted line is as small as possible. The LS method leads to the estimates

$$\hat{\beta} = \frac{\sum_{i=1}^n (x_i - \bar{x})y_i}{\sum_{i=1}^n (x_i - \bar{x})^2} \text{ and} \tag{B-2}$$

$$\hat{\alpha} = \bar{y} - \hat{\beta}\bar{x}, \tag{B-3}$$

where \bar{x} and \bar{y} are arithmetic averages. The estimated LS regression line is then

$$\hat{y} = \hat{\alpha} - \hat{\beta}x, \tag{B-4}$$

and an estimate of σ is

$$s = \sqrt{\frac{\sum_{i=1}^n (y_i - \hat{y}_i)^2}{n-2}}. \quad (\text{B-5})$$

Testing for Trend

A trend exists whenever the true slope, β , is not zero. We start the analysis with the idea that β is zero, and then ask whether the data tell us otherwise. Two quantities computed from the data are used in this assessment. The first, the *error sum of squares* (SSE), appears in the numerator of s . It is defined as

$$SSE = \sum_{i=1}^n (y_i - \hat{y}_i)^2. \quad (\text{B-6})$$

This quantity is the number that is minimized in order to find the estimates of a and β . The differences being squared in SSE represent random variations that remain after the linear fitting process. The second quantity is the *regression sum of squares* (SSR), defined by the following equation

$$SSR = \sum_{i=1}^n (\hat{y}_i - \bar{y})^2. \quad (\text{B-7})$$

Note that SSR looks at deviations between the fitted line and the default notion that the data are constant and have no slope.

One can show by algebra that

$$SSE + SSR = SST, \quad (\text{B-8})$$

where the *total sum of the squares* (SST), is defined as

$$SST = \sum_{i=1}^n (y_i - \bar{y})^2. \quad (\text{B-9})$$

SST measures the overall variation in the data. It is the numerator that would be used to estimate the variance in a sample from a normally-distributed random variable, where all the data in the sample have the same distribution (and thus no trend). This variance measures “random variation” in such a sample.

In the framework of the linear function (1), the regression’s effectiveness is measured by the SSR term defined above. When it is small, the fitted curve will not differ very much from the horizontal line $y = \bar{y}$. SSE will be approximately equal to SST , and, from the data, both SSE and SST will be estimates of mere random variation. In this case, the data do not provide evidence that β is different from zero.

On the other hand, if the y values tend to vary linearly with respect to the independent variable, x , then some of the variation in the y values can be attributed to this dependence on x . Since SSR assesses the difference between the least squares predictions of the y values and the arithmetic mean, \bar{y} , it is a measure of the variation which is “explained” by the linear relationship. When the slope of the fitted line is large, more of these differences will tend to be large, resulting in a large value of SSR .

In the equation, $SST = SSE + SSR$, the total variation is partitioned into two parts, the variation due to random error and the variation due to the linear relationship. The fraction of the total variation that is due to the linear relationship is called the coefficient of determination, or r^2 , and is defined by:

$$r^2 = \frac{SSR}{SST}. \quad (\text{B-10})$$

r^2 is a fraction that varies from 0 to 1. It will be near 0 if most of the variation is due to randomness, and it will be near 1 if most of the variation is due to the linear relationship.

The closeness to 1 needed for the data to show that the slope is not zero depends on the number of data points. If the dependent data are independent, normally-distributed at each x , with constant variance, and no trend, then the quantity, F , defined by

$$F = \frac{(n-2)r^2}{1-r^2} \quad (\text{B-11})$$

can be shown to have an F distribution with degrees of freedom 1 and $n - 2$, where n is the number of data points. When the data satisfy the assumptions except that there is a significant trend, r^2 will be closer to 1 and the computed F statistic will be much larger. Specifically, if the computed F exceeds the upper fifth percentile of the F distribution with 1 and $n - 2$ degrees of freedom, we infer that the data contain evidence that β is not zero, at the 5% level of significance. In this case, we reject the null hypothesis that $\beta = 0$ and conclude that a statistically significant trend exists, with 95% confidence.

As an example, for an assumed set of data fit to the linear model, assume the $r^2 = 0.9369$ and that n is 13. Then the calculated F is 163.3. The upper 95th percentile of the $F(1, 11)$ distribution is 4.84. Since 163.3 far exceeds the upper 95th F percentile, the linear model is statistically significant. In this example, the data show that it would be very unlikely for a trend not to exist. The linear model explains too much of the variation in the data for a trend not to exist.

Applying the Model to the NMED Data

The method described above was applied for each category of NMED event data, for the overall NMED data, and for additional subgroups of data when trends were found in the overall data. When the calculated F exceeded the 95th percentile, the trend line was shown on the graph and identified as being statistically significant.

In future reports, trending the data is expected to continue. We may employ slightly different methods than the one explained above because the NMED data in many cases do not follow the assumptions listed above for the data. In particular, three considerations apply.

- The data are counts, and thus are discrete rather than being normally distributed. This problem is most pronounced when the counts are relatively low or sparse. Also, normally-distributed data in general can be negative, but the counts are always greater than or equal to zero.
- Variations in counts tend to increase as the counts increase. If the events occur at random, with a constant occurrence rate in a particular year or quarter, then the variance of the count for that year or quarter is equal to the mean or average for that year or quarter. Thus, the assumption of a constant variance for the data in each year may not apply.
- Finally, more than one count can be associated with a single reported incident in a single event category. This situation would occur, for example, if several pieces of equipment fail in an event or if several types of overexposure occur. In these cases, the data are not independent.

One way to address the first two concerns is to identify the number of licensees in various NMED categories and study the event occurrence rates rather than the counts. The rates are more likely to come from a continuum, and might have a more constant variance.

Taking logarithms of the counts and then applying the LS method avoids the problem of possible negative trend lines. The resulting models can be converted back to the scale of the counts after the regression line is identified. In the scale of the counts, the resulting trend, if any, has a slight curvature.

Weighted regression is a method similar to the LS method described above, but it compensates explicitly for the effect of the different variances from year to year.

Another approach that deals with the first two concerns is to apply regression methods that have been designed specifically for counts. Poisson regression, for example, is based on the idea that the data in each time period are counts observed from a Poisson distribution, with an occurrence rate that is described by the model. Given occurrence rates in each time period, and independent counts, the probability of seeing the observed data is easily computed by multiplying the occurrence probabilities for the individual time periods. The slope and intercept parameter estimates are selected so that the model maximizes the resulting “likelihood function.”

The third issue may have little effect on the results of a trend analysis, as long as there are many counts with relatively few occurring in clumps, no trends in the occurrence of clumps, and no large clumps of counts coming from a single occurrence report. The best way to address the dependence issue is to identify and remove the duplicate counts prior to the trend analysis.

Appendix C

IAEA Radionuclide Categorization

Appendix C

IAEA Radionuclide Categorization

Table C-1 lists the radionuclides that this report uses to determine the significance for events involving the loss, abandonment, or theft of radioactive sources. This list is derived from the *IAEA Code of Conduct on the Safety and Security of Radioactive Sources (2004)* and from *IAEA Safety Guide RS-G-1.9, Categorization of Radioactive Sources*. Based on the amount of radioactivity involved, the radionuclides are grouped into five categories, with Category 1 being the most hazardous. These categories may be summarized as follows (derived from *IAEA Safety Guide RS-G-1.9, Categorization of Radioactive Sources*):

- Category 1: Extremely dangerous.** These sources could cause permanent injury within a few minutes if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from a few minutes to an hour.

- Category 2: Very dangerous.** These sources could cause permanent injury within minutes to hours if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from hours to days.

- Category 3: Dangerous.** These sources could cause permanent injury within hours if handled. Doses could possibly (but unlikely) be fatal to someone in close proximity to an unshielded source for periods ranging from days to weeks.

- Category 4: Unlikely to be dangerous.** These sources would not cause permanent injury, although delayed health effects are possible. Doses could possibly (but unlikely) cause temporary injury to someone in close proximity to an unshielded source for a period of many weeks.

- Category 5: Most unlikely to be dangerous.** These sources would not cause permanent injury.

Table C-1. IAEA Code of Conduct Category 1 through 5 Radionuclide Activity Thresholds

Radionuclide	Category 1		Category 2		Category 3		Category 4		Category 5	
	TBq	Ci ¹								
Am-241	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Am-241/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Cf-252	20	541	0.2	5.4	0.02	0.54	0.0002	0.0054	1.0e-08	2.7e-07
Cm-244	50	1,352	0.5	13.5	0.05	1.35	0.0005	0.0135	1.0e-08	2.7e-07
Co-60	30	811	0.3	8.1	0.03	0.81	0.0003	0.0081	1.0e-07	2.7e-06
Cs-137	100	2,703	1.0	27.0	0.10	2.70	0.001	0.0270	1.0e-08	2.7e-07
Gd-153	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-05	2.7e-04
Ir-192	80	2,162	0.8	21.6	0.08	2.16	0.0008	0.0216	1.0e-08	2.7e-07
Pm-147	40,000	1,081,200	400.0	10,812.0	40.00	1,081.20	0.4	10.8120	1.0e-05	2.7e-04
Pu-238	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Pu-239/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Ra-226	40	1,081	0.4	10.8	0.04	1.08	0.0004	0.0108	1.0e-08	2.7e-07
Se-75	200	5,406	2.0	54.1	0.20	5.41	0.002	0.0541	1.0e-06	2.7e-05
Sr-90 (Y-90)	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-08	2.7e-07
Tm-170	20,000	540,600	200.0	5,406.0	20.00	540.60	0.2	5.4060	1.0e-06	2.7e-05
Yb-169	300	8,109	3.0	81.1	0.30	8.11	0.003	0.0811	1.0e-05	2.7e-04

Notes:

1. The primary values are given in TeraBequerel (Tbq). Curie (Ci) values are provided for practical usefulness only and are rounded after conversion.

Appendix D
Revision of Data

Appendix D Revision of Data

The NMED is a dynamic database with new reports and revisions to previous reports being added on a continuing basis. Numerical changes in NMED numbers can result from several different types of technical changes to coded data. The most common types of changes to database records are:

- Record additions due to late reporting.
- Record additions or subtractions due to changes in event class(es).
- Changes between fiscal quarters due to event date changes on individual events.
- Record additions or subtractions due to changing events from non-reportable to reportable (and vice versa).
- Record additions or subtractions due to reclassifying a single combined event as multiple individual events (or vice versa).
- Record deletions due to duplicated records or NRC direction.

Figures D-1 through D-9 below display the changes in the data published in the previous annual report. A positive value indicates that records were added and a negative value indicates that records were removed.

Note that the FY10 annual report is the first to include FCP data. Consequently, Figure 1 does not include the addition of FY01-09 FCP data as a change from the previous report's data. The FY11 annual report will include the FCP data in Figure 1 and a new figure will be included to display changes specific to FCP data.

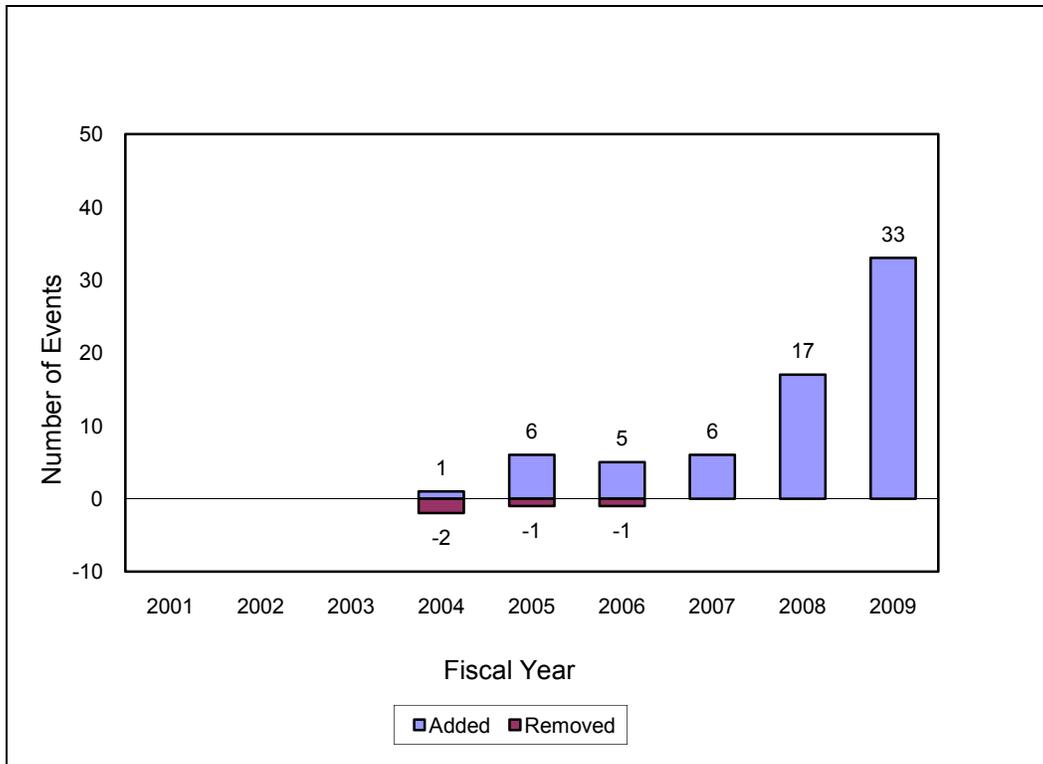


Figure D-1. Changes to All NMED Event Data

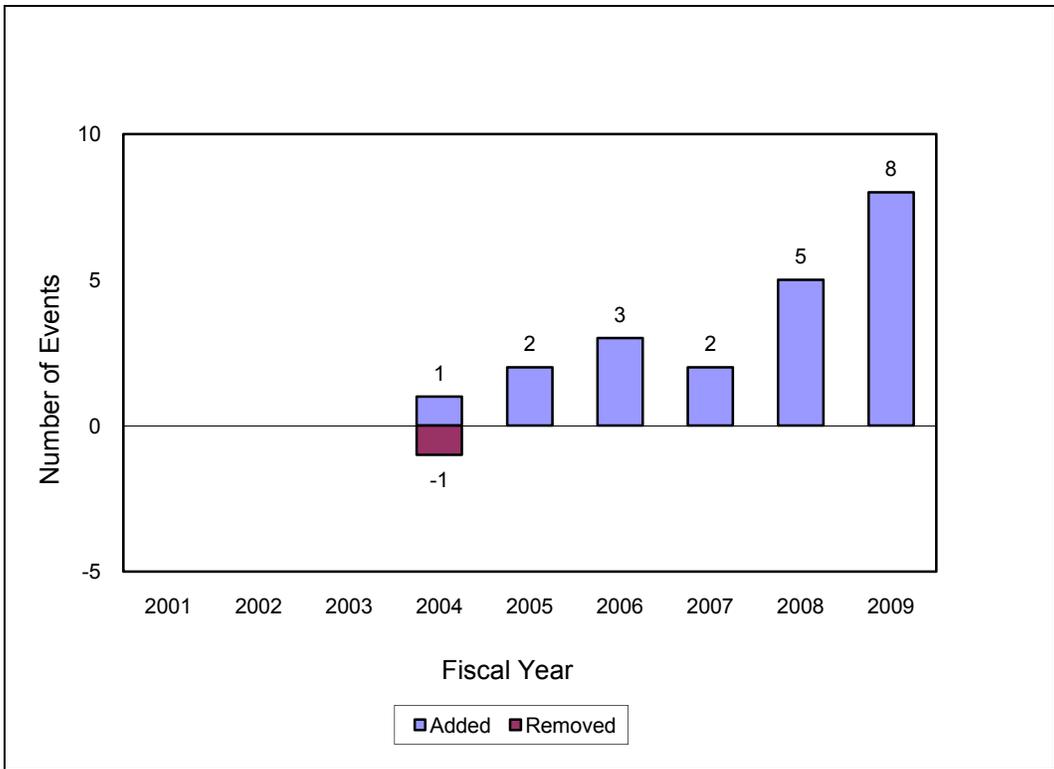


Figure D-2. Changes to LAS Data

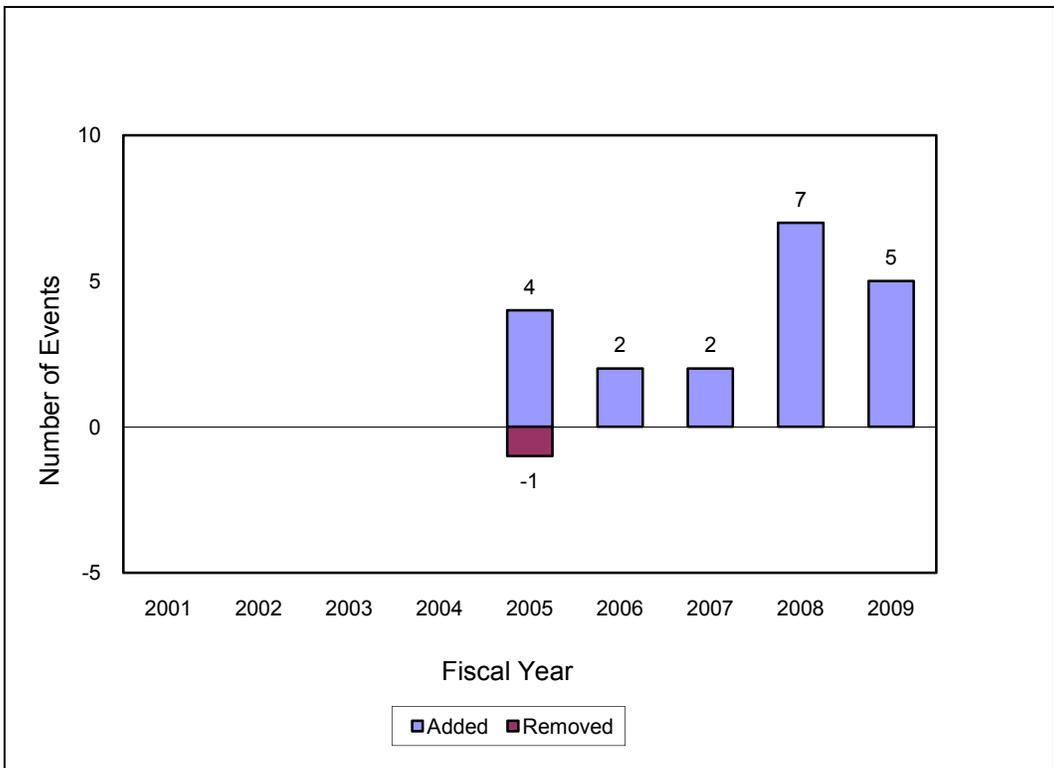


Figure D-3. Changes to MED Data

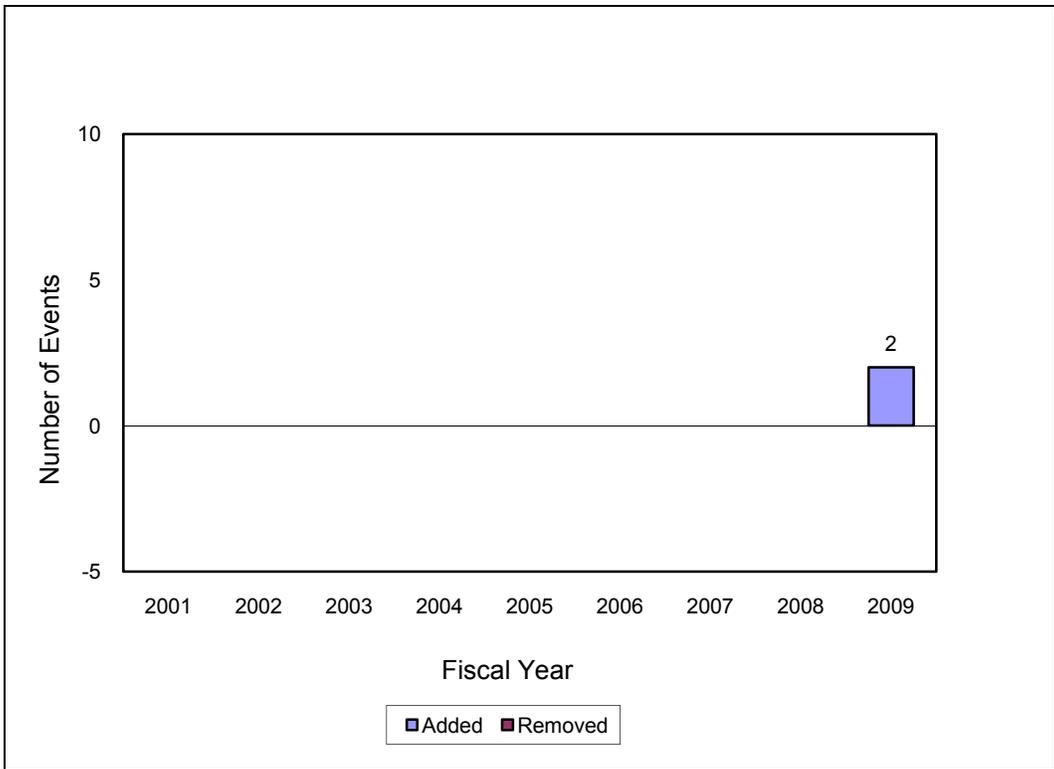


Figure D-4. Changes to EXP Data

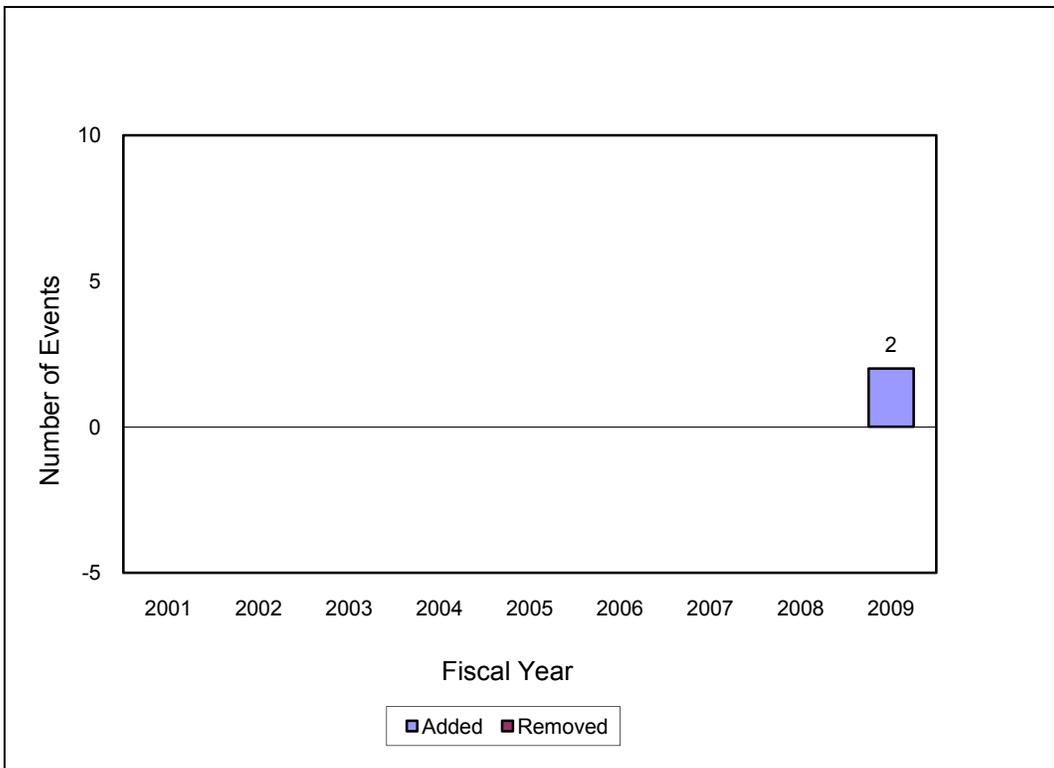


Figure D-5. Changes to RLM Data

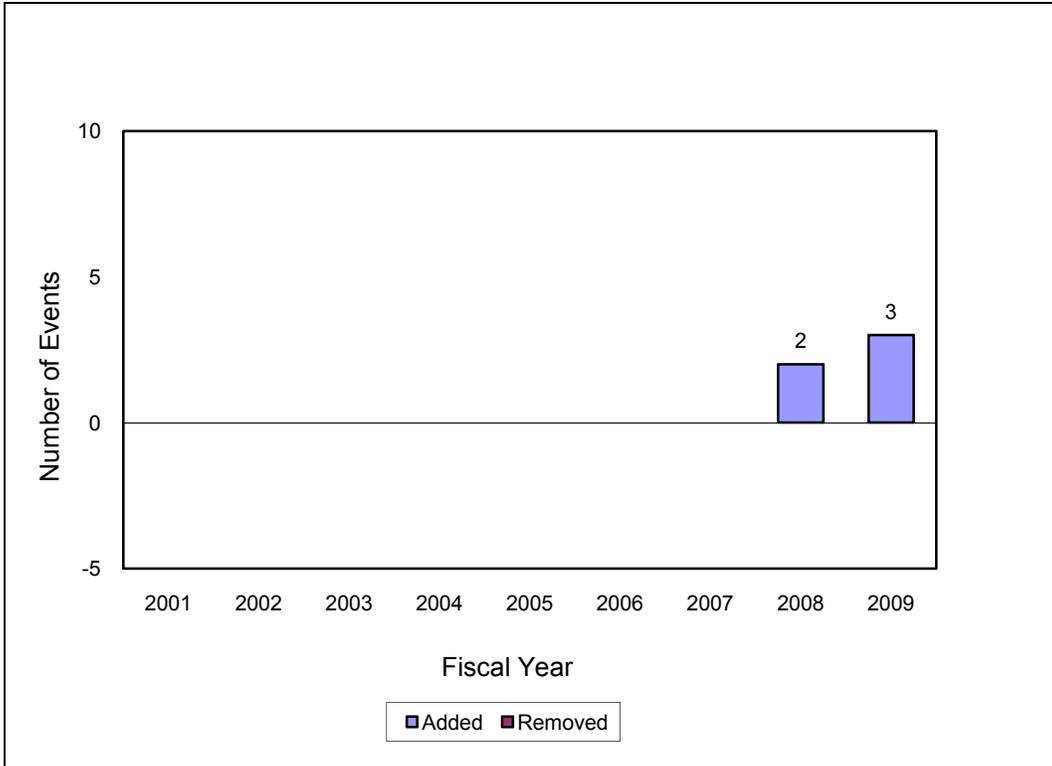


Figure D-6. Changes to LKS Data

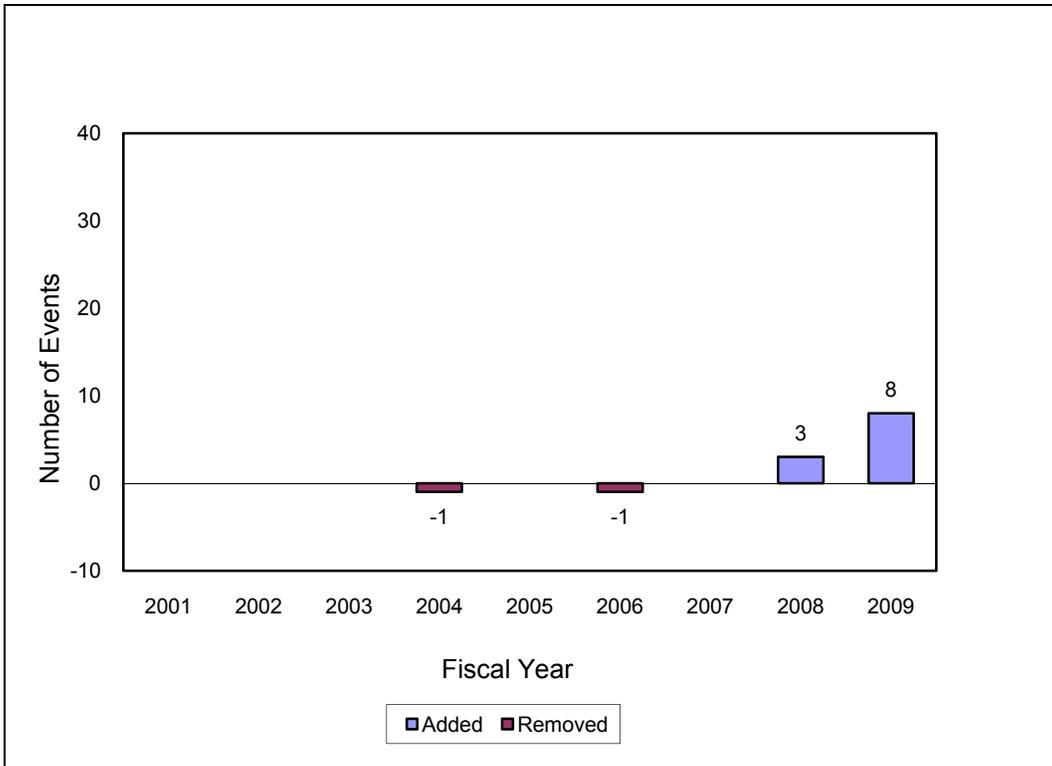


Figure D-7. Changes to EQP Data

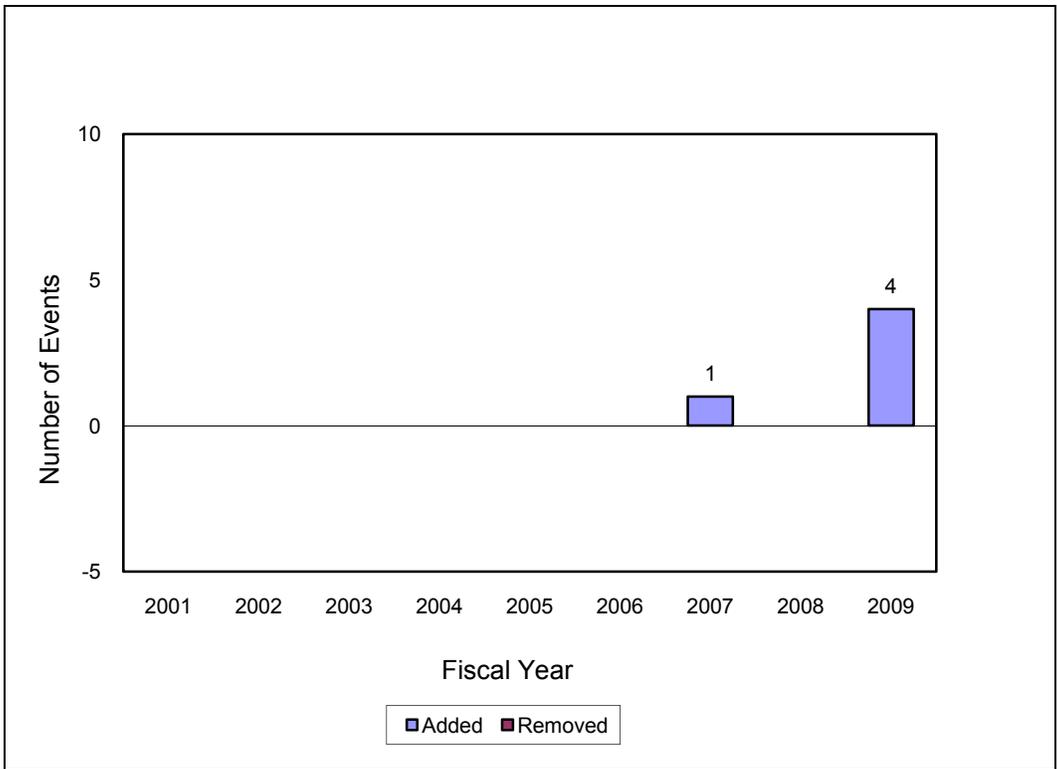


Figure D-8. Changes to TRS Data

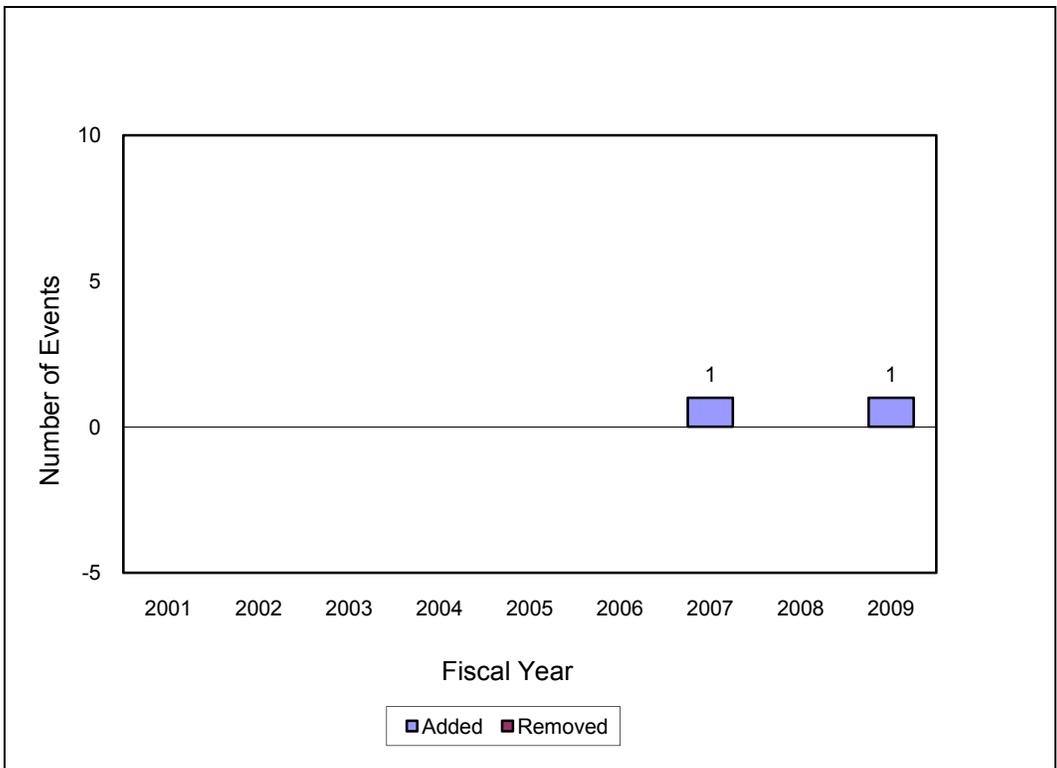


Figure D-9. Changes to OTH Data

FUEL CYCLE EVENT STUDY BREAKDOWN

The graphs below display a breakdown of the fuel cycle events that fall under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70 Subpart H. Figure 1 provides the annual number of fuel cycle events reported under Part 70 and Figure 2 provides the number of events based on the general root cause of the events. It should be noted that these events are a subset of the total number of fuel cycle related events provided in Section 2.9 of the Nuclear Material Events Database Annual Report found in Enclosure 3 of this report.

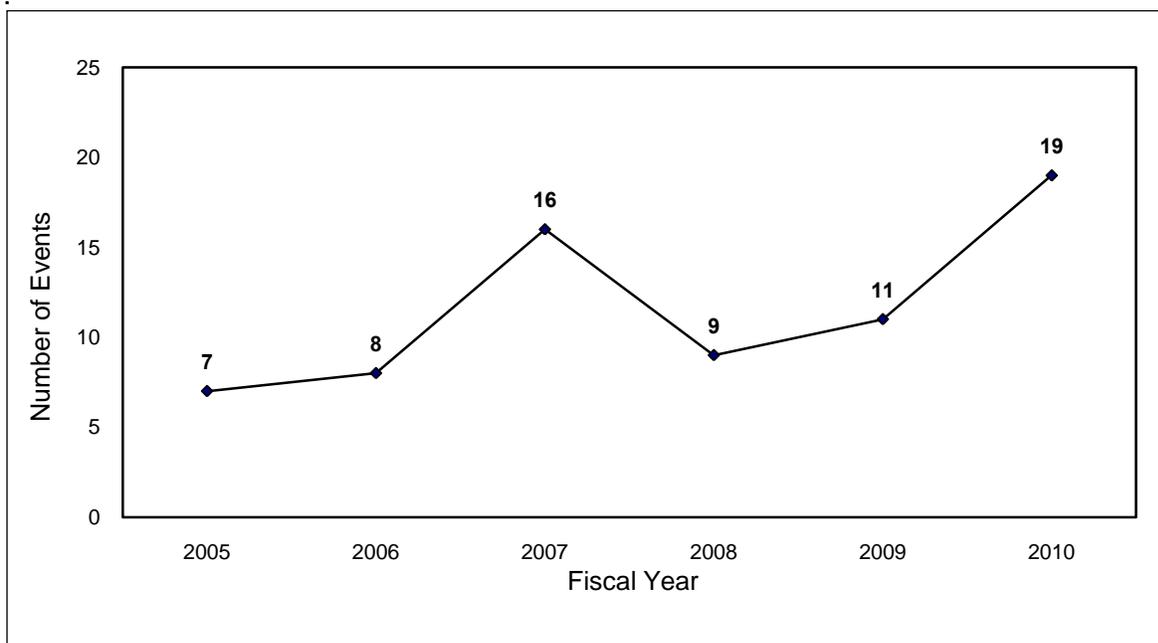


Figure 1. 10 CFR Part 70 Subpart H Fuel Cycle Events (70 total)

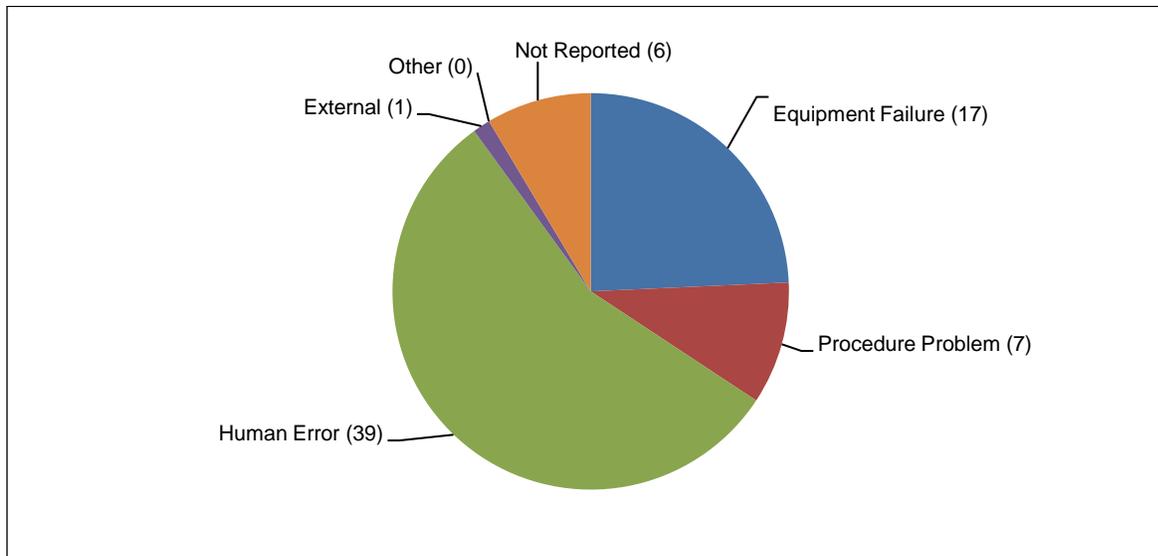


Figure 2. Event Causes

LICENSEES IDENTIFIED WITH SIGNIFICANT PERFORMANCE ISSUES

NUCLEAR FUEL SERVICES, INC.

1. IDENTIFICATION

Location: Erwin, TN
License No.: SNM-124
Docket No. 70-143
License Status: Active

2. STATUS SUMMARY

Nuclear Fuel Services, Inc. (NFS) was discussed during the 2009 Agency Action Review Meeting (AARM) because NFS had multiple and repetitive program issues that warranted additional U.S. Nuclear Regulatory Commission (NRC) oversight as described in the AARM criteria established in SECY-08-0135. Specifically, NFS demonstrated program breakdowns in safety culture, engineering processes, safety decision-making, corrective actions, and work control. While NFS has demonstrated improved performance since January 2010, it has not demonstrated sustained satisfactory performance in each of the aforementioned program areas where weaknesses were identified. The staff issued two escalated enforcement actions against NFS in 2010, both of which were due to self-revealing or NRC identified performance deficiencies in 2008 and 2009. The staff also conducted significant additional oversight in 2010 to verify that improvements were effective before authorizing startup of four individual processing lines at the facility. The staff believes that NFS continues to meet the *Performance Trend* criteria for discussion at the AARM for the same reasons the facility was discussed in 2009. Specifically, the staff believes that NFS warrants discussion at the AARM because:

1. The effectiveness of their corrective actions has not been fully demonstrated,
2. Extensive oversight is planned by the NRC, and
3. The significant issues involving the NFS safety culture have not been fully resolved in a sustainable manner.

Currently, the NRC has verified that NFS implemented sufficient corrective actions to operate all processes in accordance with NRC requirements except for the Uranium Hexafluoride process. Accordingly, NRC's Region II Office, with concurrence from NRC's Office of Nuclear Material Safety and Safeguards (NMSS), approved operation of those processes. To date, NFS has operated the NRC approved processing lines safely. NRC staff will inspect NFS's readiness to operate the Uranium Hexafluoride process when NFS requests NRC authorization for restart of that process.

Background

On August 30, 2010, a Severity Level III violation and \$140,000 civil penalty was issued for safety problems identified in the Uranium-Aluminum processing line in 2009. The NRC's reactive inspections of the Uranium-Aluminum processing line event in 2009 and an interim performance review in December 2009 identified a number of notable

concerns which resulted in a decision by NFS to shut down all processing lines until the NRC was satisfied that actions required for restart were completed, which was documented in a Confirmatory Action Letter on January 7, 2010.

On November 16, 2010, the staff issued a Confirmatory Order to document an agreement negotiated using the alternative dispute resolution (ADR) process. The ADR agreement addressed the underlying causes for violations associated with the failure to provide complete and accurate information regarding fire damper inspections in 2008 and 2009. The Confirmatory Order requires NFS to develop a safety culture improvement plan, and demonstrate the effectiveness and sustainability of that plan. Furthermore, the Confirmatory Order requires NFS to assess its current corrective action program against the criteria of NQA-1-2008, enhance the program based on the assessment results and then request that their license be amended to incorporate the enhanced corrective action program by August 16, 2011.

Recommendation

Region II and NMSS recommend that NFS be discussed at the AARM because NFS continues to meet the *Performance Trend* criteria for the same reasons the facility was discussed in 2009.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

Confirmatory Action Letter

In December 2009, NRC management engaged NFS management to discuss issues identified during reactive NRC inspections and an NRC interim performance review. The interaction resulted in a decision by NFS to shut down all processing lines until the NRC was satisfied that actions required for restart were completed. This agreement was documented in a Confirmatory Action Letter (CAL) dated January 7, 2010. The CAL documented a number of performance issues as follows:

- Inadequate management oversight by NFS of facility process changes;
- Perceived production pressures;
- Lack of questioning attitude by workers and management;
- Poor communications; and,
- An unacceptable management decision to resume operation of the process line following an upset condition without identifying or implementing sufficient corrective actions to address the underlying causes.

Since the issuance of the CAL in January 2010, NFS developed and implemented interim corrective actions for four of five processing lines and informed the NRC they were ready for inspection. The NRC conducted an inspection of each of the four processing lines and found that interim corrective actions were sufficient to authorize each of the four lines to restart. An NRC inspection of the licensee's corrective actions in January 2011 has identified that NFS did not adequately address two post-restart CAL items. These items were related to the licensee's ability to conduct thorough root cause analyses and do not affect the NRC's decision

that the licensee was capable of safely operating and restarting four process lines. Additional inspections will be conducted when NFS implements the long term corrective actions.

NRC Oversight Strategy

NRC's planned oversight strategy is designed to ensure safe operational performance and adequate security at NFS. In addition, the NRC oversight strategy is focused on ensuring that the corrective actions implemented by NFS for the issues identified in the NRC CAL dated January 7, 2010, and the NFS 2009/2010 Independent Safety Culture Assessment Report dated June 21, 2010, are effective and sustained. The NRC oversight strategy involves continued increased inspection effort by NRC inspection staff and maintaining a second on-site resident inspector. In addition, to increase the level of NRC management attention to NFS, NRC will transition the existing Safety Culture and Configuration Management Improvement Oversight Panel to an Executive Oversight Panel in the first quarter of calendar year 2011. The Executive Oversight Panel will ensure that the NRC inspection and oversight strategy is adequate to determine whether there are effective and sustainable improvements at the NFS facility, consider the effective implementation of future Commission Policy changes, implement an effective communication strategy, and ensure that the NRC oversight posture is consistent with NFS performance.

Licensee Safety Culture Improvement Strategy

Based on the 2009/2010 Independent Safety Culture Assessment report dated June 21, 2010, NFS identified a number of focus areas needing significant improvement. They have just begun their implementation of corrective actions for these areas. These focus areas included:

- Organization and Individual Accountability;
- Corrective Action Program Effectiveness;
- Resource Management;
- Technical and Professional Competency;
- Questioning Attitude;
- Work Control; and
- Safety Conscious Work Environment.

The NRC staff will evaluate the effectiveness of the NFS improvement plan and verify that improvements implemented are complete and sustainable when NFS indicates the actions taken to address these issues have been completed.

Management Changes

On January 25, 2011, Joseph (Joe) G. Henry was named President of NFS.

On January 17, 2011, Gary Darter was named Acting President replacing David Amerine. Mr. Amerine had served in the position since March 2010 when he replaced

David Kudsin as President of NFS.

On January 17, 2011, Christa Reed assumed a new position as Director of Operations. Ms. Reed replaced Tim Lindstrom, Vice President of Operations.

In March 2010, Mark Elliott was named Director of Quality, Safety and Safeguards. Mr. Elliott replaced David Ward who was serving as the Interim Director, Safety and Regulatory.

U.S. DEPARTMENT OF VETERANS AFFAIRS

1. IDENTIFICATION

Location: North Little Rock, Arkansas.
License No.: 03-23853-01VA
Docket No.: 030-34325
License Status: Active

2. STATUS SUMMARY

The U.S. Department of Veterans Affairs (VA), a master materials licensee, was discussed during the 2010 AARM based in part, on the identification of significant performance issues related to numerous medical events at the VA Philadelphia Medical Center. An enforcement action associated with these medical events was issued in March 2010 that included a Notice of Violation and a \$227,500 civil penalty. Additional performance related issues were identified at other VA facilities and the extent of conditions and concerns were still being evaluated at the time of the 2010 AARM.

The NRC continued its increased oversight of the VA licensed activities and conducted inspections at all of the other VA facilities with prostate cancer treatment programs to gain an assurance that these facilities did not have the same degree of problems as VA Philadelphia. In addition, the NRC conducted inspections of the National Health Physics Program (NHPP) to determine the circumstances that led to NHPP inspectors' failure to identify significant performance problems in the VA Philadelphia brachytherapy program. Under the VA's master material license, the NHPP is responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement.

The results of the additional inspections identified five violations involving four VA facilities: G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; VA Sierra Nevada Healthcare System, Reno, Nevada; VA New York Harbor Healthcare System, Brooklyn, New York; and the VA Boston Healthcare System, Boston, Massachusetts. A pre-decisional enforcement conference was held on June 30, 2010, and on August 20, 2010, the NRC issued a Notice of Violation and \$39,000 civil penalty to the VA for the violations.

Two violations assessed civil penalties involved the failure to develop, implement, and maintain written procedures that addressed methods to verify that the administrations were in accordance with the written directive (G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; VA Sierra Nevada Healthcare System, Reno, Nevada; and the VA Boston Healthcare System, Boston, Massachusetts); and the failure to report a medical event by the next calendar day after discovery of the medical event (VA New York Harbor Healthcare System, Brooklyn, New York).

Three additional violations were identified that were not assessed civil penalties because they were either outside of the Statute of Limitations for civil penalty or were of lesser significance. These violations involved the failure to develop, implement, and maintain written procedures that addressed methods to verify that the administrations were in accordance with the written directive (VA Boston Healthcare System, Boston,

Massachusetts); a 15-day report that did not contain all the information required (VA New York Harbor Healthcare System, Brooklyn, New York); and a written directive that did not specify the radionuclide, the treatment site, the number of sources, and the total source strength or the total dose (VA Sierra Nevada Healthcare System, Reno, Nevada).

The NRC escalated the civil penalty to underscore that the VA, as a whole, must improve not only the performance of individual VA facilities, but also the performance of the NHPP and the National Radiation Safety Committee (NRSC) in implementing their regulatory oversight responsibilities under the master material license. The NRSC has the responsibility for providing oversight of the VA's implementation of its Master Material License (MML) and associated individual facility (permittee) activities.

In June of 2010, Chairman Jaczko met with the VA's Under Secretary for Health, Robert Petzel, M.D. This meeting, which focused on mutually agreed upon responsibilities for both the NRC and the VA, was a key point in establishing more open and transparent lines of communication between the two agencies. A subsequent meeting was held on September 20, 2010, during which Mark Satorius, Regional Administrator, Region III and Charles Miller, Director, Office of Federal and State Materials and Environmental Management Programs met with senior VA leadership to discuss the VA's MML and Letter of Understanding.

In October 2010, Region III established a VA Task Group to provide focused increased oversight and performance monitoring of the VA's improvement activities developed in response to the multiple performance issues identified during the previous inspections and subsequent enforcement actions. The goal of the VA Task Group is to enhance the communications between the NRC and the VA in order to establish a consistent understanding of roles and responsibilities and provide the oversight guidance necessary for the VA to effectively implement the MML. The VA Task Group conducted independent and accompaniment inspections of VA facilities to ascertain the effectiveness of the VA's corrective actions and to determine the likely sustainability of the corrective actions. Further, the VA Task Group and Region III Senior Management have attended VA NRSC meetings to enhance communications between the NRC and the VA at a higher level and determine the extent of the NRSC's effectiveness in managing the implementation of corrective actions at the individual facilities and at the NHPP.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

The major issues are:

- a. On October 14, 2008, the NRC issued a Confirmatory Action Letter (CAL 3-08-004) to the VA as a result of multiple medical events that were identified at several VA facilities involving permanent prostate brachytherapy treatments. The CAL required the VA to: 1) conduct reactive inspections of all the active prostate brachytherapy programs; 2) develop and implement standardized procedures for conducting prostate brachytherapy treatments; 3) correct incompatible data transmission problems; 4) identify root causes and corrective actions to prevent recurrence; 5) immediately suspend any prostate brachytherapy program where medical events are identified for 20 percent or more of the prostate treatments performed and develop enhanced criteria for suspending prostate brachytherapy programs; 6) NHPP

conduct an inspection prior to restart of a suspended prostate brachytherapy program to confirm implementation of all corrective actions and provide notification to the NRC; and 7) before start-up of any new prostate brachytherapy programs at VA facilities, the NHPP conducts an inspection to confirm implementation of the standardized procedures, the individuals involved in the treatments have completed training on medical events, methods to verify needle placement in the prostate prior to seed implantation, preparation of written directives, pre-treatment and post-treatment planning, dose verification, and provide notification to the NRC. The VA has completed Items 1 through 6 of the CAL. Additionally, the VA has established the criteria required in Item 7 of the CAL for a new program; however, they have not established a new prostate brachytherapy program to date. Based on this information, the CAL will be closed prior to the date of the AARM.

- b. Assessment of the sustainability of the VA's corrective actions and performance improvements instituted as a result of the previously issued escalated enforcement actions.
- c. There are no pending or open escalated enforcement actions.