POLICY ISSUE
INFORMATION

April 6, 2010 SECY-10-0040

FOR: The Commissioners

FROM: Charles L. Miller, 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 2009

PURPOSE:

This paper provides the eighth annual report on significant nuclear materials issues and adverse 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) 2009. This paper does not address any new commitments or resource implications.

SUMMARY:

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. For FY 2009, there were two

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nuclear material licensees, Nuclear Fuel Services, Inc. and the Department of Veteran Affairs Philadelphia VA Medical Center, who met the criteria for identifying nuclear materials licensees 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 nuclear materials licensees that will 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 approving 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' performances 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: (1) Abnormal Occurrence (AO) data; (2) strategic outcomes and performance measures data; (3) data derived through escalated enforcement actions; (4) annual report data based on assessment of events reported to the Nuclear Material Events Database (NMED); (5) generic and special event study results; and (6) 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.

(1) Abnormal Occurrence Data:

The staff determined that nine of the events reported to NRC in FY 2009, involving the Materials and Waste Programs, met the criteria for AO events. These AO events include three events at NRC-licensed facilities and six events at facilities licensed in Agreement States. Seven of the nine AO events were medical events and the remaining two events involved radiation exposure to an embryo/fetus. 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 FY 2000 through FY 2009 data.

The staff's analysis and evaluation resulted in the finding that human error was a main contributor to the root causes of these AO events. The causes for these nine events include (1) misidentification of the target organs listed in the written directive; (2) errors in programming the equipment software; (3) malfunction of the medical equipment; (4) lack of training and procedures, (5) failure to recognize a potential issue with the method of treatment and (6) receiving false negative pregnancy tests.

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

(2) 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 2009 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero, and there were no events reported during FY 2009 that met any of the strategic outcomes. Also, the safety and security goals for the performance measures were not exceeded in FY 2009.

(3) Data Derived Through Escalated Enforcement Actions:

For the 2009 calendar year (CY) period (January 1, 2009, through December 31, 2009), NRC issued 89 escalated enforcement actions involving NRC materials licensees (some of these actions involved multiple violations grouped together and issued as a problem). 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, as well as Orders and Demands for Information (DFI). The escalated enforcement actions issued in CY 2009 for the Materials and Waste Programs include 66 Severity Level III NOVs and 23 Orders, which include 19 confirmatory orders that were issued to confirm commitments associated with Alternative Dispute Resolution (ADR) settlement agreements, 3 orders imposing civil penalties, and 1 individual action order. Also, for these 89 escalated enforcement actions, 20 civil penalties and 2 DFIs were issued.

In CY 2009 there was a decrease in the number of escalated enforcement actions compared to CY 2008, which resulted in 118 escalated enforcement actions for the Materials and Waste Programs. Also, in CY 2009 there were no cases involving Severity Level I or II violations compared to an average of approximately three per year for previous years. The decrease in escalated enforcement actions may be due, in part, because of the improved performance observed by material licensees in complying with the increased control orders issued in CY 2005. In addition, the total number of NRC material licensees decreased due to the States of Pennsylvania, Virginia, and New Jersey becoming Agreement States by the end of CY 2009.

(4) 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 event-reporting requirements 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, in which historical data is aggregated for evaluation of potential trends. A copy of the FY 2009 NMED Annual Report is available in Enclosure 2 of this paper. Copies of previous NMED Annual Reports may be found at http://nmed.inl.gov/.

In order to eliminate the random fluctuations in the event data from year to year and to assess an average trend of the data, the last 10 FY of data is reviewed. For the 10 year period covering October 1, 1999, through September 30, 2009, a total of 5,261 events (1,742 NRC and 3,519 Agreement State events) associated with materials licensees were reported to NRC, compared to last year's total of 5,227 events that were reported for the 10 year period, covering October 1, 1998, through September 30, 2008. It should be noted for the purposes of the NMED Annual Report 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.

For the current 10 year period, the NMED annual report indicated a downward statistical trend for the number of reported NRC regulated events. There could be several possible reasons for this trend, including changes in NRC regulations or NRC's change to a performance based inspection program, which results in improved licensee programs. However, a specific reason could not be determined for this and other statistical trends found in this report, although NMED, enforcement, event coordination and performance metrics data were evaluated.

For FY 2009, 38 of the 456 total reportable events were considered safety significant events as described in the FY 2009 NMED Annual Report. There were 3 lost/abandoned/stolen radioactive material events, 12 medical events, 1 radiation overexposure event, 14 release of material or contamination events, 2 leaking sealed source events, 1 equipment failure event, 3 transportation events, and 2 events that met the "Other" event category. For the 3 significant lost/abandoned/stolen radioactive material events, it should be noted that there were 2 sources that were classified under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004) as Category 2 sources and 1 source, which included an aggregate of a 100 small Am-241 sources, was classified as a Category 3 source. All of the IAEA classified Category 2 and 3 sources were recovered. A summary of the

significant events that took place in FY 2009 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.

(5) Generic and Special Event Study Results:

In 2008, the staff performed a special study to evaluate portable gauge losses and thefts. The staff reviewed event data from 10 years prior (CY 1998 thru CY 2007) to determine any trends in the area of portable gauge losses and thefts in general as well as any measurable results from the 10 CFR 30.34(i) rulemaking that became effective in July 2005. The study at that time did not show a clear trend or provide an indication of the effectiveness of the 10 CFR 30.34(i) rulemaking.

This year, since 2 additional years of portable gauge event data was available, the staff decided to re-evaluate the portable gauge losses and thefts to determine if there are any trends or measurable results from the 10 CFR 30.34(i) rulemaking. The results of this year's portable gauge study are described below.

Many portable gauge designs contain Americium-241/Beryllium (Am/Be) and Cesium-137 (Cs-137) sources. Generally each portable gauge contains only 10 milliCuries (mCi) of Cs-137 and 40 mCi of Am-241. Based on portable gauge event data from the last 10 years (CY 2000 thru CY 2009), the total amount of unrecovered Am/Be reported lost or stolen was 13.3 Ci, which would be rated as IAEA Category 3 amount of material. In addition there were 3.17 Ci of unrecovered Cs-137, which would also be rated as IAEA Category 3 amount of material.

Analysis of the portable gauge event data for the last 10 years also determined the following:

- Theft of gauges from a vehicle occurs more often when at a residence or other location than at a hotel;
- More gauges are stolen (72 percent) than missing (28 percent), and a missing gauge is more likely to be recovered than a stolen gauge; and
- More gauges appear likely to be recovered if stolen from a residence (54 percent) than from other locations including the jobsite (Average ~ 44 percent).

From examining the data described above, the data does indicate a statistically significant decreasing trend in the number of portable gauge lost and theft events in the last 10 years. The data also indicates that there has been a significant decrease in the amount of portable gauge events since 2005, which would indicate that the 10 CFR 30.34(i) rulemaking appears to have an effect on the number of portable gauge lost and theft events. A graph of this data may be found in Enclosure 3.

It should be noted that a study is also being performed regarding the effectiveness of the new fuel cycle regulations (i.e., Subpart H of 10 CFR Part 70). This study is scheduled to be completed by November 2010, and the results from this study will be provided in next year's annual report on licensee performance in the materials and waste programs.

(6) 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: (1) very serious events (those triggering NRC's strategic level measures); (2) significant licensee issues or events; or (3) licensee performance trends. For FY 2009, 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 Department of Veteran Affairs Philadelphia VA Medical Center. The staff's analysis regarding these licensees may be found in Enclosure 4. 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 2009. 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 Cynthia Carpenter for/

Charles L. Miller, Director
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:
1. Annual Trend in Abnormal Occurrence Events from FY 2000 - 2009
2. Nuclear Material Events Database Annual Report FY 2009
3. Portable Gauge Trend Analysis for January 1, 2000, to December 31, 2009
4. Licensees Identified with Significant Performance Issues

ANNUAL TREND IN ABNORMAL OCCURRENCE EVENTS FROM FY 2000 - 2009

Table 1 shows the number of events reported annually that were determined to meet the Abnormal Occurrence (AO) criteria. A total of 98 events were found to meet the AO criteria for the period FY 2000 - 2009. Of these 98 events, 33 of the events were by U.S. Nuclear Regulatory Commission (NRC) licensees and 65 of the events were by Agreement State licensees. Approximately 85 percent of the AO events for the last 10 years are 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 FYs 2000 through 2009 are compared. Also, there were no discernable trends when analyzing NRC AO data and Agreement State AO data separately.

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. The average number of AOs per year over the last 10 years is approximately 10.

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
2000	0	0	1	6	1	0	0	0	**2**	**6**
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**
2009	0	0	3	6*	0	0	0	0	**3**	**6**
Totals	**0**	**1**	**27**	**56**	**3**	**8**	**3**	**0**	**33**	**65**

*Include events involving a dose to embryo/fetus.

February 2010

Nuclear Material Events Database

Annual Report

Fiscal Year 2009

Prepared for the U.S. Nuclear Regulatory Commission
by the Idaho National Laboratory (INL/EXT-10-17653)

Enclosure 2

INL/EXT-10-17653

Nuclear Material Events Database

Annual Report

Fiscal Year 2009

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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, and (8) Other. Events involving irretrievable well-logging sources abandoned in accordance with 10 CFR 39.77 are excluded from this report.

CONTENTS

FIGURES

TABLES

ACRONYMS

ALARA	as low as reasonably achievable
ALI	annual limit on intake
AO	abnormal occurrence
AU	authorized user
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
CT	computed tomography
DAC	derived air concentration
DDE	deep dose equivalent
DOE	Department of Energy
DOH	Department of Health
DOT	Department of Transportation
DSHS	Department of State Health Services
ECD	electron capture detector
EPA	Environmental Protection Agency
EQP	equipment
EXP	radiation overexposure
FBI	Federal Bureau of Investigation
FY	fiscal year
HAZMAT	hazardous material
HDR	high dose rate
HEPA	high-efficiency particulate air
HHSA	Health and Human Services Agency
IAEA	International Atomic Energy Agency
ICE	Immigration and Customs Enforcement
INL	Idaho National Laboratory
LAS	lost/abandoned/stolen material
LKS	leaking sealed source
LS	least squares
MED	medical
NMED	Nuclear Material Events Database
NA	not applicable

NRC	Nuclear Regulatory Commission
NR	not recovered
OTH	other
PNNL	Pacific Northwest National Laboratory
RLM	release of licensed material or contamination
RSO	radiation safety officer
SNM	special nuclear material
SSE	error sum of squares
SSR	regression sum of squares
SST	total sum of the squares
TDHS	Texas Department of Health Services
TEDE	total effective dose equivalent
TRS	transportation
UK	United Kingdom

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 2009 are summarized below. Note that a single event may be listed in more than one event type category.

Lost/Abandoned/Stolen Radioactive Sources/Material

Three 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, two Category 2 sources, and one Category 3 source were lost, all of which were subsequently recovered. The Category 2 source events involved an unsecured radiography exposure device that fell from the tailgate of a truck and a radiography exposure device that was inadvertently left at a job site. The Category 3 source event involved the loss of a 55-gallon drum during shipping that contained 100 Am-241 sources. Individually, the Am-241 sources were less than the Category 3 threshold, but collectively they met the Category 3 threshold.

Medical Events

Twelve significant events occurred, all of which were classified as potential Abnormal Occurrences. Four of the events involved gamma knife treatments to the wrong location. Three events involved radiopharmaceutical misadministrations. Three events involved the incorrect placement of prostate brachytherapy seeds. One event involved a high dose rate treatment to the wrong location. The remaining event involved the misadministration of Y-90 spheres.

Radiation Overexposure Events

One significant event occurred. This event involved the overexposure of a worker at a low-level mixed waste treatment facility due to a failure of the respiratory protection system.

Release of Licensed Material or Contamination Events

Fourteen significant events occurred. One event involved a source that was breached with a saw while modifying calibration equipment. Five events involved the release of uranium tetrafluoride at a uranium hexafluoride production facility; one of which was actually a compilation of 40 events that occurred over a 5-month period. Three events involved the transportation of potentially contaminated individuals from commercial nuclear power plants or nuclear fuel fabrication facilities to offsite medical facilities. Four events involved contamination at medical facilities due to spills or legacy storage contamination. The remaining event involved a spill of special nuclear material solution at a fuel fabrication facility.

Leaking Sealed Source Events

Two significant events occurred. One event involved a source that was breached with a saw while modifying calibration equipment (also classified as a significant Release of Licensed Material or Contamination event). The other event involved a leaking brachytherapy seed that was removed from a patient.

Equipment Failure Events

One significant event occurred. This event involved a source that disconnected from a level measurement gauge and caused the overexposure of four non-radiation workers.

Transportation Events

Three significant events occurred, all of which involved radioactive sources becoming unshielded during shipping. The sources included contaminated nuclear fuel inspection equipment, F-18 from a radiopharmacy, and Cs-137 sources being shipped for calibration.

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.

Nuclear Material Events Database Annual Report: Fiscal Year 2009

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 approximately 20,000 records of material events submitted to the NRC from approximately January 1990 through December 2009.

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):

1. Lost/Abandoned/Stolen Material (LAS),
2. Medical (MED),
3. Radiation Overexposure (EXP),
4. Release of Licensed Material or Contamination (RLM),
5. Leaking Sealed Source (LKS),
6. Equipment (EQP),
7. Transportation (TRS), and
8. 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, 1999, and September 30, 2009. The data were downloaded from the NMED on January 14, 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 (FY00-09).

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.

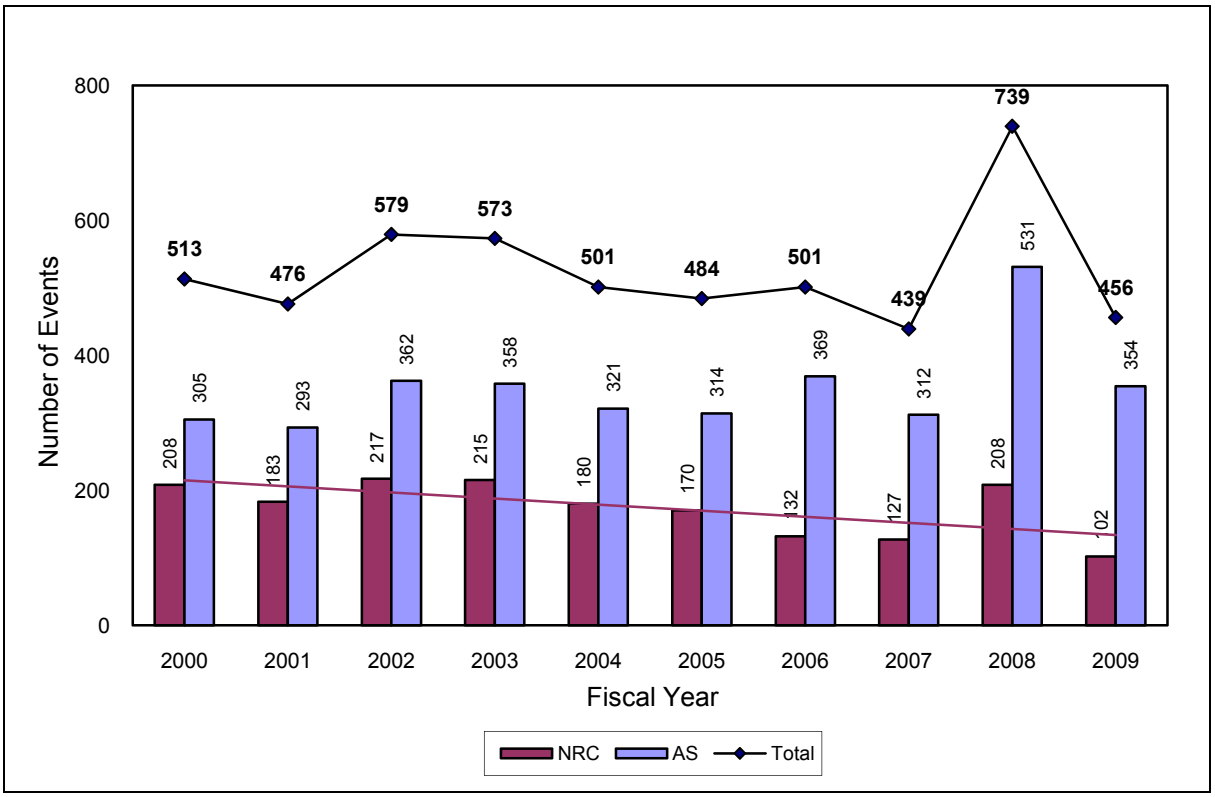


Figure 1. All NMED Events (5,261 total)

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

1. In FY09, 419 occurrences accounted for 456 events; a single occurrence can be classified in different event categories.
2. 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.
3. 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).
4. 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.

5. 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.

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)	-	-	-
Other (OTH)	NA	NA	NA

Notes:

1. ↗ indicates a statistically significant increasing trend.
2. ↘ indicates a statistically significant decreasing trend.
3. - indicates no statically significant trend.
4. 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).

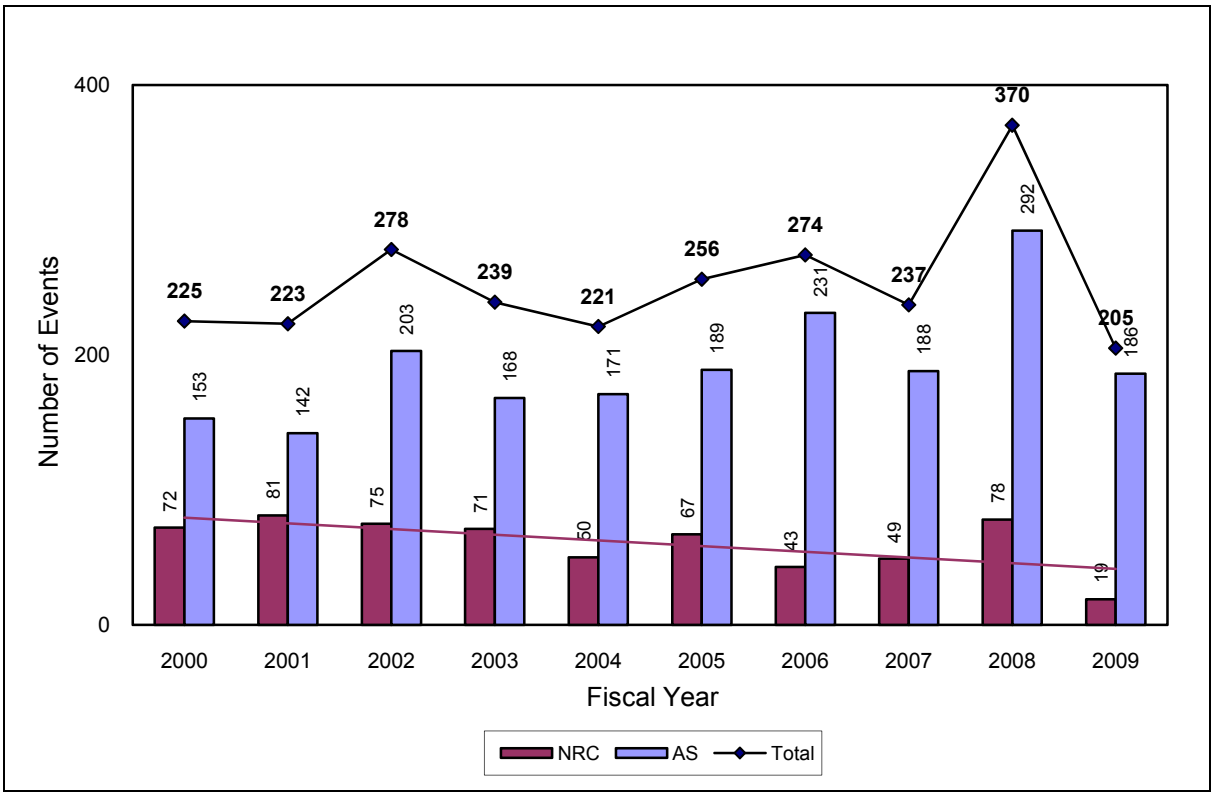


Figure 2. Lost/Abandoned/Stolen Material Events (2,528 total)

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.

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 2,528 LAS events that occurred during the ten-year period involved the loss of approximately 4,670 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, 49 Category 2 sources, and 19 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 2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
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	3	7	3	5	5	8	3	2	11	2	**49**
	NR	0	1	0	0	0	1	0	0	0	0	**2**
3	LAS	1	0	3	0	1	6	4	1	2	1	**19**
	NR	1	0	0	0	0	2	0	0	0	0	**3**
4	LAS	72	83	82	87	76	108	95	56	65	47	**771**
	NR	26	32	30	28	30	34	48	19	36	26	**309**
5	LAS	90	131	123	137	107	149	108	70	125	70	**1110**
	NR	39	62	52	59	36	56	42	20	55	21	**442**
< 5	LAS	2	2	4	2	4	7	0	2	0	2	**25**
	NR	2	2	2	1	4	4	0	0	0	2	**17**
Activity Not Known[1]	LAS	2	3	15	1	8	3	7	3	11	5	**58**
	NR	0	2	6	0	3	0	1	0	0	0	**12**
Nuclide Not Known[2]	LAS	1	1	1	1	0	3	0	0	0	0	**7**
	NR	0	0	0	1	0	0	0	0	0	0	**1**
Other[3]	LAS	253	151	307	274	249	223	255	263	415	241	**2631**
	NR	180	92	200	170	170	136	129	133	343	163	**1716**
Total	**LAS**	**424**	**378**	**538**	**507**	**450**	**507**	**472**	**397**	**629**	**368**	**4670**
	NR	**248**	**191**	**290**	**259**	**243**	**233**	**220**	**172**	**434**	**212**	**2502**

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. Therefore, 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 vial 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.

5. 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 five 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 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 (FY00-09)

Radionuclide	Half Life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Aggregate IAEA Category[5]
Am-Be	432.7 years	1	3	2.95454	3
Ir-192	73.83 days	4	16	0.00002	5
Total		**5**	19	**2.95456**	**3**

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 1/14/2010 (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).

Table 4. Summary of IAEA Category 1 through 3 Sources Not Recovered (FY09)

Radionuclide	Half Life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Aggregate IAEA Category[5]
		0			
Total		**0**			

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 1/14/2010 (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 FY09 Data

Two hundred five LAS events occurred in FY09 involving the loss of approximately 368 sources, 212 of which have not been recovered. Of the 368 lost sources, none were Category 1, two were Category 2, and one was Category 3. All of the Category 2 and 3 sources were recovered.

Significant Events - Category 1 Source Events

None.

Significant Events - Category 2 Source Events

Item Number 090554 - A licensee reported the loss and recovery of a radiography exposure device on 6/22/2009. The device contained a 1.998 TBq (54 Ci) Ir-192 source. On 6/22/2009, when a radiographer left the shop to travel to a work site, he placed the exposure device on the tailgate of his work truck. The device was not secured and the tailgate remained in the open position. Approximately 25 minutes later, the radiographer realized that the device had fallen off the truck. The radiographer proceeded back along the same route he had taken to the work site. He noticed a police vehicle traveling on the same remote rural road and he stopped the officer for assistance. The police officer had just recovered the device from a private individual, who had found the device on the road approximately one-half mile from the shop and contacted the police. The device was not damaged and had been out of the licensee's control for about 40 minutes. Corrective actions included additional training for the radiographer.

Item Number 090661 - A refinery reported finding a radiography exposure device that contained a 1.81 TBq (49 Ci) Ir-192 source. A radiographer had completed a job at the refinery on 8/5/2009. The radiographer loaded gear into his truck, but left the exposure device at the job site. Approximately 10 to 15 minutes later, refinery maintenance personnel noticed the device and notified their fire department. Another radiographer at the refinery heard the call on the radio and responded to the incident location. However, he did not have a radiation survey meter to approach the device. He noticed the plug was in and the device appeared to be locked with no key in the lock. They barricaded the area and kept the device under surveillance until a survey meter was brought to the scene. The radiographer surveyed the

device and confirmed that the source was in the shielded position. The device was transported to the storage location.

Significant Events - Category 3 Source Events

Item Number 090765 - A manufacturer of radiation source devices reported that they had not received a shipment of Am-241 sources according to schedule on 7/23/2009. The shipment consisted of a 55-gallon drum containing 100 Am-241 sources (considered as one source for this report), each with an activity of 1.48 GBq (40 mCi) and a total activity of 148 GBq (4 Ci). Individually, the Am-241 sources were less than the Category 3 threshold, but collectively they met the Category 3 threshold. The manufacturer contacted the carrier to inquire about the shipment. The carrier stated that the shipment had been delivered on 7/23/2009 and signed for by a certain individual. The manufacturer stated that there was no individual with that name working for them. The Federal Bureau of Investigation (FBI), Los Angeles Tactical Assault Group, California Health and Human Services Agency (HHSA), and North Carolina Radiation Control investigated the incident. The 55-gallon drum was located by the carrier at their Sun Valley, California, warehouse. The carrier stated that the drum might be damaged. The FBI, Los Angeles Sheriff's HazMat, and HHSA responded to the warehouse. Using a Victoreen 451P ion chamber, the highest surface radiation reading was approximately 5.6 mR/hour. No damage of the shipping drum was identified. The drum was delivered to the manufacturer on 7/27/2009 and all 100 Am-241 sources were accounted for. It was determined that the incident was caused by miscommunication. The carrier discussed with their employees the issue of physically locating containers when there are inquiries specific to hazardous material instead of relying on the computer system. In addition, personnel received training regarding shipments of hazardous material.

Events of Interest

Item Number 090534 - A construction company reported that a moisture/density gauge was damaged in a traffic accident on the afternoon of 6/5/2009 at a construction site on Illinois Route 49. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.296 GBq (8 mCi) Cs-137 source. A drunk driver entered the construction zone at a speed in excess of 70 miles per hour and struck the gauge, dragging it approximately 350 to 500 feet from the site of the impact. The source rod was in a shallow test position at the time of the impact. The impact separated the handle (with the indexing rod and source rod) from the base of the gauge. Personnel thought they had recovered all of the gauge pieces, but subsequent surveys taken one hour later at the gauge storage location revealed that the Cs-137 source was missing. The Illinois Emergency Management Agency dispatched an inspector, who confirmed that the Am-Be source was present but the Cs-137 source was missing. After overnight searches located an area of elevated radiation levels, the source was recovered the next morning within a grassy area about 5 feet from the road bed. Wipe tests showed no signs of contamination. The source was secured and transported to the storage location pending transfer to the manufacturer. The gauge and loose source were shipped to the manufacturer and received by them in August 2009. This event did not result in any notable radiation exposures. This event was classified as an EQP and LAS event.

Item Number 090582 - A coal company reported the loss and recovery of a source housing that contained a 3.7 GBq (100 mCi) Cs-137 source. On 7/9/2009, a scrap material yard notified the coal company that a load of their scrap set off the radiation monitor alarms. The scrap yard's radiation safety officer (RSO) discovered a piece of pipe with the source housing mounted on it. The RSO obtained proper permits, packaged the gauge, and returned it to coal company. The shutter was found 75% open and was subsequently locked closed. Surveys showed that the shielding was intact. The estimated age of the source is 20 years and the current activity is between 2.22 and 2.59 GBq (60 and 70 mCi). The source did not appear to be damaged and a leak test indicated no leakage. Through employee and contractor interviews, the coal company does not believe there were any personnel radiation overexposures. The source was placed in secure storage awaiting shipment to the manufacturer for proper disposal. An investigation determined that the source housing had been accidently removed by maintenance personnel

during pipe replacement on 7/2/2009; they failed to notice the radioactive markings due to a protective cover. Corrective actions included making similar source housings more visible and training personnel.

Item Number 090667 - The Texas Department of State Health Services (DSHS) reported that U.S. Customs Service detected radioactivity in a package at the post office facility at the Dallas Fort Worth Airport. Contents of the package included a couple of electronic devices, some dice, a small plastic container, and some other articles. The package was being sent to an address in Fort Worth, Texas. The radionuclide was identified as Sr-90 and radiation surveys measured 3 uSv/hour (0.3 mrem/hour) with a closed window and 600 uSv/hour (60 mrem/hour) with an open window. The activity was estimated to be approximately 46.62 kBq (1.26 uCi). The Environmental Protection Agency (EPA), FBI, and Immigration and Customs Enforcement (ICE) were notified. The EPA collected the radioactive material and took it to their facility for storage. On 8/26/2009, DSHS along with members of Customs and Border Protection (CBP), the International Mail Branch, ICE, and a warrant deputy performed an onsite inspection at the residence of the individual listed as the recipient. The individual stated that he had ordered the items from Thailand, but did not know that they were radioactive. A radiological survey of the residence identified contamination on several sets of dice, two small bowls, and a piece of aluminum foil that were located in a backpack in a closet. An additional container was identified in the individual's truck, which was identical to the one discovered at the airport. DSHS placed the items in a container and transported it to their main facility for storage.

Item Number 090679 - A commercial nuclear power plant reported the loss of an unirradiated local power range monitor detector that contained special nuclear material (SNM). The detector contained an estimated maximum quantity 216 kBq (5.84 uCi) of U-234 and U-235 combined (approximately 80 wt% U-234 and 20 wt% U-235). The loss was discovered during the annual physical inventory of SNM on 7/22/2009. According to SNM inventory sheets, the detector was expected to be stored in a canister in a spent fuel pool drum. Subsequent investigation concluded that the detector was disposed of as an SNM discard and shipped to the licensed facility in Barnwell, South Carolina, on 2/18/2005 for burial as radioactive waste. This event was caused by insufficient procedures. Corrective actions included procedure modification and personnel training.

Item Number 090719 - A nuclear fuel fabrication facility reported that a small container of about 11.42 kg (25 pounds) of scrap fuel pellets (approximately 2,000 pellets enriched to 4.8% U-235) could not be readily located. On 5/18/2009, the facility's internal tracking system identified that a seven-inch polypack containing fuel pellets was missing. A plant-wide search did not locate the fuel pellets. However, the empty polypack was found without its identifying label. Personnel independent of the affected area conducted a material balance inventory, which concluded that the material did not leave the area. The material balance inventory results and findings were reviewed by the NRC and an independent contractor, a material control and accounting expert, who agreed with the conclusion and methodology used. Based on this material balance and other investigative actions conducted by the facility, there is no indication that the material left the affected area. An NRC inspection team concluded that the SNM likely remained on site and was processed through the normal scrap process flow. Retraining on item control requirements for production personnel was completed prior to restart of production activities. Enhanced accountability and control measures for item control of scrap containers was also completed prior to restart of production activities.

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.

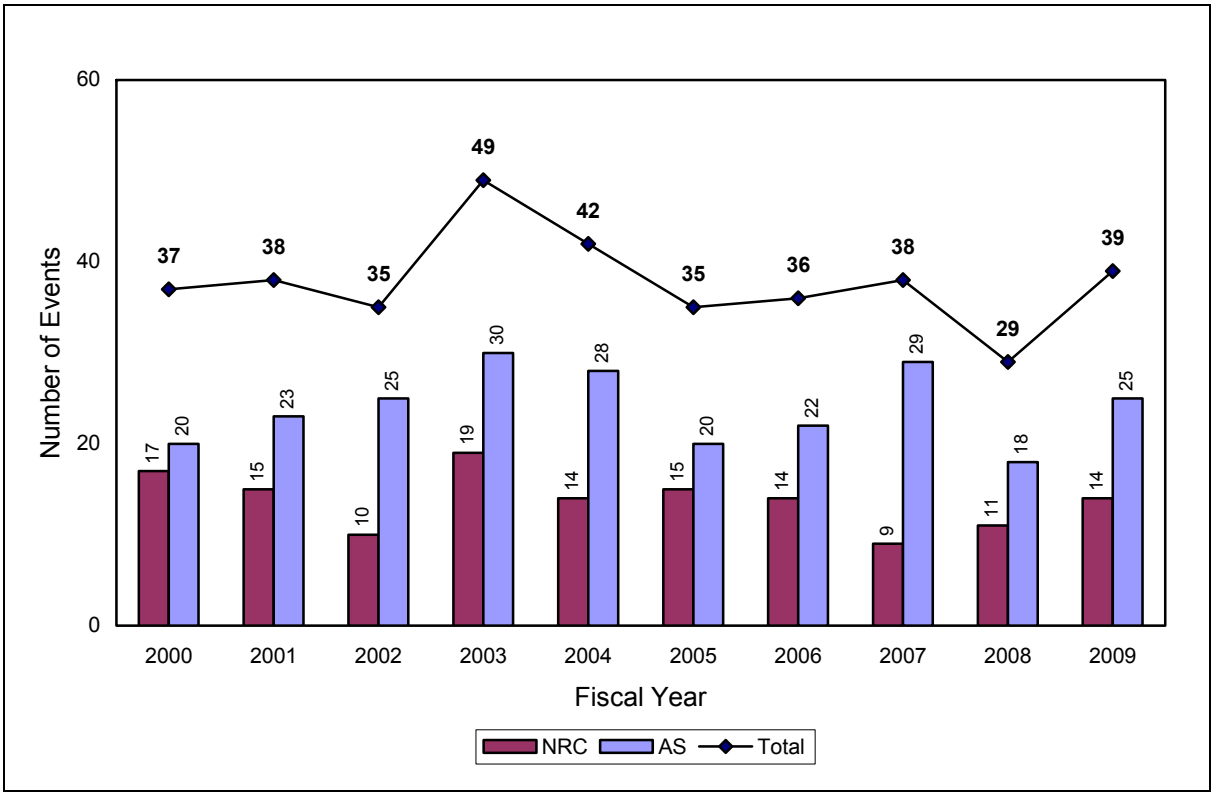


Figure 3. Medical Events (378 total)

A major revision to 10 CFR 35 became effective October 2002. This revision relaxed previous reporting requirements and could result in a decreased number of reportable medical events. Note that Agreement State agencies had until April 2005 to adopt compatible regulations.

Table 5 lists the number of MED events that were significant enough to be classified as Abnormal Occurrences (AOs) in NUREG 0090, "Report to Congress on Abnormal Occurrences." For this report, MED events classified as AOs (potential AOs for FY09) are considered significant.

Table 5. Medical AO Events

	Fiscal Year										
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009[1]	Total
Events	5	2	6	10	12	7	7	11	11	12	**83**

Notes:

1. Events in FY09 are currently marked as potential AOs, because the AO determination process has not yet been completed for this year. In 2010 (typically April or May), the final AO determination will be made and the events published in NUREG 0090.
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 FY09 Data

Thirty-nine MED events occurred in FY09, 12 of which were classified as significant events.

Significant Events - Potential AOs

Item Number 080707 - A patient received an unintended dose of 1,798 cGy (rad) to the esophagus. The patient was being treated for a thyroid condition with a capsule containing 5.58 GBq (150.7 mCi) of I-131. The patient attempted to swallow the capsule on 10/15/2008, but it became lodged in the patient's throat due to an esophageal obstruction. Hospital staff attempted to aid the patient in swallowing the capsule by providing soda and applesauce. The patient coughed up the soda and applesauce, which were surveyed and found to be radioactive. More soda and applesauce were given to dissolve the capsule, which eventually passed the obstruction after approximately 2.5 hours. If the capsule had not become lodged in the esophagus, the esophagus would have received a dose of 1,012 cGy (rad). Therefore, this event resulted in an additional dose to the esophagus of 786 cGy (rad), or 77.7% more than intended. The event was discussed with the patient during a follow-up visit with the physician on 10/22/2008. Potential adverse effects include esophagitis and radiation fibrosis. To prevent recurrence, patients known to have difficulty swallowing will be evaluated for other options, like smaller capsules, liquid I-131, etc. An NRC medical consultant concluded that no significant adverse effect to the patient is expected.

Item Number 080896 - A patient prescribed a gamma knife procedure to treat trigeminal neuralgia on the right side of the face was instead treated on the left side on 12/16/2008. The gamma knife contained 121.88 TBq (3,294 Ci) of Co-60. The prescribed dose was 4,000 cGy (rad) to 50% isodose and the patient received 4,000 cGy (rad) to the wrong site. The patient was notified of the incident and no adverse effects are expected. A site inspection was performed on 12/18/2009. The cause was determined to be human error. The treatment planning sheet had been mismarked as to the location of the treatment and review of the document did not identify the error. Corrective actions included implementing stricter verification procedures, requiring that the physician order accompany the patient during each phase of their treatment, and requiring that multiple individuals verify that the site referred to in the physician order matches that with the site being treated.

Item Number 090019 - A patient prescribed to receive 8,000 cGy (rad) to the 5th intracranial nerve during trigeminal neuralgia treatment only received 10 to 20 cGy (rad) on 12/2/2008. The 7th intracranial nerve, on the other hand, received 1,495 cGy (rad). The 5th intracranial nerve was prescribed 8,000 cGy (rad) and the written directive was completed and signed by all appropriate parties. However, the gamma knife unit, containing 125.8 TBq (3,400 Ci) of Co-60, was improperly prepared and the wrong nerve was designated for treatment. Fortunately, the authorized neurosurgeon instructed the licensed medical physicist to pause the treatment 9.17 minutes into the 45 minute regime. He then consulted with the neuroradiologist and they determined that the wrong nerve was targeted. The patient was notified and

correct treatment was successfully performed on the same day. The clinical staff concluded that the root cause was misidentification of the anatomical target site as listed on the written directive. No adverse effects are expected as a result of the medical event. Corrective actions included procedure modifications requiring that the neuroradiologist provide precise information on the magnetic resonance imaging of the correct target site. The written directive will also be modified to ensure the correct site is defined.

Item Number 090391 - A patient received a high dose rate (HDR) mammosite treatment to the wrong site between 2/23 and 2/27/2009. The patient was to receive treatment twice a day for a total of 10 fractions with an expected dose of 3,400 cGy (rad) to the intended site. An HDR unit was used with a 184.223 GBq (4.979 Ci) Ir-192 source. A dummy wire was inserted into the balloon to check and measure the tube length for dose calculations. A computed tomography (CT) scan was performed daily to verify the position of the treatment site. After treatment calculations were performed, reviewed, and approved, the treatment began on 2/23/2009. On 2/27/2009, a different therapy physicist was checking the patient's charts and thought that there may have been an error. On 3/2/2009, the original physicist checked the findings and discovered that there had been an error in the placement of the source during treatments. The source was not fully inserted into the balloon, but was 3 cm from where it should have been. That incorrect source placement resulted in the tumor site only receiving 1,010 cGy (rad), 30% of the intended dose. An unintended site received the total treatment. The patient is being followed for any sequelae (pathological conditions) to the event. The oncologist discussed the event with the patient. Corrective actions included modifying the mammosite worksheet to add the expected catheter length of 95 cm beside the block where the measured catheter length is recorded, requiring that the catheter measurement wire be kept in place during CT simulation following catheter measurement, and reviewing and revising all mammosite policies and procedures to strengthen accuracy of measurement, planning, treatment, and quality control.

Item Number 090395 - Ninety-three I-125 seeds were implanted outside of the target organ during a prostate brachytherapy implant procedure performed on 1/19/2009. The incident was initially suspected on 2/23/2009 and was confirmed on 3/19/2009. The seeds retained their planned pattern grouping, with the superior end of the seed cloud being approximately 2 cm from the apex of the prostate gland. The seeds appeared distal to the prostate and the dose appeared to be maximally confined to soft tissue, including muscle and subcutaneous fat. An NRC medical consultant concluded that the prostate did not receive sufficient dose to effectively treat the patient's cancer; the prostate received approximately 1,000 cGy (rad) instead of the intended 14,500 cGy (rad). The probability of other long-lasting negative health effects to the patient is low. This event was caused by the failure to adequately visualize and identify the prostate prior to implant. Corrective actions included procedure modification and personnel training.

Item Number 090415 - A patient was prescribed 11.1 MBq (300 uCi) of I-123, but was administered 72.5 MBq (1.96 mCi) of I-131 on 12/29/2008. A referring physician requested an uptake study and scan to be followed by I-131 therapy for thyrotoxicosis. The authorized user (AU) directed the secretary to schedule the uptake study using I-123. However, the secretary scheduled the patient for a whole body scan using I-131. On the day of the study, the nuclear medicine technologist took the patient's history, which included the fact that she still had her thyroid. The technologist failed to seek clarification from the AU and did not review the AU's approval. The technologist proceeded with the whole body study using the I-131. Upon discovery of the error, the AU had an uptake study performed. The AU notified the patient and referring physician. Results of the uptake study revealed that the patient was thyrotoxic. The AU prescribed a therapy dose of 370 MBq (10 mCi) of I-131. An error in scheduling precipitated this event. The failure of the technologist to seek clarification and review the physician's order caused the event. Corrective actions included a requirement for verification of the prescription by two technologists and the need to consult with the AU if there are any questions regarding the ordered procedure.

Item Number 090497 - A patient received a 53% under dose during a prostate seed implant procedure on 5/11/2009. The patient was prescribed to receive 64 I-125 seeds. The seeds each contained an activity of 16.428 MBq (0.444 mCi), with a total activity of 1.052 GBq (28.422 mCi). The prescribed dose to the

prostate was 14,400 cGy (rad) and the administered dose was 6,768 cGy (rad). The post-plan CT was evaluated on 5/12/2009 and determined that the prostate volume that received the prescribed dose was 47% (i.e. V100%=47%). Evaluation of the post-procedure ultrasound revealed that some of the seeds were implanted outside the prostate gland due to the small size of the patient's prostate gland. The patient and physician have been notified. An investigation determined that the cause was miscalculation of the size of the patient's prostate gland. Corrective actions taken by the hospital included modifying procedures to require agreement by both the urologist and radiation oncologist on placement of seeds for patients with small prostate gland size (20 cc or less).

Item Number 090565 - A patient received a significant dose to an untargeted area during a gamma knife stereotactic radiosurgery on 3/20/2009. The incident occurred due to an error in the imaging process used for treatment planning. The fiducial marker box used to register the CT images was misaligned. The CT locator box had not been firmly seated on the targeting frame, which resulted in a target shift of approximately 2 mm. Due to the small size of the target (7 mm by 4 mm by 3 mm) and the small size of the radiation shots (4 mm collimators), that shift of 2 mm resulted in only approximately 52% of the target receiving the prescribed dose of 1,100 cGy (rad). Normal tissue (temporal bone) outside of the intended treatment volume received a dose of 1,100 cGy (rad). The patient was prescribed a single fraction treatment. No adverse consequences are expected from this event. The physician did not feel additional treatment was advisable and counseled the patient regarding the incident. Corrective actions included additional training for the CT technologist on correct placement of the fiducial box, the medical physicist will double check the box placement on all similar treatments in the future, and policies and procedures were updated. According to the NRC Registry of Radioactive Sealed Sources and Devices, this gamma knife unit contains Co-60 sources with a combined maximum activity of 244.2 TBq (6,600 Ci).

Item Number 090580 - A patient received a gamma knife treatment on 7/2/2009 to two metastatic sites using an 18-mm collimator instead of the prescribed 8-mm collimator. The gamma knife treatment was prescribed for seven discrete brain metastatic sites using the 8-mm collimator. The prescribed dose was 2,400 cGy (rad). After the second discrete site had been treated, it was determined that an 18-mm collimator had been used instead of the 8-mm collimator. Following the discovery, the collimator was changed to the 8-mm collimator. Treatment to the remaining five discrete sites was administered with the 8-mm collimator. The use of the 18-mm collimator instead of the 8-mm collimator increased the treatment site dose by 3%. The 18-mm collimator caused the volume of each of the two treatment area to increase by 2.35 cm3. That additional tissue received a dose of 2,400 cGy (rad). If the 8-mm collimator had been used, that tissue would have received a dose of approximately 430 cGy (rad). Both the physician and patient were notified of the incident. It was stated that the previous patient had been treated with the 18-mm collimator as prescribed. The medical physicist neglected to change the collimator prior to treatment. Corrective actions included sending a notice to all neurosurgeons and radiation oncologists stressing that they should each independently check collimator size prior to each treatment.

Item Number 090662 - Forty-six Cs-131 brachytherapy seeds were improperly positioned during a prostate implant procedure on 7/29/2009. The error was suspected when the physician reviewed the CT scan results on 8/6/2009, and was confirmed on 8/11/2009. It was determined that the seeds went into soft tissue 4 to 5 cm inferior to the prostate. Post-implant dosimetry calculations indicated that none of the prostate received the prescribed dose of 6,500 cGy (rad). The D90 value (the minimum dose received by 90% of the prostate volume) was 300 cGy (rad). An unintended volume of 30.1 ml of soft tissue received 100% of the prescribed dose of 6,500 cGy (rad). The patient was advised by the physician and elected to receive follow-on treatment with a linear accelerator. An NRC medical consultant concluded that the soft tissue dose could increase the risk of soft tissue fibrosis or impotency. This event was caused by inadequate ultrasound identification of the prostate during implant due to the patient's unusual anatomy and obesity. Corrective actions included procedure modification to include steps to ensure that the prostate and surrounding associated anatomy is adequately visualized prior to implant.

Item Number 090732 - A patient was administered 1.7 GBq (45.9 mCi) of Y-90 spheres instead of the intended 0.939 GBq (25.38 mCi). The event occurred on 9/15/2009. The patient and the referring physician were notified on 9/17/2009. It was determined that the technologist mistakenly administered the wrong amount. Corrective actions included providing refresher training to involved staff members.

Item Number 090748 - A patient received less dose than prescribed during the administration of 6.92 GBq (187 mCi) of I-131 through a feeding tube on 9/21/2009. Daily measurements of the exposure rate were consistent with radioactive decay, but not the expected biological elimination. The patient's feeding tube was replaced on 9/25/2009. The activity in the feeding tube after removal from the patient was estimated at over 2.96 GBq (80 mCi). It was estimated that the patient only received 0.78 GBq (21 mCi). The patient and physician were notified. An assessment is being performed of any possible medical effects on the patient. The cause of the incident was determined to be human error. The technologist injected the I-131 into the wrong port of the feeding tube. Corrective actions included developing a written procedure for g-tube administrations and training will be provided to the nuclear medicine technologists.

Events of Interest

Item Number 090471 - A nine-month-old infant was administered a 1,291 MBq (34.9 mCi) dose of Tc-99m Sestamibi for a cardiac scan, instead of the prescribed 74 MBq (2 mCi) dose of Tc-99m dimercaptosuccinic acid for a renal-glomerular filtration study. The incident occurred on 4/22/2009 and the patient's legal guardian was notified on that same date. The administered dose exceeded the prescribed dose by 1,650%. It was estimated that the patient's heart received a dose of 3.68 cSv (rem), small intestine received 1.09 cSv (rem), gall bladder received 3.99 cSv (rem), kidney received 1.86 cSv (rem), and the whole body received a dose of 5.22 cSv (rem). The effect on the patient is unknown. The cause of the incident was human error. Corrective actions included reprimanding personnel, modifying procedures, providing additional training to personnel, obtaining new equipment, and improving radioactive material labeling and handling.

Item Number 090615 - A patient received 700 cGy (rad) to the wrong site, approximately 10 cm from the intended location, during a high dose rate (HDR) afterloader procedure performed on 7/21/2009. The Ir-192 source contained an activity of 339.18 GBq (9.167 Ci). A positioning error resulted in the incident and delivered the dose to the entrance of the vagina rather than intrauteral. The applicator used in the procedure uses a collet to hold a 3-mm source tube in place. Subsequent investigation revealed that the collet on the applicator had not been tightened sufficiently to prevent movement of the source tube within the applicator. The patient and physician were notified. The patient was retreated with the prescribed dose three days later without incident. Corrective actions included generating a new procedure to measure the distance from the end of the source tube to the cylinder prior to patient treatment and providing additional training to all staff involved in HDR treatments.

Item Number 090754 - A patient was administered a therapeutic dose of 3.7 GBq (100 mCi) of I-131 on 9/30/2009, instead of the prescribed diagnostic dose of 0.15 GBq (4 mCi). The patient had received a therapeutic dose in August 2008 and was scheduled for the diagnostic follow up on 9/30/2009. During scheduling, the dose was incorrectly entered as therapeutic instead of diagnostic. The hospital notified the patient's physician and consulted with the patient on 9/30/2009. The hospital also notified their risk management group and began an investigation into the incident. Corrective actions included generating a new written procedure, improving the patient identification verification, and an engineering change to the system.

Embryo/Fetus or Nursing Child Dose Events

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 FY09, both of which are classified as potential AOs.

Item Number 090579 - A pregnant patient was administered 2 GBq (54.1 mCi) of I-131 on 3/30/2009. The patient had a false negative pregnancy test on 3/30/2009. The authorized user contacted the patient's obstetrician/gynecologist and it was determined that the therapy was administered five days post-conception. The dose equivalent to the embryo/fetus is 11.9 cGy (rad), with 0.97 cGy (rad) to the embryo/fetus thyroid. Corrective actions included that the staff plans to over-emphasize the risks associated with becoming pregnant following administration of radioiodine.

Item Number 090755 - A pregnant patient was administered 925 MBq (25 mCi) of I-131 on 9/21/2009. The patient had undergone pregnancy screening consisting of interviews and a urine-based pregnancy test with negative results. Eight days after the administration, the patient missed an expected menstrual cycle and performed a home pregnancy test with positive results. That test result was confirmed with a positive serum-based test on the same day administered by her physician. The authorized user estimated that conception would have been approximately three weeks prior to administration. Total effective dose equivalent (TEDE) estimates are approximately 6.7 cSv (rem) to the embryo, with no thyroid developed at this stage of pregnancy. The patient was advised of the incident. No general corrective actions are anticipated, but the event will be used as an opportunity for refresher training and a risk audit.

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 Agreement State-regulated events do not represent a statistically significant trend in the number of events (indicated by the absence of a trend line). Therefore, variations within those annual values represent random fluctuation around the average of the data. However, the Total and NRC-regulated events represent statistically significant decreasing trends (indicated by the trend lines).

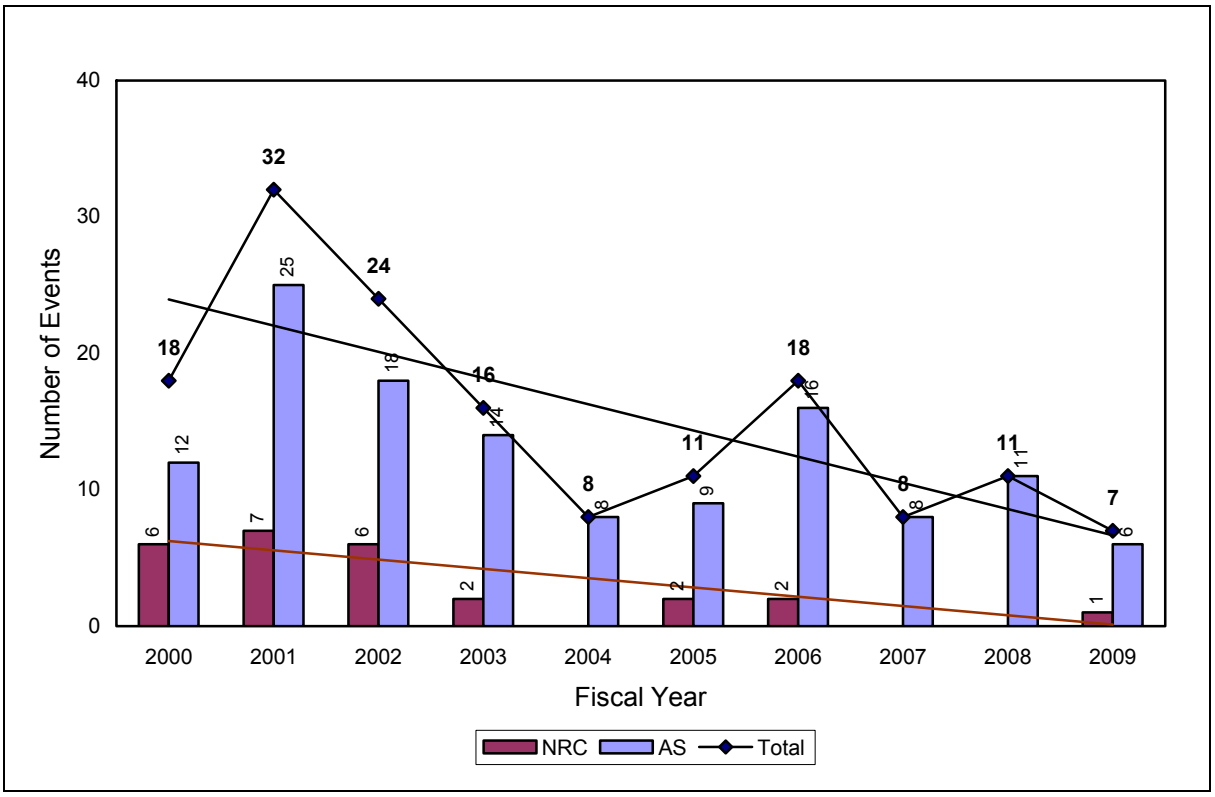


Figure 4. Radiation Overexposure Events (153 total)

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										
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
Immediate	1	2	1	2	1	0	1	1	0	0	**9**
24-Hour	1	1	0	1	1	1	3	1	3	1	**13**
30-Day	16	29	23	13	6	10	14	6	8	6	**131**
Total	**18**	**32**	**24**	**16**	**8**	**11**	**18**	**8**	**11**	**7**	**153**

2.4.2 FY09 Data

Seven EXP events occurred in FY09, one of which was classified as a significant event.

Significant Events - Immediate Reports

None.

Significant Events - Within 24-Hour Reports

Item Number 090452 - A low-level mixed waste treatment facility reported an overexposure to a worker with a whole body dose of 6.8 cSv (rem) committed effective dose equivalent (CEDE) and a bone surface dose of 120 cSv (rem) committed dose equivalent (CDE). The individual's deep dose equivalent (DDE) from his dosimetry for the first quarter 2009 was 0.3 mSv (30 mrem). Dose calculations were completed by a consultant. The total calculated intakes were: Am-241 153 Bq (4.14 nCi), Pu-239/240 89.9 Bq (2.43 nCi), and Pu-238 16.8 Bq (0.455 nCi). The assumed cause is a failure of the respiratory protection system. On 2/12/2009, the worker was sent for a lung count at the Pacific Northwest National Laboratory (PNNL). The lung count was ordered due to the worker performing operations in an area where airborne contamination levels could cause more than 2.5 DAC-hours (with respiratory protection factors applied) and greater than 520 DAC-hours (with no respiratory protection factors applied) in one day. The worker's first lung count detected approximately 14.8 Bq (0.4 nCi) Am-241. The initial estimated dose was 16 cSv (rem) CDE. On 3/25/2009, the waste facility stated that further testing by PNNL resulted in a revision to the initial calculated dose and the new calculated dose would exceed 50 cSv (rem) CDE. The date of exposure (2/3/2009) was assumed based on air sample data and the use of respiratory protection that may not have provided adequate coverage (use of filtering respirator instead of supplied air). On 2/3/2009, the worker was in a containment in which air sample results were about 3.7 E-4 Bq/ml (1 E-8 uCi/ml) gross alpha activity concentration for several hours and was wearing a powered air purifying respirator. Bioassay results (fecal) from one other worker, who was also in the containment, showed a small amount of activity and a dose was assigned that did not exceed the limit. That other worker's lung count was less than detection limits. The Washington Division of Radiation Protection conducted an investigation of the incident. The waste facility curtailed work in containment, conducted training on removal of anti-contamination clothing and respirators, and investigated the failure of respiratory protection. Corrective actions included testing each worker with a challenge gas prior to high risk work, increasing engineering controls to mitigate airborne contaminants, conducting specific training using phosphorescent powder and black lights for workers, performing more frequent bioassay samples, inclusion of nasal smears for immediate detection of intakes, using supplied air respirators over air filtering respirators for high risk work, and training for workers, managers and health physics staff. Work has resumed in containment areas and no further exposures have occurred. As of 4/14/2009, this incident was classified as an International Nuclear Event Scale level 2 event.

Events of Interest

Item Number 080722 - A petroleum refining company reported that a 9.62 GBq (260 mCi) Cs-137 source disconnected from a level measurement gauge. As a result of the source disconnect, four non-radiation workers received annual exposures that exceeded the limit. The individuals received 2.962, 0.960, 0.280,

and 0.166 cSv (rem). On 10/28/2008, it was noted that the gauge was no longer giving proper readings and a maintenance crew was sent to perform repairs. Radiation surveys revealed elevated levels. The manufacturer was contacted and sent a technician to the facility. The technician identified elevated radiation levels and determined that the source had separated from the operating rod. The source was still located in the gauge housing, but was not shielded. On 10/29/2008, the manufacturer removed the gauge from the tank it was mounted on. The gauge and source were packaged for transportation back to the manufacturer's facility for inspection and repair. As of 12/22/2008, this incident was classified as an International Nuclear Event Scale level 2 event. This event was classified as an EQP and EXP event.

Item Number 090666 - A well logging company reported a radiation overexposure to a member of the public during transportation of a 92.5 GBq (2.5 Ci) Cs-137 source on 7/12/2009. The source was shipped via common carrier from Arkansas to Texas. One month after receiving the source in Texas, the well logging company discovered that the source had been shipped in a container designed to carry a 185 GBq (5 Ci) Am-Be source. The well logging company recreated the event and determined that the dose rate in the cab of the transport truck was 0.25 mSv/hour (25 mrem/hour). The trip was estimated to take six hours to complete, resulting in a calculated dose to the driver of 1.5 mSv (150 mrem). The driver was informed of the incident. The driver was offered medical assistance, which he refused. The individual who surveyed the package before it left Arkansas stated that he did not observe any unusual dose rates. Corrective actions included providing additional training to personnel involved in the packaging of the source. The Texas Department of State Health Services and the Arkansas Department of Health investigated the possibility of other individuals receiving radiation exposure from the incident. This event was classified as an EXP and TRS event.

Item Number 090773 - A coal-fired power plant reported the potential radiation overexposure of an employee. Starting in early September, the plant welder worked in the immediate vicinity of seven fixed nuclear gauges used to monitor coal flow through chutes at the plant. The gauges each contained a 1.85 GBq (50 mCi) Cs-137 source. On 9/18/2009, it was noted that the gauges had not been taken out of service during the welder's work. The NRC dispatched an inspector on 10/5/2009 to begin a reactive inspection. It was determined that the welder could have potentially received in excess of 1 mSv (100 mrem) during the 10 days he worked in the immediate vicinity of the gauges. On 10/14/2009, the company's preliminary exposure calculations revealed a dose to the welder between 1.8 and 13 mSv (180 and 1,300 mrem), with the best maximum exposure estimate of approximately 6.21 mSv (621 mrem). The company identified 13 other persons who were potentially exposed to radiation during the same time period. Of those 13, the company believes that five of them may have received doses in excess of the limit for members of the public, ranging from 1.4 to 5 mSv (140 to 500 mrem). This event was caused by insufficient gauge labeling, an inadequate lockout/tagout procedure, and inadequate training. Corrective actions included labeling the equipment, modifying the lockout/tagout procedure, and training personnel. As of 10/16/2009, 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 Total and NRC-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 Agreement State-regulated events represent a statistically significant decreasing trend (indicated by the trend line).

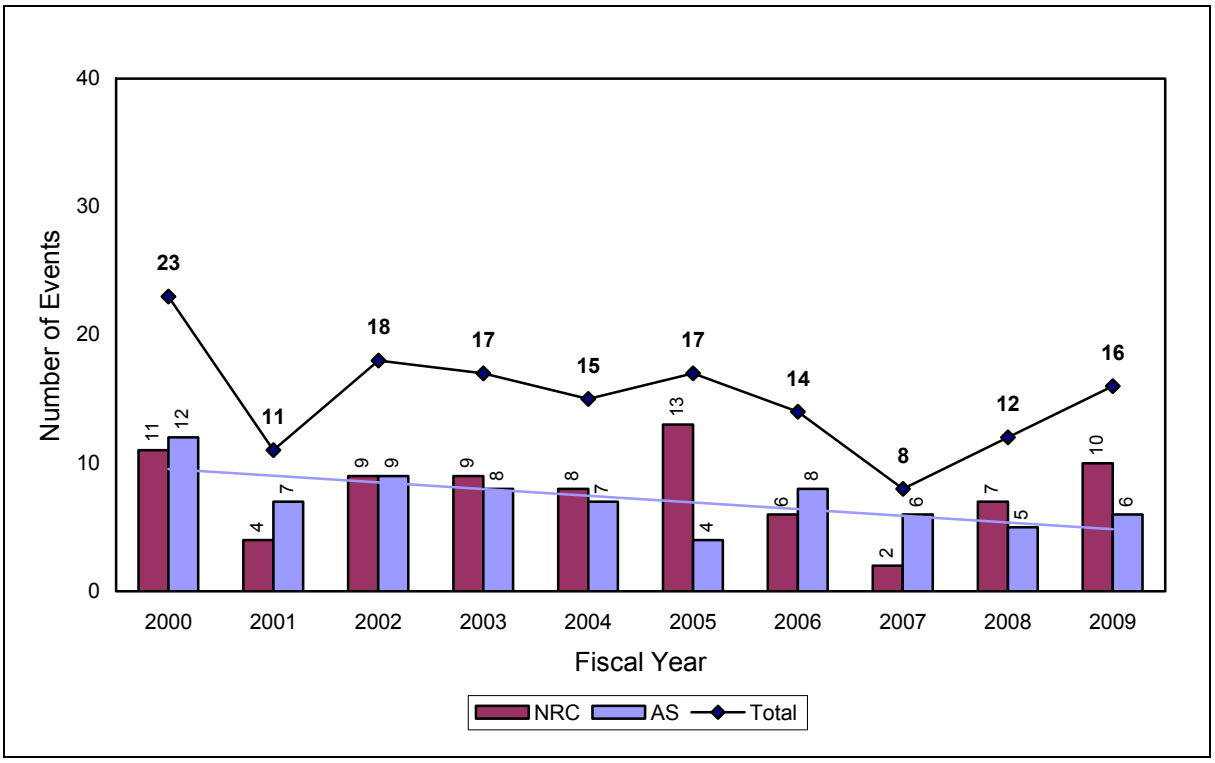


Figure 5. Release of Licensed Material or Contamination Events (151 total)

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										
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
Immediate	1	1	0	0	2	0	0	0	2	1	**7**
24-Hour	19	9	15	16	13	17	12	8	8	13	**130**
30-Day	3	1	3	1	0	0	2	0	2	2	**14**
Total	**23**	**11**	**18**	**17**	**15**	**17**	**14**	**8**	**12**	**16**	**151**

2.5.2 FY09 Data

Sixteen RLM events occurred in FY09, fourteen of which were classified as significant events.

Significant Events - Immediate Reports

Item Number 080792 - A radiation detection equipment manufacturing company reported breaching a 1.85 GBq (50 mCi) Cs-137 source while modifying a piece of calibration equipment. The RSO stated that the source was cut in half with a thin blade saw. Following the incident, the remaining sections of the source were assayed and the activity was 1.78 GBq (48 mCi). A Texas Department of Health Services (TDHS) inspector was dispatched to the scene to investigate. Initial reports stated that 40 or more employees were involved and that contamination was spread by foot traffic throughout the facility. The company hired a contractor to perform assessment and decontamination activities beginning on 11/14/2008. The inspector identified that contamination levels were fairly low with some spots reading approximately five times background (between 10,000 and 15,000 cpm on a scintillation detector). The Department of Energy (DOE) Radiation Emergency Assistance Center/Training Site was contacted for guidance. Four employees identified as having potential intakes provided urine samples and received whole body counts on 11/19/2008. Three of those individuals received less than 0.1 mSv (10 mrem) CEDE from the incident. The fourth individual, who cut the source, received 0.3 mSv (30 mrem) CEDE. That individual stated that he covered his mouth with his jacket during the cutting process because it was creating a lot of dust. The company intends to provide whole body counts to all of their employees. The entire facility was posted and controlled as a contaminated area. The contamination was mostly on floor areas outside the work area. On 4/16/2009, the company stated that all areas had been decontaminated, surveyed, and released. On 5/6/2009, TDHS conducted radiological surveys of the facility. One small area less than 100 cm2 was identified above fixed release limits. That area was decontaminated and released. Corrective actions included modifying procedures and making an engineering change to the system. This event was classified as an EQP, LKS, and RLM event.

Significant Events - Within 24-Hour Reports

Item Number 080629 - A commercial nuclear power plant reported that an injured, radioactively contaminated individual was transported offsite by ambulance to a hospital. The individual fell while working inside the condenser, a radioactively contaminated area. His protective clothing was slightly contaminated, but his body was not. The protective clothing read approximately 80 counts above background. A radiation protection technician accompanied the individual to the hospital.

Item Number 080883 - A nuclear fuel fabrication facility reported that a spill of SNM solution occurred on 12/5/2008. Approximately one liter of solution dripped from a faulty fitting, causing contamination of the piping, storage tanks, and equipment support structure. Due to the inaccessibility of some areas affected by the spill, decontamination could not be completed until stored solutions could be transferred from the area to reduce ambient radiation levels. The area was isolated and personnel access was restricted. Decontamination was completed on 12/12/2008. An investigation determined that a valve had been left in the “locked open” position following a transfer of SNM on 12/4/2008. During the transfer on 12/5/2008, personnel missed the procedural step to verify that the valve was closed. At the time, the mix

and measure column was full and the column subsequently overflowed to the knockout column before the transfer was secured. During the overflow, an elbow in the wet off gas line leaked material. The leaking pipe fitting was repaired and an operational stand-down was conducted to reinforce management expectations for safe operations.

Item Number 080891 - A hospital reported finding Cs-137 contamination in a source safe drawer on 12/10/2008. A contractor removed Cs-137 sources from the safe drawer, packaged, and shipped them without incident. Radiation surveys were conducted in the safe, which revealed contamination levels greater than 5,000 dpm/100 cm2 in the lower drawer. It was determined that the Cs-137 contamination involved was less than 0.37 MBq (10 uCi). The hospital stated that the lower drawer had not been used during recent source storage and transfer operations and believes that the contamination resulted from previous use. Individuals involved in transferring the sources were surveyed and no contamination was identified. The storage area and passageway into the area were surveyed and no contamination was identified. The hospital secured the storage safe and storage area, and the area was posted with "no access" signs. The hospital completed decontamination efforts and the Ohio Bureau of Radiation Protection verified that no contamination was present on 12/22/2008. The area was released for use. The hospital stated that the Cs-137 sources were old and had leaked under shielding, which prevented earlier detection. This event was classified as an EQP, LKS, and RLM event.

Item Number 090132 - A hospital reported personnel contamination from an I-131 spill in their hot laboratory that occurred on 1/29/2009. A technician was preparing a radioiodine therapy dose of 3.7 GBq (100 mCi) for a patient procedure. The technician was removing the vial from the fume hood to perform a dose calibration when the vial slipped from his hands and broke on the floor. The technician was contaminated on his hands, torso, and legs. The estimated contamination activity on the individual was below 1.85 MBq (50 uCi). Initial decontamination efforts managed to reduce the contamination on the individual such that only his hands remained contaminated. The estimated activity on the individual following decontamination was less than 0.11 MBq (3 uCi). All individuals involved in facility decontamination, as well as the contaminated technician, took prophylactic potassium iodide. The RSO stated that decontamination would continue until only fixed contamination remained. He estimated that as much as 80% of the contamination had been contained or removed within a few hours of the incident. Dose rates in the area were initially over 50 mR/hour. Additional shielding was moved into the area so that necessary nuclear medicine procedures could be completed while decontamination was finished. Dose rates behind the shielding were less than 1 mR/hour. A State Agency inspector went to the site to ascertain the dose rates in the area, the extent of contamination, and ensure bioassays were being properly conducted. Bioassays were conducted to determine the extent of uptakes to personnel. The doses received by personnel were estimated by the State Agency as being less than 0.25 mSv (25 mrem) CEDE to the technician and less than 0.1 mSv (10 mrem) CEDE to the RSO. The radiopharmacy was shut down and operations relocated to another temporary facility within the hospital. Waste generated from initial decontamination efforts was secured within the hot laboratory fume hood. The room was released for routine occupancy on 4/6/2009. Corrective actions included providing additional training to personnel and implementing some minor procedural changes.

Item Number 090236 - A nuclear fuel fabrication facility reported that a radioactively contaminated worker was sent to an offsite hospital for treatment on 2/12/2009. The operator was using rubber gloves mounted to a glovebox to change an in-line filter inside the glovebox when he noticed liquid on his right sleeve. Several small holes/cuts were later discovered in the fingers of the glovebox glove. Contamination of the hands was prevented because the operator wore disposable gloves while his hands were inside the glovebox gloves. The operator responded immediately to an emergency eye wash/safety shower. The Safety Department was notified and the operator was determined to be contaminated above limits. Decontamination attempts were unsuccessful due to nitric acid burns on his forearm. The operator was sent to the medical facility for further evaluation. The operator was treated for second degree burns at a local medical facility and released. The minor skin contamination resulted in no intake of radioactive

material or penetrating radiation exposure to the individual. There were no actual or potential safety consequences to other workers, the public, or the environment. The radiological material involved in this event was a few millimeters (about 100 grams) of highly enriched uranyl nitrate solution. This event was caused by deterioration of the glovebox gloves over time. The glovebox gloves were replaced, along with gloves in similar gloveboxes, with gloves manufactured from a heavier butyl rubber material that is more resistant to damage.

Item Number 090237 - A uranium hexafluoride production facility reported that an unplanned contamination event occurred on 2/16/2009. Additional controls were imposed requiring wearing half-faced respirators in the affected area. Air samples from the area were analyzed and the airborne radioactivity average was approximately 3.06E-6 Bq/ml (8.27E-11 uCi/ml). The airborne radioactivity exceeded the action level of 30% of a DAC (1.85E-6 Bq/ml or 5.0E-11 uCi/ml). One DAC is 6.29E-6 Bq/ml (1.7E-10 uCi/ml). A material elevator was leaking around an inspection cover, which resulted in airborne uranium tetrafluoride (green salt). The facility attributes the contamination to a failed gasket. The airborne contamination was discovered during routine air sampling, which is performed daily. There is no plan to perform personnel testing for uptake or ingestion. See NMED Items 090314, 090404, and 090488 for similar events. This event was classified as an EQP and RLM event.

Item Number 090314 - A uranium hexafluoride production facility reported that an unplanned contamination event occurred on 2/22/2009. Health physics personnel identified elevated average airborne radioactivity levels of approximately 2.26e-6 Bq/ml (6.12e-11 uCi/ml) in the affected area. Additional controls were imposed requiring wearing half-faced air purifying respirators. The highest average airborne radioactivity level was 3.06e-6 Bq/ml (8.27e-11 uCi/ml). During decontamination activities, the average airborne radioactivity remained elevated for more than 24 hours. Routine bioassays from the affected personnel indicated no elevated uptake of radioactivity. An equipment inspection determined that the cause of this event was a release of material from the uranium tetrafluoride (green salt) elevator and conveyor system. The facility will evaluate potential engineered controls to manage solids and reduce the pressure applied to the elevators during filter bumping. See NMED Items 090237, 090404, and 090488 for similar events. This event was classified as an EQP and RLM event.

Item Number 090404 - A uranium hexafluoride production facility reported that during maintenance activities on 3/24/2009, approximately 100 pounds of UF4 (green salt) was released from a rotary valve on the secondary dust collector drop leg drain pipe. Four personnel were in the area wearing respiratory protection and anti-contamination clothing. The personnel left the area and access was restricted until 3/26/2009. The UF4 contaminated four floors of the building and the four personnel. Personnel contamination was removed with removal of the anti-contamination clothing and subsequent showers. Bioassay samples from these four individuals showed that all received an acute internal dose less than 0.1 mSv (10 mrem). Most of the floor contamination was cleaned within four hours and the remainder was completed on 3/26/2009. No contamination was released outside the building. This event was caused by the failure to install a pipe blind next to the drain pipe's rotary valve, even though plant knowledge indicated that the rotary valve could be reasonably expected to leak. The pipe blind was subsequently installed. See NMED Items 090237, 090314, and 090488 for similar events. Corrective actions included the installation of slide valves at the secondary green salt dust collector air lock locations, replacing a dust collector air lock, and installing vacuum gauges and other instruments to allow troubleshoot the dust collector blowback system.

Item Number 090457 - A commercial nuclear power plant reported transporting a radioactively contaminated injured person offsite to a medical facility on 4/20/2009. The person had fallen about four feet off of the reactor head (while the reactor head was on the head stand). Due to the individual's injuries and difficulty in completing a full frisk, the individual was transported offsite as potentially contaminated. The plant representative that traveled to the hospital stated that the individual's clothing (protective clothing and modesty garments) was contaminated at 200 corrected cps above background. No skin contamination was identified. All material brought to the hospital from the site was transported

back to the site. The ambulance, other equipment, people, and structures that came in contact with the contaminated individual were surveyed and revealed no contamination.

Item Number 090488 - A uranium hexafluoride production facility experienced 40 events between 10/17/2008 and 3/29/2009 that involved leakage from process equipment. Three of these events were reported separately (see NMED Items 090237, 090314, and 090404). The material involved in each event was either natural uranium or UF4 (green salt) in the form of a dry powder or dust. The quantity of material in each event was conservatively assumed to have exceeded five times the lowest annual limit on intake (ALI), although this could not be confirmed for the majority of the events. In each event, appropriate protective measures were applied when contamination was discovered. Protective measures included turning on precautionary lights and requiring the wearing of respirators for personnel entering the affected areas. Cleanup of affected areas was conducted. A review of personnel bioassay data indicated no resulting increase in personnel dose measurements due to these events. Review of liquid and gaseous effluent data and sampling data from the restricted area boundary all indicated no significant increase in effluent measurements, and all analytical results were well within regulatory limits. There was no impact to plant workers or members of the public as a result of the events. Routine contamination surveys are being conducted in accordance with Health Physics program procedures and results are reviewed with the plant ALARA committee.

Item Number 090583 - A uranium hexafluoride production facility reported an unplanned contamination event that occurred on 7/10/2009, which resulted in additional radiological controls being required for more than 24 hours. The additional control imposed was the wearing of air purifying respirators in the affected area. The isotope responsible for the increased controls was natural uranium in the chemical form of UF4 (green salt). The amount of unplanned contamination that was released was estimated to exceed five times the ALI (3 grams). The airborne activity averaged approximately 2.26 uBq/ml (6.11E-11 uCi/ml). The processes in the area of elevated levels of airborne radioactivity have been secured and potential leakage paths are being investigated. The facility stated that bioassay sampling of any potentially exposed individuals will be performed within the routine sampling frequency, but prior to 7/30/2009.

Item Number 090589 - A university reported a contamination event that occurred during the administration of 136.9 MBq (3.7 mCi) of I-131 to a cat on 7/8/2009. An inspector from the Oklahoma Department of Environmental Quality was present during the treatment, though not in the injection room because of space concerns. The university's RSO directly observed the procedure and stated that the technician administering the dose appeared to have precisely followed procedures. The RSO did not report anything unusual except that the cat, which was enclosed in a bag, struggled somewhat. The problem was discovered when a radiation survey of the technician was performed and contamination was identified on protective clothing covering the hand and on the outer surface of the opposite forearm. Measurements revealed that the cat read 2.5 nSv/hour (0.25 urem/hour) at 30 cm, while measurements in the area where the cat was injected read over 0.6 mSv/hour (60 mrem/hour) without the cat being present. The university believes that the cat had not received the majority of the dose and that the majority of the I-131 ended up on the injection shelf and floor of the treatment room. Thyroid screening of the technician, RSO, and a control person with a NaI probe did not reveal any internal absorption. The technician did not have any removable contamination on her skin. A whole body scan at a hospital for the technician is being scheduled. She was also given potassium iodide. The area where the incident occurred has been closed off. The cat is being held in a cage in the room. The syringe assembly, carrying case, and all protective clothing worn by the technician are being preserved. The facility is getting advice from a team of experts and the investigation is ongoing. The event may have been caused by mechanical failure of the preloaded syringe assembly or the struggling cat may have caused the needle stick out through the subcutaneous injection site, which caused the dosage to be injected outside the cat.

Item Number 090646 - A hospital reported that an unplanned contamination incident occurred on 3/18/2009. A patient used the restroom shortly after receiving 9.25 GBq (250 mCi) of I-131. The toilet

overflowed upon flushing and contaminated the floor. Despite several attempts to decontaminate the floor, the room had to be sealed off for six days before contamination levels dropped to acceptable levels to be released for use. The hospital estimated that there was approximately 74 MBq (2 mCi) of I-131 contaminating the floor.

Events of Interest

None.

2.6 Leaking Sealed Sources

2.6.1 Ten-Year Data

Figure 7 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 7 displays the anomalous events as yellow shaded bars. The trend analysis determined that the Total and 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 NRC-regulated events (excluding the anomalous data) represent a statistically significant decreasing trend (indicated by the trend line).

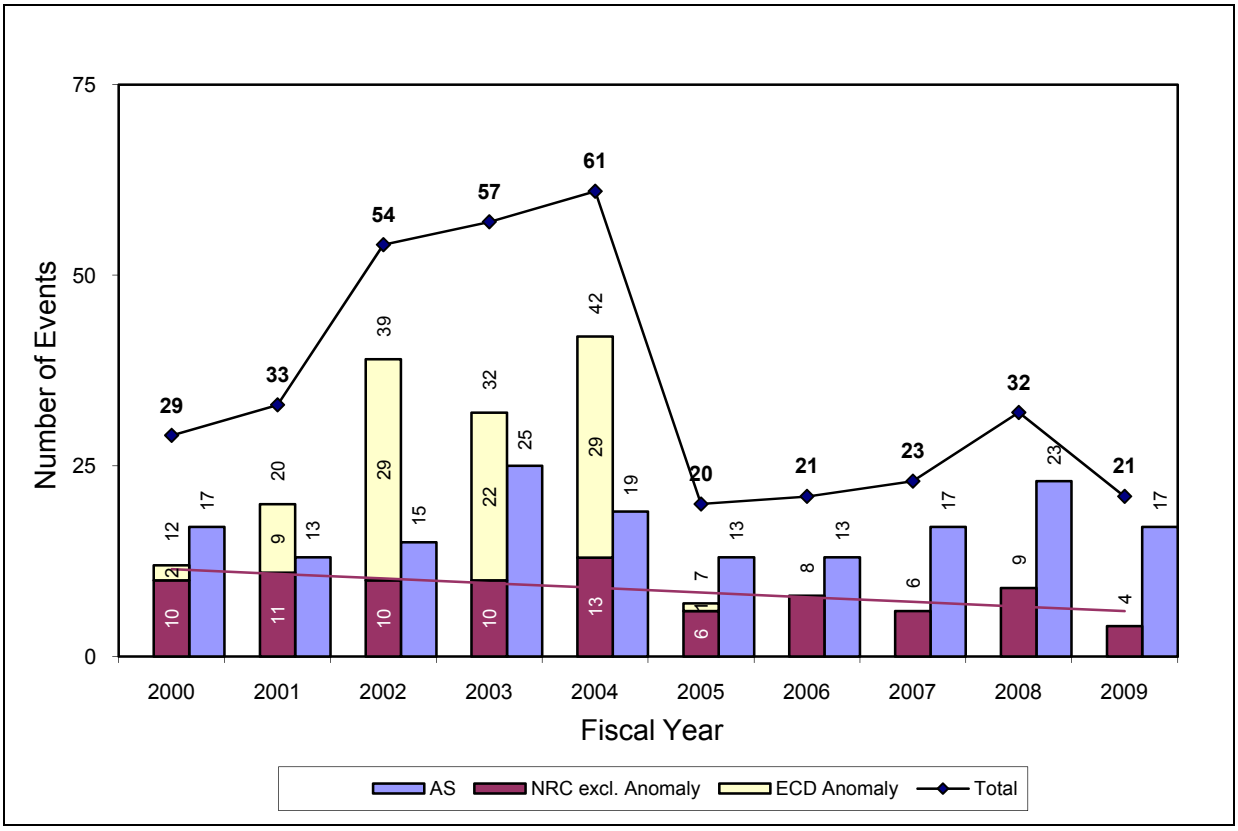


Figure 6. Leaking Sealed Source Events (351 total)

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

2.6.2 FY09 Data

Twenty-one LKS events occurred in FY09, two of which were classified as significant events.

Significant Events

Item Number 080792 - A radiation detection equipment manufacturing company reported breaching a 1.85 GBq (50 mCi) Cs-137 source while modifying a piece of calibration equipment. The RSO stated that the source was cut in half with a thin blade saw. Following the incident, the remaining sections of the

source were assayed and the activity was 1.78 GBq (48 mCi). A Texas Department of Health Services (TDHS) inspector was dispatched to the scene to investigate. Initial reports stated that 40 or more employees were involved and that contamination was spread by foot traffic throughout the facility. The company hired a contractor to perform assessment and decontamination activities beginning on 11/14/2008. The inspector identified that contamination levels were fairly low with some spots reading approximately five times background (between 10,000 and 15,000 cpm on a scintillation detector). The DOE Radiation Emergency Assistance Center/Training Site was contacted for guidance. Four employees identified as having potential intakes provided urine samples and received whole body counts on 11/19/2008. Three of those individuals received less than 0.1 mSv (10 mrem) CEDE from the incident. The fourth individual, who cut the source, received 0.3 mSv (30 mrem) CEDE. That individual stated that he covered his mouth with his jacket during the cutting process because it was creating a lot of dust. The company intends to provide whole body counts to all of their employees. The entire facility was posted and controlled as a contaminated area. The contamination was mostly on floor areas outside the work area. On 4/16/2009, the company stated that all areas had been decontaminated, surveyed, and released. On 5/6/2009, TDHS conducted radiological surveys of the facility. One small area less than 100 cm2 was identified above fixed release limits. That area was decontaminated and released. Corrective actions included modifying procedures and making an engineering change to the system. This event was classified as an EQP, LKS, and RLM event.

Item Number 090704 - A hospital reported that a brachytherapy seed removed from a patient's bladder following prostate implantation on 8/18/2009 was damaged and leaking. The seed contained an apparent activity of 30.34 kBq (0.82 uCi). Prior to completing the implant procedure, the physician imaged the bladder and identified two seeds in the bladder and a strand of seeds close to the bladder. The seeds and strand were removed from the patient with forceps. Post surgery, radiation monitoring revealed contamination on the strand, the two seeds, and urine that was collected during surgery. Steps were taken to identify the source of contamination as either from the removed sources or from sources that remained implanted. The catheter and Foley bag were exchanged and the patient's urine was monitored. The seeds and strand that were removed from the patient were rinsed, separated, and immersed in a solution to determine leakage. After approximately 10 minutes, one of the loose seeds showed over 2,000,000 dpm or 33.3 kBq (0.9 uCi) in the solution. The other loose seed and the strand were determined not to be leaking. The Foley bag was changed several times post operation. The leaking seed had a visible nick on the surface. Routine visual inspection of the seeds during surgical preparation revealed no anomalies. Urine from the patient during two hours in post operation was collected on a periodic basis while the patient was being heavily hydrated in an attempt to flush any residual contamination from his bladder. Radioactivity in the urine dramatically lessened. Arrangements were made to have the patient return in a few days for analysis of another urine sample and a direct thyroid scan. The urine sample revealed no radioactivity. The thyroid scan results were inconclusive due to the patient's elevated background. Based on the urinalysis, the hospital is confident that no leaking seeds remain in the patient. The hospital believes that the seed was damaged during removal from the patient. No corrective actions were necessary. This event was classified as an EQP and LKS event.

Events of Interest

Item Number 090102 - A hospital reported that a routine leak test of bulk I-125 brachytherapy seeds on 1/21/2009 revealed removable contamination at between 85.1 and 103.6 kBq (2.3 and 2.8 uCi). The hospital had 223 I-125 seeds stored in a container and could not determine which seeds were leaking. A leak test of the seeds conducted in October revealed no removable contamination. There were 164 seeds added to the storage container since that October leak test. The hospital contacted the seed vendor, who agreed to assay the seeds to determine which seeds are leaking. It is not known if the seeds were damaged during patient loading or by the manufacturer. The hospital stated that there is no reason to suspect that any leaking seeds were implanted into patients. However, all patients were contacted for bioassays. The total activity of the seeds in the vial was approximately 2.9 GBq (78.71 mCi). The vial of seeds was returned to the seed vendor on 1/21/2009. This event is classified as an EQP and LKS event.

Item Number 090358 - A university reported a damaged Am-241 source that contained an activity of 31,295 Bq (845.8 nCi) as of 10/1/2005. The source was discovered leaking during a routine inventory and leak test on 2/23/2009. A pinhole leak was discovered in the source's activity area. After further assessment on 2/24/2009, it was determined that more than half of the source activity was lost. Currently, there is 592 Bq (160 nCi) remaining on the source and 592 Bq (160 nCi) of contamination on the sponge insert in the source container. Approximately 1,924 Bq (521 nCi) of activity cannot be accounted for. The university performed contamination surveys of the source storage area, source use area, and the common laboratory area. The surveys were performed using a Geiger-Mueller instrument and pancake probe and wipes were counted using a liquid scintillation counter. No significant contamination was identified. The apparent cause of the incident was that the activity concentration was too great and the alpha particles and/or residual process chemicals destroyed the aluminized mylar backing, which allowed a significant amount of the Am-241 to escape. The university will properly dispose of the source as radioactive waste. They will not procure another similar source. This event was classified as an EQP, LAS, and LKS event.

Item Number 090368 - A hospital reported a potential leaking 11.17 MBq (302 uCi) I-125 brachytherapy seed. A patient was being treated for prostate cancer on 2/26/2009. Following a treatment of 15 I-125 seeds, the magazine used to inject the seeds into the patient was surveyed and indicated removable radioactive contamination. The staff initially believed that a seed was stuck inside the magazine. However, upon disassembly, the staff determined that the magazine was empty. The procedure continued without incident. The patient was x-rayed and all seeds were accounted for. A survey of the room, instruments, and packaging material revealed no removable contamination. The contamination was confined to the inside of the magazine. It was believed that either contaminated seeds were placed inside the magazine or a weld failed on a seed and it began to leak during the procedure. A physician prescribed a treatment to block uptake to the patient's thyroid. The patient's thyroid bioassay was indistinguishable from background and a blood test was negative for I-125. The patient's urine sample result was very close to background and very close to the counts associated with the hospital's 2.96 kBq (80 nCi) standard source. Thyroid scans and urine bioassays continued for the next eight weeks to determine if an implanted seed was leaking. The hospital notified the manufacturer of the incident and assumed that at some time they had received a leaking seed. Neither thyroid uptake studies nor urine bioassays of the patient revealed I-125 uptake. The hospital concluded that the patient had not received the leaking seed. They believe that the contaminated magazine came from another patient's procedure. The manufacturer had not detected radioactive contamination on the magazine prior to shipping. The patient was notified of the incident. The medical event aspect of this incident was retracted on 3/26/2009, but the event remains a reportable equipment failure and leaking source event. This event was classified as an EQP and LKS event.

Item Number 090418 - A hospital reported a leaking Cs-131 brachytherapy source that contained an apparent activity of 0.16 GBq (4.3 mCi) and a maximum actual activity of 2.41 GBq (65 mCi). Initial contamination was identified on 2/26/2009 on equipment used in a surgical area where implantation of brachytherapy sources occurs. Other associated equipment was assessed and additional contamination was detected on forceps, needles, loading trays, glass vials, spacers, and trash associated with preparation and administration on 2/25/2009. The hospital surveyed other equipment and sources which had been prepared in the area and by the same personnel to determine if cross contamination was present. None was detected. The hospital and the seed manufacturer assessed the impact on the treated patient if a confirmed leaking source had been implanted. It was determined that the affect on the patient treatment was negligible and that no significant change in the dose profile was expected. Contamination levels suggested that only one or two sources out of 98 implanted were potentially leaking. The hospital believes that the seed damage occurred at their facility because no contamination was identified on any incoming packaging, equipment related to assay of the sources, or the sterilization process. Contamination suggested that the rupture occurred at the time of loading. The hospital estimated a minimum leak test result of 5.92 kBq (0.16 uCi). Survey records for the hot lab and room used for

loading the seeds indicated that no contamination was detected during routine area surveys. Analysis of the incident indicated that if the procedures had been followed, the contamination would have been detected prior to the needle loading process. However, subsequent surveys identified significant contamination in associated wastes and other areas of use and storage. The hospital's investigation discovered that the individual responsible for performing the surveys and documenting the results had falsified the information. The individual later confirmed that fact and was subsequently terminated. Additional corrective actions included hiring new personnel and providing additional training to personnel. This event was classified as an EQP and LKS event.

2.7 Equipment

2.7.1 Ten-Year Data

Figure 9 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.

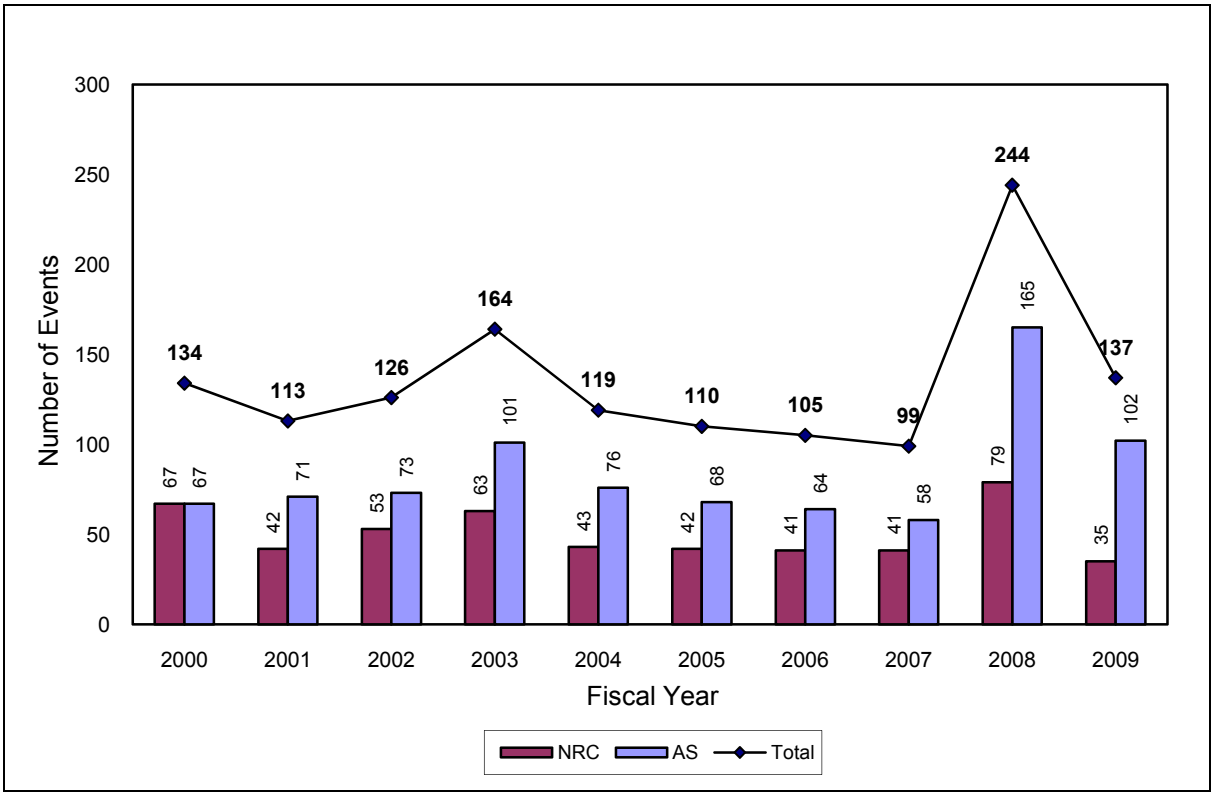


Figure 7. Equipment Events (1,351 total)

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.

In response to questions from NMED users, and to ensure accurate event coding, a change was made in the EQP event coding methodology. Previously, EQP events were marked as reportable, even if they did not meet all CFR reporting thresholds. For example, a damaged gauge event would have been marked reportable if it met one, but not necessarily all three thresholds of 30.50(b)(2)(i), (ii), and (iii). This coding practice primarily stemmed from NMED's original and underlying purpose as a means to capture operational experience for trending and historical research, not necessarily to limit inclusion to reportable events.

Starting 10/01/2006 (FY07), NMED only marks EQP events as reportable if they meet all applicable reporting thresholds [(i), (ii), and (iii)]. If the report to NMED is not sufficient to clearly determine that all thresholds were met, the event reportability will be coded as Uncertain, and the event will be included in the normal request for additional information process. If follow up information specifies that the event does not meet all thresholds, the reportability will be changed to Not Reportable.

The overall effect of this change will be a decrease in the number of EQP events. Note that this coding change will only be applied to NMED events entered or updated beginning 10/01/06, which will tend to cause or exacerbate decreasing trends.

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

2.7.2 FY09 Data

One hundred thirty-seven EQP events occurred in FY09, one of which was classified as a significant event.

Significant Events

Item Number 080722 - A petroleum refining company reported that a 9.62 GBq (260 mCi) Cs-137 source disconnected from a level measurement gauge. As a result of the source disconnect, four non-radiation workers received annual exposures that exceeded the limit. The individuals received 2.962, 0.960, 0.280, and 0.166 cSv (rem). On 10/28/2008, it was noted that the gauge was no longer giving proper readings and a maintenance crew was sent to perform repairs. Radiation surveys revealed elevated levels. The manufacturer was contacted and sent a technician to the facility. The technician identified elevated radiation levels and determined that the source had separated from the operating rod. The source was still located in the gauge housing, but was not shielded. On 10/29/2008, the manufacturer removed the gauge from the tank it was mounted on. The gauge and source were packaged for transportation back to the manufacturer's facility for inspection and repair. As of 12/22/2008, this incident was classified as an International Nuclear Event Scale level 2 event. This event was classified as an EQP and EXP event.

Events of Interest

Item Number 080625 - A radiography equipment manufacturer reported a 10 CFR 21 defect involving a radiography source assembly that could potentially cause a substantial safety hazard. The defect involved a female source connector and was only found in sources manufactured in specific lot. The manufacturer sold 659 Ir-192 sources and six Co-60 sources that utilized the defective connectors from that lot. An Ir-192 source disconnect incident that occurred on 8/21/2008 (NMED Item 080494) prompted the manufacturer to perform an investigation that identified the defect. It was determined that the defect could give the user the false impression that the source is connected to the drive cable when there is only a partial connection. The manufacturer also identified one Co-60 source retrieval event and requested that source be returned to them for evaluation (NMED Item 080566). Evaluation revealed that the defect could have contributed to the source disconnect event. Customers who have received a defective source from the specified lot have been contacted and arrangements have been made to determine if their sources contain the defect. If any source is suspected of being defective, the source will be replaced. The manufacturer decided that the supplier of the defective lot will be removed from their approved supplier list pending further evaluation of their production process. That will prevent their use as a supplier for components until completion of their evaluation and re-approval at a later date.

Item Number 080675 - A radiography equipment manufacturer reported a defective radiography source assembly that could potentially cause a substantial safety hazard. An Ir-192 source disconnect incident that occurred on 9/30/2008 (NMED Item 080639) prompted the manufacturer to perform an investigation that identified the defect. The defect was discovered on the inner sleeve of the connector. The circular recess for the ball of the male connector was undersized per specifications and prevented the ball from fully seating into the female connector, making it easier for the source wire to disconnect. All inventory of connectors using this defective lot of sleeves were 100% re-tested and defective parts were removed from inventory The affected customers are being notified of potential problems and will be advised to conduct inspections of male to female connections of the connector to ensure full engagement. Any suspect connections may be returned to the manufacturer for evaluation and replacement. All remaining lots of components (sleeves or other components) from the manufacturer's supplier are quarantined for re-

inspection or scrap. The supplier has been suspended from use. Further evaluation and investigations of the inner sleeves are on-going. This incident is also related to the incident captured in NMED Item 080811. The manufacturer stated that this incident involved a second 10 CFR Part 21 defect, distinct from the defect listed in NMED Item 080625.

Item Number 080792 - A radiation detection equipment manufacturing company reported breaching a 1.85 GBq (50 mCi) Cs-137 source while modifying a piece of calibration equipment. The RSO stated that the source was cut in half with a thin blade saw. Following the incident, the remaining sections of the source were assayed and the activity was 1.78 GBq (48 mCi). A Texas Department of Health Services (TDHS) inspector was dispatched to the scene to investigate. Initial reports stated that 40 or more employees were involved and that contamination was spread by foot traffic throughout the facility. The company hired a contractor to perform assessment and decontamination activities beginning on 11/14/2008. The inspector identified that contamination levels were fairly low with some spots reading approximately five times background (between 10,000 and 15,000 cpm on a scintillation detector). The DOE Radiation Emergency Assistance Center/Training Site was contacted for guidance. Four employees identified as having potential intakes provided urine samples and received whole body counts on 11/19/2008. Three of those individuals received less than 0.1 mSv (10 mrem) CEDE from the incident. The fourth individual, who cut the source, received 0.3 mSv (30 mrem) CEDE. That individual stated that he covered his mouth with his jacket during the cutting process because it was creating a lot of dust. The company intends to provide whole body counts to all of their employees. The entire facility was posted and controlled as a contaminated area. The contamination was mostly on floor areas outside the work area. On 4/16/2009, the company stated that all areas had been decontaminated, surveyed, and released. On 5/6/2009, TDHS conducted radiological surveys of the facility. One small area less than 100 cm2 was identified above fixed release limits. That area was decontaminated and released. Corrective actions included modifying procedures and making an engineering change to the system. This event was classified as an EQP, LKS, and RLM event.

Item Number 080811 - A technical college reported a radiography source disconnect that occurred on 11/13/2008. The incident involved an exposure device and a 1.62 TBq (43.9 Ci) Ir-192 source. The students cranked the source out to do the area survey. After completing the survey, they were unable to return the source to the exposure device. The RSO was contacted and determined a possible misconnect. The manufacturer was contacted, retrieved the source, and performed further evaluation. The exposure device and source were returned to the manufacturer. The cause was a defective male connection on the source assembly. This incident is related to NMED Item 080675.

Item Number 080862 - A medical equipment manufacturer reported a 10 CFR 21 issue related to high dose rate (HDR) afterloader sources becoming stuck during extension or retraction. An event occurred at a hospital on 12/2/2008, when a new source wire became jammed during the third position verification test procedure. The source contained 340.4 GBq (9.2 Ci) of Ir-192. Just prior to the test, a service contractor had completed a successful source exchange on the brachytherapy high dose rate remote afterloader unit. The source would not retract using the electronic devices provided on the unit. The source was manually retracted to the shielded position by a service technician within a few minutes of the event. The manufacturer believed that a small piece of debris prevented the source from fully retracting. Debris (very fine dust) was identified, a sample of which was sent to the manufacturer for analysis. The source, cable, and associated equipment were also packaged and returned to the manufacturer for further examination. The manufacturer stated that the fine debris was determined to be nickel-titanium dust, the same material the source wire is made of. To prevent recurrence, they established a maintenance protocol to remove and clean various components that have an accumulation of the debris. Two similar events occurred at other hospitals on 12/11/2008 and 12/30/2008. In each case, the problem occurred during a routine source exchange and patients were not involved. The emergency retract handle was used in each occurrence to retract the source into the HDR unit.

Item Number 090096 - A construction company reported that a moisture/density gauge was badly damaged when it was run over by a smooth drum roller on 1/22/2009. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. Initial radiation surveys were within expected levels near the gauge. However, while moving pieces of the gauge to the transportation case, the radiation levels increased. It was ultimately determined that the Cs-137 had become separated from the gauge, but had been resting under the gauge's shielding. The Am-Be source remained in the gauge. The contact dose rate for the Cs-137 source was 5 R/hour. A lead-shielded canister and lead shot were used to shield the Cs-137 source. The gauge pieces and sources were placed in a transport case and taken to the construction company's storage facility. The highest dose rate on contact with the transport case was 6 mR/hour. On 2/23/2009, a manufacturer representative picked up the gauge for disposal. Leak test results were negative. No significant radiation exposure was received and no contamination was identified.

Item Number 090237 - A uranium hexafluoride production facility reported that an unplanned contamination event occurred on 2/16/2009. Additional controls were imposed requiring wearing half-faced respirators in the affected area. Air samples from the area were analyzed and the airborne radioactivity average was approximately 3.06E-6 Bq/ml (8.27E-11 uCi/ml). The airborne radioactivity exceeded the action level of 30% of a DAC (1.85E-6 Bq/ml or 5.0E-11 uCi/ml). One DAC is 6.29E-6 Bq/ml (1.7E-10 uCi/ml). A material elevator was leaking around an inspection cover, which resulted in airborne uranium tetrafluoride (green salt). The facility attributes the contamination to a failed gasket. The airborne contamination was discovered during routine air sampling, which is performed daily. There is no plan to perform personnel testing for uptake or ingestion. See NMED Items 090314, 090404, and 090488 for similar events. This event was classified as an EQP and RLM event.

Item Number 090314 - Item Number 090314 - A uranium hexafluoride production facility reported that an unplanned contamination event occurred on 2/22/2009. Health physics personnel identified elevated average airborne radioactivity levels of approximately 2.26e-6 Bq/ml (6.12e-11 uCi/ml) in the affected area. Additional controls were imposed requiring wearing half-faced air purifying respirators. The highest average airborne radioactivity level was 3.06e-6 Bq/ml (8.27e-11 uCi/ml). During decontamination activities, the average airborne radioactivity remained elevated for more than 24 hours. Routine bioassays from the affected personnel indicated no elevated uptake of radioactivity. An equipment inspection determined that the cause of this event was a release of material from the uranium tetrafluoride (green salt) elevator and conveyor system. The facility will evaluate potential engineered controls to manage solids and reduce the pressure applied to the elevators during filter bumping. See NMED Items 090237, 090404, and 090488 for similar events. This event was classified as an EQP and RLM event.

Item Number 090358 - A university reported a damaged Am-241 source that contained an activity of 31,295 Bq (845.8 nCi) as of 10/1/2005. The source was discovered leaking during a routine inventory and leak test on 2/23/2009. A pinhole leak was discovered in the source's activity area. After further assessment on 2/24/2009, it was determined that more than half of the source activity was lost. Currently, there is 592 Bq (160 nCi) remaining on the source and 592 Bq (160 nCi) of contamination on the sponge insert in the source container. Approximately 1,924 Bq (521 nCi) of activity cannot be accounted for. The university performed contamination surveys of the source storage area, source use area, and the common laboratory area. The surveys were performed using a Geiger-Mueller instrument and pancake probe and wipes were counted using a liquid scintillation counter. No significant contamination was identified. The apparent cause of the incident was that the activity concentration was too great and the alpha particles and/or residual process chemicals destroyed the aluminized mylar backing, which allowed a significant amount of the Am-241 to escape. The university will properly dispose of the source as radioactive waste. They will not procure another similar source. This event was classified as an EQP, LAS, and LKS event.

Item Number 090368 - A hospital reported a potential leaking 11.17 MBq (302 uCi) I-125 brachytherapy seed. A patient was being treated for prostate cancer on 2/26/2009. Following a treatment of 15 I-125 seeds, the magazine used to inject the seeds into the patient was surveyed and indicated removable radioactive contamination. The staff initially believed that a seed was stuck inside the magazine. However, upon disassembly, the staff determined that the magazine was empty. The procedure continued without incident. The patient was x-rayed and all seeds were accounted for. A survey of the room, instruments, and packaging material revealed no removable contamination. The contamination was confined to the inside of the magazine. It was believed that either contaminated seeds were placed inside the magazine or a weld failed on a seed and it began to leak during the procedure. A physician prescribed a treatment to block uptake to the patient's thyroid. The patient's thyroid bioassay was indistinguishable from background and a blood test was negative for I-125. The patient's urine sample result was very close to background and very close to the counts associated with the hospital's 2.96 kBq (80 nCi) standard source. Thyroid scans and urine bioassays continued for the next eight weeks to determine if an implanted seed was leaking. The hospital notified the manufacturer of the incident and assumed that at some time they had received a leaking seed. Neither thyroid uptake studies nor urine bioassays of the patient revealed I-125 uptake. The hospital concluded that the patient had not received the leaking seed. They believe that the contaminated magazine came from another patient's procedure. The manufacturer had not detected radioactive contamination on the magazine prior to shipping. The patient was notified of the incident. The medical event aspect of this incident was retracted on 3/26/2009, but the event remains a reportable equipment failure and leaking source event. This event was classified as an EQP and LKS event.

Item Number 090418 - A hospital reported a leaking Cs-131 brachytherapy source that contained an apparent activity of 0.16 GBq (4.3 mCi) and a maximum actual activity of 2.41 GBq (65 mCi). Initial contamination was identified on 2/26/2009 on equipment used in a surgical area where implantation of brachytherapy sources occurs. Other associated equipment was assessed and additional contamination was detected on forceps, needles, loading trays, glass vials, spacers, and trash associated with preparation and administration on 2/25/2009. The hospital surveyed other equipment and sources which had been prepared in the area and by the same personnel to determine if cross contamination was present. None was detected. The hospital and the seed manufacturer assessed the impact on the treated patient if a confirmed leaking source had been implanted. It was determined that the affect on the patient treatment was negligible and that no significant change in the dose profile was expected. Contamination levels suggested that only one or two sources out of 98 implanted were potentially leaking. The hospital believes that the seed damage occurred at their facility because no contamination was identified on any incoming packaging, equipment related to assay of the sources, or the sterilization process. Contamination suggested that the rupture occurred at the time of loading. The hospital estimated a minimum leak test result of 5.92 kBq (0.16 uCi). Survey records for the hot lab and room used for loading the seeds indicated that no contamination was detected during routine area surveys. Analysis of the incident indicated that if the procedures had been followed, the contamination would have been detected prior to the needle loading process. However, subsequent surveys identified significant contamination in associated wastes and other areas of use and storage. The hospital's investigation discovered that the individual responsible for performing the surveys and documenting the results had falsified the information. The individual later confirmed that fact and was subsequently terminated. Additional corrective actions included hiring new personnel and providing additional training to personnel. This event was classified as an EQP and LKS event.

Item Number 090443 - During a March 2009 inspection at a hospital, an equipment failure involving a gamma knife unit was identified. During a patient treatment on 12/15/2008, the couch moved three feet out of the beam area. The emergency stop button was activated, but the system did not respond. Personnel manually pulled the couch out of the unit and closed the door to shield the Co-60 sources, which contained a total activity of 111 TBq (3,000 Ci). This event did not result in a medical event and the radiation exposure to all personnel involved with the incident was minimal. The manufacturer was

contacted, responded within 20 minutes, and repaired the gamma knife unit. Patient treatment resumed the same day and was completed without incident (the administered dose was within 1% of the prescribed dose). The manufacturer determined that this event was caused by a couch sensor error due to a known software problem.

Item Number 090466 - A hospital reported an equipment malfunction involving an HDR unit that resulted in a potential 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. It is unknown whether the 185 GBq (5 Ci) Ir-192 source wire successfully entered needle 13 as planned or if it 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 possibly differed by approximately 180 cGy (rad) to a small volume of the prostate in the vicinity of needle 13. If so, then the total dose to the prostate would differ from the prescribed dose by less than 5%. The incident could have 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 are: Sterilization of the extension adaptor (manufacturer's written product information cautions that sterilization may cause adhesive failure), and reuse of extension adaptors (manufacturer's written product information recommends for single use only). Corrective actions included providing additional training to personnel.

Item Number 090468 - A trash-to-energy plant reported that a shipment of commingled commercial and industrial trash set off their radiation monitor alarms on 4/16/2009. Department of Transportation (DOT) Exemption 11406 was issued and the load was returned to the originating facility. The waste was secured at the facility until a consultant could survey and process the load on 4/21/2009. The consultant separated out 190 intact industrial smoke detectors containing Ra-226 and 26 intact industrial smoke detectors containing Am-241. There were also about 20 smoke detectors that were broken into various pieces. Almost all of those devices had Ra-226 markings. The Am-241 detectors contained an activity of 2.96 MBq (80 uCi) each and the Ra-226 detectors contained an activity of 1.48 MBq (40 uCi) each. The consultant determined that the original owner of the smoke detectors was a fire suppression company. That company intends to bestow the detectors upon the successor company to the original distributor.

Item Number 090561 - A paper and packaging manufacturer reported that a fixed gauge fell about four feet off a digester blow line onto a grating platform. The gauge contained a 15.14 GBq (409.2 mCi) Cs-137 source. Staff working in the area noticed the gauge and alerted their supervisor and RSO. After ensuring the shutter was closed and the source was present, the gauge was moved to a secure location. Wipe surveys were performed to check for source leakage and contamination. Radiation meter surveys confirmed the presence of the source and identified normal dose rates. There is a concern that the welds failed, which attached the gauge to the mounting on the digester blow line. The gauge manufacturer was notified and assisted in the return of the gauge and further assessment of the cause of the failure.

Item Number 090564 - A veterinarian facility reported a potential personnel overexposure due to the malfunction of a teletherapy unit, which contained 137.83 TBq (3,725 Ci) of Co-60. The on/off indicator and entrance door interlock failed on 6/22/2009, resulting in two individuals entering the treatment room while the source was exposed. A cat was being treated when the malfunction occurred. A technologist wearing dosimetry entered the room, but did not get exposed to the direct beam of radiation. The veterinarian was exposed to the direct beam when he removed the cat from the treatment table. The veterinarian initially stated that his lower arms were in the beam for approximately 1.5 to 2 minutes. The direct radiation beam is approximately 70 R/minute at the treatment site. A California Health and Human

Services Agency (HHSA) inspector arrived at the facility on 6/24/2009 to investigate the incident. The technologist's dosimetry was submitted to the vendor for emergency evaluation. The facility suspended use of the teletherapy device pending results of the onsite investigation. Following an on-site re-enactment of the event, the HHSA determined that the veterinarian received between 1.8 and 3.6 mSv (180 and 360 mrem) to a portion of the whole body (left chest and shoulder) and between 3.0 and 6.0 mSv (300 and 600 mrem) to the forearms. The veterinarian was a radiation worker, but was not wearing dosimetry. It was determined that the source failed to retract to the fully shielded position when the unit was in the 180 degree position because the spring tension had decreased during use. The spring tension was increased. Corrective actions included revising operating and emergency procedures for the teletherapy unit, retraining staff in the revised procedures, and performing emergency drills at least semiannually.

Item Number 090598 - A hospital reported an equipment failure involving a gamma knife unit. During a patient treatment on 5/18/2009, the couch moved out of the beam area. The emergency stop button was activated, but the system did not respond. Personnel manually pulled the couch out of the unit and closed the door to shield the Co-60 sources, which contained a total activity of 111 TBq (3,000 Ci). This event did not result in a medical event and the radiation exposure to all personnel involved with the incident was minimal. The manufacturer was contacted, responded to the site, and repaired the gamma knife unit. Patient treatment resumed the same day and was completed without incident. The manufacturer determined that this event was caused by a couch sensor error due to a known software problem.

Item Number 090647 - A paper and packaging manufacturer reported that the failure of the shutter on a generally licensed fixed gauge, which contained a 2.96 GBq (80 mCi) Cs-137 source. The gauge was removed by the manufacturer on 12/11/2008 from its installed location and was placed into storage pending disposal. On 7/30/2009, the manufacturer's representative was onsite to remove and package a total of 14 decommissioned gauges for disposal. A Washington Department of Health (DOH) inspector was onsite to conduct a reciprocity inspection of the manufacturer's activities. Several of the gauges showed varying degrees of corrosion. The gauge showed significant corrosion and was missing a cover plate. The manufacturer's representative reported no unusual radiation measurements prior to packaging activities. However, during packaging the gauge was rolled over and the DOH inspector measured a dose rate of 500 mR/hour at the opening. The manufacturer's representative adequately secured and shielded the gauge prior to shipment. The Cs-137 source had a decayed activity of 1.87 GBq (50.4 mCi) on 7/30/2009. Apparently the shutter and lead shielding was either broken or misaligned and failed to function as designed. There was no significant exposure to personnel.

Item Number 090702 - A petroleum service company reported that a mobile slurry unit, in which a density gauge was mounted, caught fire on 9/2/2009. The gauge contained a 7.4 GBq (200 mCi) Cs-137 source. The incident occurred at an oil field temporary job site. The fire melted the lead at the top of the shield, thereby exposing the source (as evidenced by elevated radiation readings with a survey meter). It was confirmed that the source remained in the holder and no release of radioactive material occurred. The gauge manufacturer properly packaged the gauge and transported it to their facility on 9/3/2009.

Item Number 090704 - A hospital reported that a brachytherapy seed removed from a patient's bladder following prostate implantation on 8/18/2009 was damaged and leaking. The seed contained an apparent activity of 30.34 kBq (0.82 uCi). Prior to completing the implant procedure, the physician imaged the bladder and identified two seeds in the bladder and a strand of seeds close to the bladder. The seeds and strand were removed from the patient with forceps. Post surgery, radiation monitoring revealed contamination on the strand, the two seeds, and urine that was collected during surgery. Steps were taken to identify the source of contamination as either from the removed sources or from sources that remained implanted. The catheter and Foley bag were exchanged and the patient's urine was monitored. The seeds and strand that were removed from the patient were rinsed, separated, and immersed in a solution to determine leakage. After approximately 10 minutes, one of the loose seeds showed over 2,000,000 dpm or 33.3 kBq (0.9 uCi) in the solution. The other loose seed and the strand were determined not to be

leaking. The Foley bag was changed several times post operation. The leaking seed had a visible nick on the surface. Routine visual inspection of the seeds during surgical preparation revealed no anomalies. Urine from the patient during two hours in post operation was collected on a periodic basis while the patient was being heavily hydrated in an attempt to flush any residual contamination from his bladder. Radioactivity in the urine dramatically lessened. Arrangements were made to have the patient return in a few days for analysis of another urine sample and a direct thyroid scan. The urine sample revealed no radioactivity. The thyroid scan results were inconclusive due to the patient's elevated background. Based on the urinalysis, the hospital is confident that no leaking seeds remain in the patient. The hospital believes that the seed was damaged during removal from the patient. No corrective actions were necessary. This event was classified as an EQP and LKS event.

Item Number 090753 - A nuclear fuel fabrication facility reported a high heat event/fire in the packed column scrubber in the exhaust gas treatment system which occurred on 9/27/2009. The incinerator was shutdown on 9/25/2009 in preparation for performing efficiency testing of the final high-efficiency particulate air (HEPA) filters in the uranium recovery exhaust gas treatment system. The high heat event/fire was terminated in a timely fashion by reinitiating water flow to the packed column. Indications of high heat and possible fire in the packed column included high temperatures and observed smoke from mechanical flanges on the downstream ducting of the packed column. Subsequent to the observed high heat event in the packed column, high temperatures of the downstream north HEPA housing (in service) were observed. The high temperatures in the HEPA housing were believed to be from the high heat event in the packed column. The continuous airborne effluent sample for the stack downstream of the HEPA filters was counted to evaluate whether a release had occurred. The results of the sample were at the low end of the normal range for that stack, indicating no active release had occurred. Continuous monitoring of the system assured the termination of the packed column and HEPA housing high heat event. The systems were continuously monitored and cooled down to near ambient conditions on 9/28/2009. A valve was removed between the quench column and the packed column of the scrubber system. The valve on the packed column side showed high heat damage. A visual inspection on the bottom of the packed column indicated significant degradation of the internals, including the lower fiberglass distribution plate and high surface area polypropylene balls. That evidence pointed to a high heat event/fire within the packed column. The ignition source is still under investigation as the furnace was completely cold. There is an electric re-heater mounted immediately above the packed column which may have been the ignition source. Disassembly of the packed column is awaiting access platform construction. The HEPA filter housing was opened on 10/1/2009 for inspection. Significant deterioration was identified of one of the two HEPA units in each of the primary and final banks. A Condition Report in the Corrective Action Program has been initiated and a casual analysis is being performed.

Item Number 090816 - A radiography company reported the inability to retract a 3.145 TBq (85 Ci) Ir-192 source into the radiography exposure device on 8/20/2009. The company stated that personnel dosimeters went offscale during the incident. Personnel radiation monitoring badges were sent to the vendor for emergency processing. Preliminary reports indicate that the highest exposure was 4.5 mSv (450 mrem). The Alabama Office of Radiation Control investigated the incident and determined that a crimped source guide tube was the reason for the inability to retract the source. The damaged guide tube was taken out of service and replaced with a new guide tube.

2.8 Transportation

2.8.1 Ten-Year Data

Figure 9 displays the annual number and trend 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.

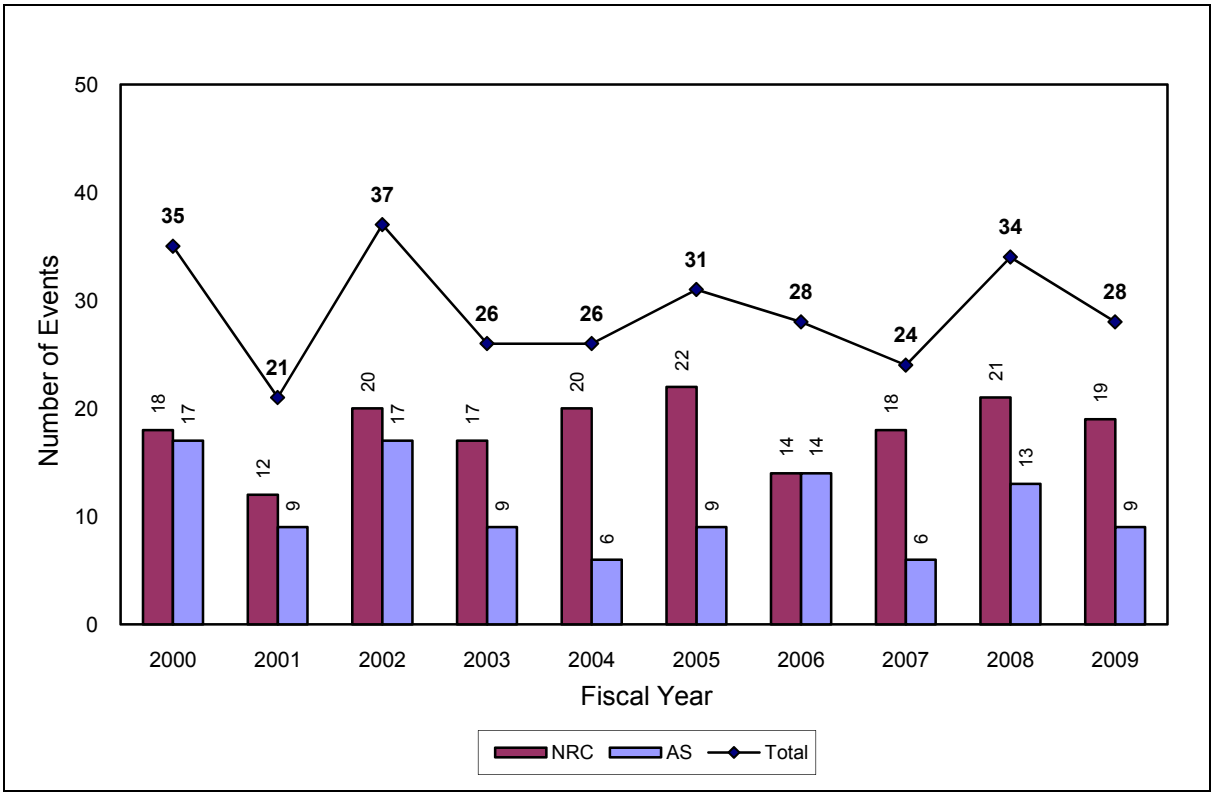


Figure 8. Transportation Events (290 total)

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

2.8.2 FY09 Data

Twenty-eight TRS events occurred in FY09, three of which were classified as significant events.

Significant Events

Item Number 090377 - A nuclear services company received a package from a commercial nuclear power plant on 10/29/2008 with external radiation levels exceeding the limit of 2 mSv/hr (200 mrem/hr). Using a Geiger-Mueller instrument, the dose rate on the underside of the package was approximately 16 mSv/hr (1,600 mrem/hr). Using an ion chamber instrument, the dose rate was approximately 8 mSv/hr (800 mrem/hr). Measurements at all other locations were within regulatory limits. After completing several confirmatory surveys on 10/31/2008, the nuclear services company notified the power plant and the carrier of the discrepancy. The package consisted of a metal box and contained items that had surface contamination. The items included fuel inspection equipment shipped under exclusive use conditions in accordance with 49 CFR 173.427. The radioactive material was a mixture of solid metal oxides, including Mn-54, Fe-55, Co-58, Co-60, Zr-95, Nb-95, Ag-110m, Sb-124, Sb-125 and Cs-134 as surface contamination. The total activity manifested for the package was 1.2 GBq (32.4 mCi). The maximum

external surface dose rate listed on the manifest at the time of shipment was 1.7 mSv/hour (170 mrem/hour) on contact. The location of the maximum external surface dose rate was a discrete point on the bottom of the package and at the approximate center of the package, and was determined to be a discrete radioactive particle. The hot particle was determined to be Co-60 with an estimated activity of 74 MBq (2 mCi). This event was caused by shifting of the equipment inside the package, which was caused by the failure to properly prepare the package for shipment. Subsequent evaluations also determined that five of the ten individuals involved in preparing the shipment had not received function-specific training. Corrective actions included generating new procedures and personnel training.

Item Number 090394 - A medical imaging products manufacturer received a package of 37 GBq (1 Ci) of F-18 from a radiopharmacy on 3/18/2009 that had a 1.7R/hr external dose rate. The manufacturer immediately contacted the radiopharmacy and notified them of the dose rate. The radiopharmacy determined that the shielding somehow moved enroute. The manufacturer accepted the delivery and placed the package in a restricted room. Corrective actions taken by the radiopharmacy included suspending subsequent similar shipments and revising and retesting packaging.

Item Number 090398 - A university received a Yellow II package on 3/18/2009 that exceeded external radiation level limits. The package contained two sealed Cs-137 sources. One source contained 1.36 GBq (36.8 mCi) and the other 0.44 GBq (11.77 mCi) for a combined activity of 1.8 GBq (48.6 mCi). A medical center had sent the two Cs-137 sources to the university for calibration. Radiation alarms went off at the loading dock and at the calibration laboratory when the package was delivered. The transportation index on the package stated 0.2. However, the exposure rate was 900 mR/hour on contact and 20 mR/hour at one meter. A wipe test of the package did not identify any removable contamination. The university's RSO concluded that the two sealed sources were outside of the lead-shielded container. The RSO contacted the medical center and the courier. The individual that prepared the package stated that the package must have been opened either during transport or by the calibration laboratory. The university emphatically stated that they had not opened the package. A State of Wisconsin inspector made arrangements to be present on 3/20/2009 to monitor the opening of the package. On 3/20/2009, the package was carefully opened and multiple wipe tests were conducted to assure that there was no contamination inside the package. The package contained an open lead pig. The sources were loose in the box. One source was located under the bottom of the styrofoam tray and the other was stuck in the styrofoam tray. There were multiple problems with the packaging, markings, and shipping paperwork. The main problems were that the lead pig was not adequately taped shut and the inner packaging was not sufficient to hold the pig in place. It did not appear that this was an approved shipping container. The sealed sources were wipe tested and were not leaking. The university stated that the package did not appear to have the same packaging as described by the medical center. Specifically, there was clear tape on the outer box and there was no bubble wrap inside the box. The medical center stated that paper tape and bubble wrap were used. The courier's RSO denied that the package was opened by their personnel during shipment. The U.S. Department of Transportation (DOT) investigated the incident and identified several violations pertaining to DOT regulations. The root cause of the incident was that medical center personnel were not properly trained on DOT requirements/regulations. The medical center failed to use the packaging required by the Type A container certification. Corrective actions taken by the university included discussing the reporting and notification requirements with personnel during radiation safety office staff meeting and developing a poster describing reportable events. Corrective actions taken by the medical center included providing DOT training and certification to personnel performing packaging and shipping radioactive material responsibilities.

Events of Interest

Item Number 090454 - A nuclear services company reported a leaking tank trailer containing a total activity of 743.7 MBq (20.1 mCi) of various radionuclides. The leakage was identified at a Point of Entry Station in Helper, Utah, on 3/31/2009. The Point of Entry supervisor observed that colored material had splashed onto the side of the tank, estimating a loss of approximately 1/2 gallon of contaminated fluid.

The fluid had run down the side of the tank and was dripping on the ground. Carbon County Sheriff personnel were contacted, arrived on the scene, and spread kitty litter beneath the leak to absorb the material. The nuclear services company personnel arrived on the scene that evening. It was determined that the contaminated fluid was dripping from a break in the pressure gauge hose located at the rear of the tank. The hose was severed into two sections. Both loose ends of each hose section had been taped with duct tape. The hose was disconnected and both valves were plugged. The nuclear services company personnel collected the kitty litter that had been contaminated. Radiation surveys were performed to assure that all contaminated material had been collected. Materials collected were placed in six or seven one-gallon containers for transportation to the nuclear services company facility. The tank was returned to the facility on 4/1/2009. The radionuclide activity in the tank totaled 743 MBq (20.08 mCi), primarily consisting of 739 MBq (19.97 mCi) of H-3, with small contributions from Tc-99, Th-228, Th-232, U-233, U-234, U-235, U-236, and U-238. The tank contained approximately 3000 gallons of contaminated fluid at the time of shipment. The nuclear services company had performed an inspection of the tank prior to shipment, but had missed the fact that the hose was severed and had been taped.

Item Number 090650 - A uranium hexafluoride production facility reported that a vehicle accident involving a UF6 shipment occurred on 8/2/2009. Shortly after midnight, a tractor-trailer carrying a cylinder (model 48Y) containing approximately 28,000 pounds of non-enriched UF6 overturned on Interstate 64, near Sandstone, West Virginia. Local authorities, including law enforcement and hazardous material (HAZMAT) response agencies, responded to the scene and closed Interstate 64. Local authorities initially ordered a precautionary evacuation for the town of Sandstone. The cab of the tractor-trailer was involved in a fire that was subsequently extinguished. The fire had no affect on the UF6 cylinder, which separated from the trailer during the accident. HAZMAT crews at the scene reported that there had been no release of UF6. The uranium hexafluoride production facility dispatched a four-person team to assess the cylinder for damage prior to moving it to another trailer. The team determined that the cylinder sustained only minor cosmetic damage (limited to one bent lifting lug) and verified that there was no leakage. The cylinder was reloaded on another vehicle and was returned to the uranium hexafluoride production facility.

Item Number 090666 - A well logging company reported a radiation overexposure to a member of the public during transportation of a 92.5 GBq (2.5 Ci) Cs-137 source on 7/12/2009. The source was shipped via common carrier from Arkansas to Texas. One month after receiving the source in Texas, the well logging company discovered that the source had been shipped in a container designed to carry a 185 GBq (5 Ci) Am-Be source. The well logging company recreated the event and determined that the dose rate in the cab of the transport truck was 0.25 mSv/hour (25 mrem/hour). The trip was estimated to take six hours to complete, resulting in a calculated dose to the driver of 1.5 mSv (150 mrem). The driver was informed of the incident. The driver was offered medical assistance, which he refused. The individual who surveyed the package before it left Arkansas stated that he did not observe any unusual dose rates. Corrective actions included providing additional training to personnel involved in the packaging of the source. The Texas Department of State Health Services and the Arkansas Department of Health investigated the possibility of other individuals receiving radiation exposure from the incident. This event was classified as an EXP and TRS event.

Item Number 090775 - A nuclear fuel fabrication facility reported that Certificate of Compliance conditions for a shipping container were not followed. The facility routinely ships low-enriched UO2 pellets to a facility in Germany. Beginning in May 2005, the facility was required to obtain individual Transit Certificates for each use of the shipping container transiting United Kingdom (UK) territorial waters. On 4/1/2009, the facility determined that two Transit Certificates were invalid because they had been altered by one of their employees. The UK Department of Transportation subsequently identified a third altered Transit Certificate. The employee altered the Transit Certificates due to schedule pressures. Corrective actions included disciplinary action against the employee, procedure modification, and personnel training.

2.9 Other

2.9.1 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.

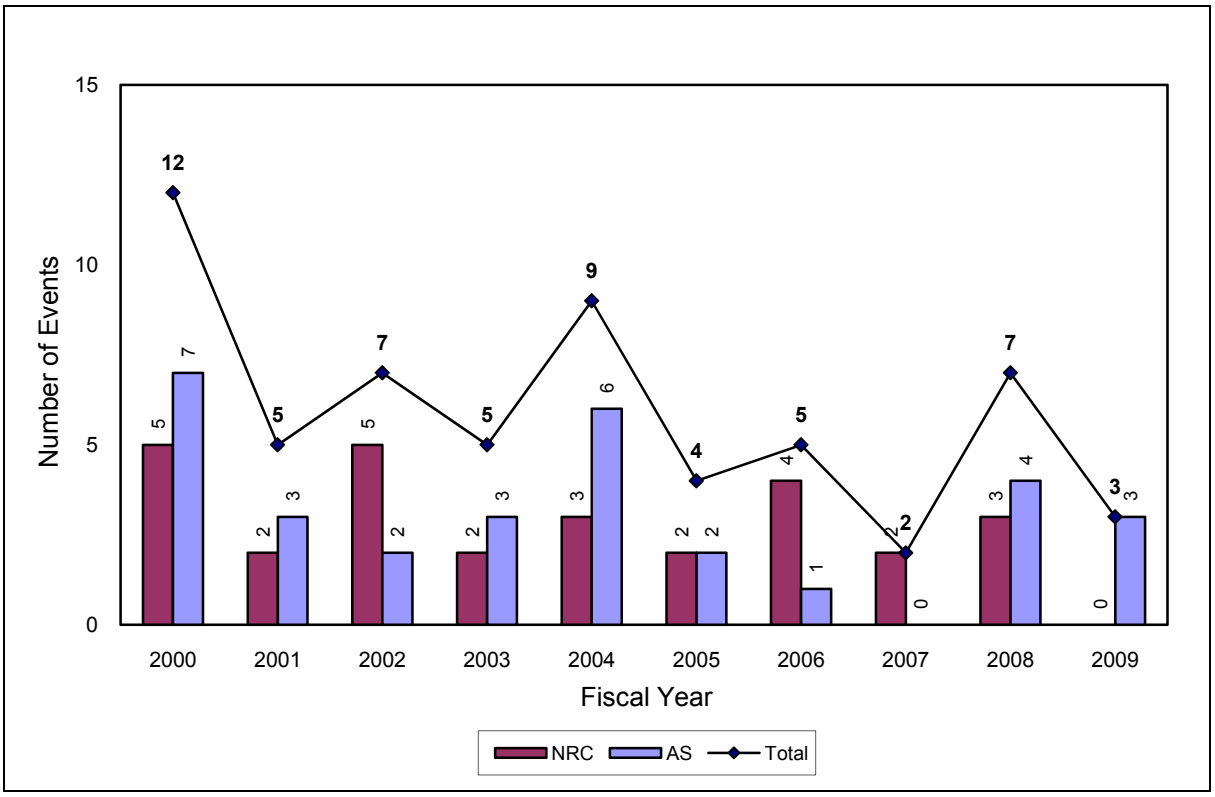


Figure 9. Other Events (59 total)

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

2.9.2 FY09 Data

Three OTH events occurred in FY09, two of which were classified as significant events.

Significant Events

Item Number 090579 - A pregnant patient was administered 2 GBq (54.1 mCi) of I-131 on 3/30/2009. The patient had a false negative pregnancy test on 3/30/2009. The authorized user contacted the patient's obstetrician/gynecologist and it was determined that the therapy was administered five days post-conception. The dose equivalent to the embryo/fetus is 11.9 cGy (rad), with 0.97 cGy (rad) to the embryo/fetus thyroid. Corrective actions included that the staff plans to over-emphasize the risks associated with becoming pregnant following administration of radioiodine.

Item Number 090755 - A pregnant patient was administered 925 MBq (25 mCi) of I-131 on 9/21/2009. The patient had undergone pregnancy screening consisting of interviews and a urine-based pregnancy test with negative results. Eight days after the administration, the patient missed an expected menstrual cycle and performed a home pregnancy test with positive results. That test result was confirmed with a positive serum-based test on the same day administered by her physician. The authorized user estimated that

conception would have been approximately three weeks prior to administration. TEDE estimates are approximately 6.7 cSv (rem) to the embryo, with no thyroid developed at this stage of pregnancy. The patient was advised of the incident. No general corrective actions are anticipated, but the event will be used as an opportunity for refresher training and a risk audit.

Events of Interest

Item Number 090075 - A paper and packaging manufacturer reported that maintenance personnel removed a fixed gauge (Kay-Ray/Sensall model 7063-P, serial #S96L2501) and failed to close the shutter. The gauge contained an 18.5 GBq (500 mCi) Cs-137 source. The manufacturer performed a reenactment of the incident and dose calculations. The maximum dose calculated was 547 uSv (54.7 mrem). Personnel from the Alabama Office of Radiation Control were dispatched on 12/17/2008 to investigate and determined that the maximum dose to any one person was less than 10 uSv (1 mrem). The incident was caused by maintenance personnel not following written procedures and not notifying the RSO prior to removing the gauge. Corrective actions included revisions to the annual radiation safety training program, revisions to policy procedures for lock out/tag out of gauges containing radioactive material, discussions with personnel on the incident and reviews of the radiation safety policies, training for appropriate personnel in the closing and locking of shutters, and the relocation of the radiation sign that was temporarily removed.

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.

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. Abandoned well logging sources are included in this category. LAS events are categorized as follows:

1. Any lost, stolen, or missing licensed material in an aggregate quantity greater than or equal to 1,000 times the quantity specified in Appendix C to 10 CFR 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.
2. Any lost, stolen, or missing licensed material in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR 20.
3. An irretrievable well logging source. Note, although these events are entered into the NMED as LAS events for tracking purposes, once they have been properly dispositioned in accordance with 10 CFR 39.77, they are not considered lost and are therefore excluded from this report.
4. An attempt made, or believed to have been made, to commit a theft or unlawful diversion of more than 10 Ci of H-3 at any one time or more than 100 Ci in any one calendar year.
5. An attempt made, or believed to have been made, to commit a theft or unlawful diversion of more than 15 pounds of source material at any one time or more than 150 pounds of source material in any one calendar year.
6. An attempt made, or believed to have been made, to commit a theft or unlawful diversion of special nuclear material.
7. Any loss (other than normal operating loss), theft, or unlawful diversion of special nuclear material.

Medical (MED)

10 CFR 35 was revised effective October 24, 2002. For events that occurred after this date, medical events are defined as follows:

1. Any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:
   a) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
      - the total dose delivered differs from the prescribed dose by 20% or more;
      - the total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or
      - the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.
   b) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

- an administration of a wrong radioactive drug containing byproduct material;
- an administration of a radioactive drug containing byproduct material by the wrong route of administration;
- an administration of a dose or dosage to the wrong individual or human research subject;
- an administration of a dose or dosage delivered by the wrong mode of treatment; or
- a leaking sealed source.

c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

10 CFR 35 was revised effective October 24, 2002. For events that occurred prior to this date, medical events are defined as follows:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:
   a) Involving the wrong individual, or wrong radiopharmaceutical; or
   b) When both the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.
2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:
   a) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
   b) When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage.
3. A gamma stereotactic radiosurgery radiation dose:
   a) Involving the wrong individual, or wrong treatment site; or
   b) When the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose.
4. A teletherapy radiation dose:
   a) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
   b) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;
   c) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30% or more of the weekly prescribed dose; or
   d) When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.
5. A brachytherapy radiation dose:
   a) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
   b) Involving a sealed source that is leaking;

c) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

d) When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose.

6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

   a) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

   b) When the dose to the individual exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

Events are not considered MED events if they involve:

1. Only accelerator produced radiopharmaceuticals.
2. Only a linear accelerator.
3. A dose calculation error made by the prescribing physician that was administered as (incorrectly) prescribed.
4. Patient intervention.

Events are considered MED events if they involve:

1. A radiopharmaceutical containing by-product material was prescribed, but a radiopharmaceutical containing accelerator produced material was administered.
2. A radiopharmaceutical containing accelerator produced material was prescribed, but a radiopharmaceutical containing by-product material was administered.
3. A linear accelerator is used for therapy by mistake instead of a teletherapy unit or a teletherapy unit instead of a linear accelerator.

MED events occur to patients only. Hospital patients are always considered to be patients, rather than members of the general public, for purposes of determining whether to categorize an event as an MED or EXP event. For example, if a patient was administered a radiopharmaceutical that was prescribed for another patient, the event would be categorized as an MED event (radiopharmaceutical given to the wrong patient) rather than an EXP event.

Radiation Overexposure (EXP)

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 classified into the NMED Event Table 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 events are categorized as follows:

1. A total effective dose equivalent of 0.25 Sv (25 rem) or more.
2. A total effective dose equivalent exceeding 0.05 Sv (5 rem) in a period of 24 hours.

3. An eye dose equivalent of 0.75 Sv (75 rem) or more.
4. An eye dose equivalent exceeding 0.15 Sv (15 rem) in a period of 24 hours.
5. A shallow-dose equivalent to the skin or extremities of 2.5 Gy (250 rad) or more.
6. A shallow-dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem) in a period of 24 hours.
7. A dose in excess of the occupational dose rate for adults in 20.1201.
8. A dose in excess of the occupational dose limits for a minor in 20.1207.
9. A dose in excess of the limits for an embryo/fetus of a declared pregnant woman in 20.1208.
10. A dose in excess of the limits for an individual member of the public in 20.1301
11. A dose in excess of any applicable limit in the license.

Release of Licensed Material or Contamination (RLM)

The RLM event category includes two types of events. The first type is a radioactive release to air or water exceeding the old 10 CFR Part 20 appendix governing maximum permissible concentrations (MPCs) or the new 10 CFR Part 20 appendix containing annual limit on intakes (ALIs). 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, or air, or water) or areas of contamination associated with the release, this information is classified individually into the NMED Event Table. RLM events are categorized as follows:

1. An unplanned contamination event that requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.
2. An unplanned contamination event that involves a quantity of material greater than five times the lowest ALI specified in Appendix B of 10 CFR 20.
3. An unplanned contamination event that has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
4. The release of radioactive material, inside or outside of a restricted area, such that had an individual been present for 24 hours, the individual could have received an intake five times the ALI (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).
5. The release of radioactive material, inside or outside of a restricted area, such that had an individual been present for 24 hours, the individual could have received an intake in excess of one ALI (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).
6. Levels of radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the license.
7. Levels of radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times any applicable limit set forth in 10 CFR 20 or in the license (whether or not involving exposures of any individual in excess of the limits in 10 CFR 20.1301).

8. For licensees subject to the provisions of the Environmental Protection Agency's (EPA's) generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.
9. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
10. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when the quantity of material involved is greater than five times the lowest ALI specified in Appendix B of 10 CFR 20.

Leaking Sealed Source (LKS)

The LKS event category includes events involving leaking sealed 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. A source is considered leaking if a leak test can detect greater than 0.005 μCi 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 30. Some specific reporting criteria are also listed in 10 CFR 31 (generally licensed material), 10 CFR 34 (radiography), and 10 CFR 35 (medical use of byproduct material).

Equipment (EQP)

The EQP event category includes all types of radiological equipment problems, including generally licensed device problems covered in 10 CFR 31; radiography equipment problems covered in 10 CFR 34; irradiator problems covered in 10 CFR 36; well logging problems covered in 10 CFR 39, and other types of equipment covered in 10 CFR 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 material as an integral part, or whose function is to interact with such material.

Examples of these problems include such things as a radiography source disconnect, a moisture density gauge being run over by a bulldozer, an irradiator source rack drive cable breaking, a well logging source being ruptured during a source recovery attempt, a fan motor failure in an exhaust hood used to store radioiodine, failure of a glove box connector gasket, or a damaged Type B shipping container. The radioactive material or source need not be damaged or leaking for the event to be considered an EQP event. Damage to a device housing, shutter, operation controls, or even a version of a software containing an error are covered in this category.

1. A defect or non-compliance involving the construction or operation of a facility or an activity that is subject to the licensing requirements under 10 CFR Parts 30, 40, 50, 60, 61, 70, 71, or 72.
2. A defect or non-compliance involving a basic component that is supplied for a facility or an activity that is subject to the licensing requirements under 10 CFR Parts 30, 40, 50, 60, 61, 70, 71, 72 or 76.
3. A piece of equipment that is disabled or fails to function as designed when the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive material exceeding regulatory limits, or to mitigate the consequences of an accident.
4. A piece of equipment that is disabled or fails to function as designed when the equipment is required to be available and operable.
5. A piece of equipment that is disabled or fails to function as designed when no redundant equipment is available and operable to perform the required safety function.

6. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when the damage affects the integrity of the licensed material or its container.
7. The actual or possible failure of, or damage to, the shielding of radioactive material or the on-off mechanism or indicator on a generally licensed device.
8. An unintentional disconnection of a radiography source assembly from the control cable.
9. The inability to retract a radiography source assembly to its fully shielded position and secure it in this position.
10. The failure of any radiography component (critical to safe operation of the device) to properly perform its intended function.
11. An irradiator source stuck in an unshielded position.
12. Damage to an irradiator's source racks.
13. Failure of the cable or drive mechanism used to move an irradiator's source racks.
14. Inoperability of an irradiator's access control system.
15. Structural damage to an irradiator's pool liner or walls.
16. Abnormal water loss or leakage from an irradiator's source storage pool.
17. Irradiator pool water conductivity exceeding 100 microsiemens per centimeter.
18. A licensee knows, or has reason to believe, that a well logging sealed source has been ruptured.

Transportation (TRS)

The TRS category includes a variety of transportation related events as follows:

1. The presence of removable surface contamination that exceeds the limits of Section 71.87(I).
2. The presence of external radiation levels that exceed the limits of Section 71.47.
3. Any significant reduction in the effectiveness of any approved Type B or fissile packaging during use.
4. Any defects with safety significance in Type B or fissile packaging after first use with the means employed to repair the defects and prevent their recurrence.
5. The conditions of approval in the certificate of compliance were not observed in making a shipment.
6. An accident involving a vehicle carrying licensed material regardless of whether the licensed material is damaged or spilled as a result of the accident.
7. Fire, breakage, spillage, or suspected contamination involving shipment of radioactive material.

Other (OTH)

The OTH event category includes the following types of events:

1. Doses to an embryo/fetus or nursing child. According to 10 CFR 35.2, these are not medical events.
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 categories.
4. Events not reportable to the NRC but included in the NMED program for informational purposes.

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),..., (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

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

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

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

This quantity is the number that is minimized in order to find the estimates of α 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

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

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

$$SSE + SSR = SST \,, \tag{B-8}$$

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

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

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:

$$r^2 = \frac{SSR}{SST} \,. \tag{B-10}$$

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

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

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.

1. 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.
2. 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.
3. 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]	TBq	Ci [1]	TBq	Ci [1]	TBq	Ci [1]	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.

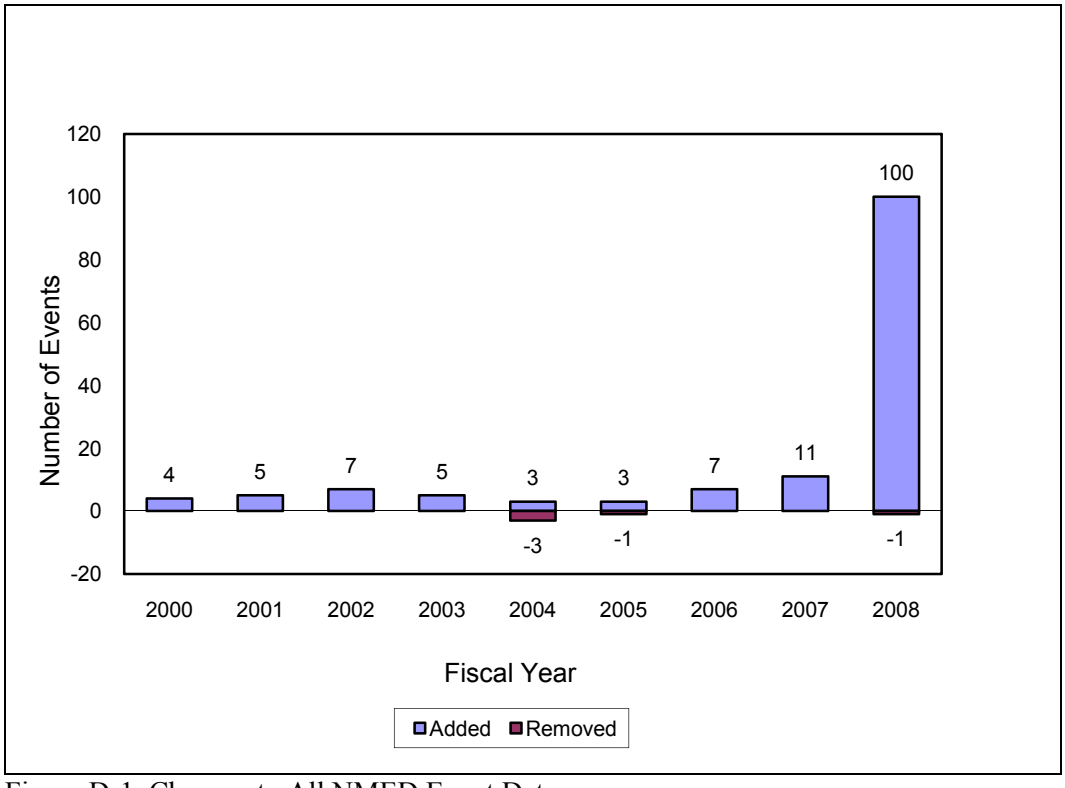


Figure D-1. Changes to All NMED Event Data

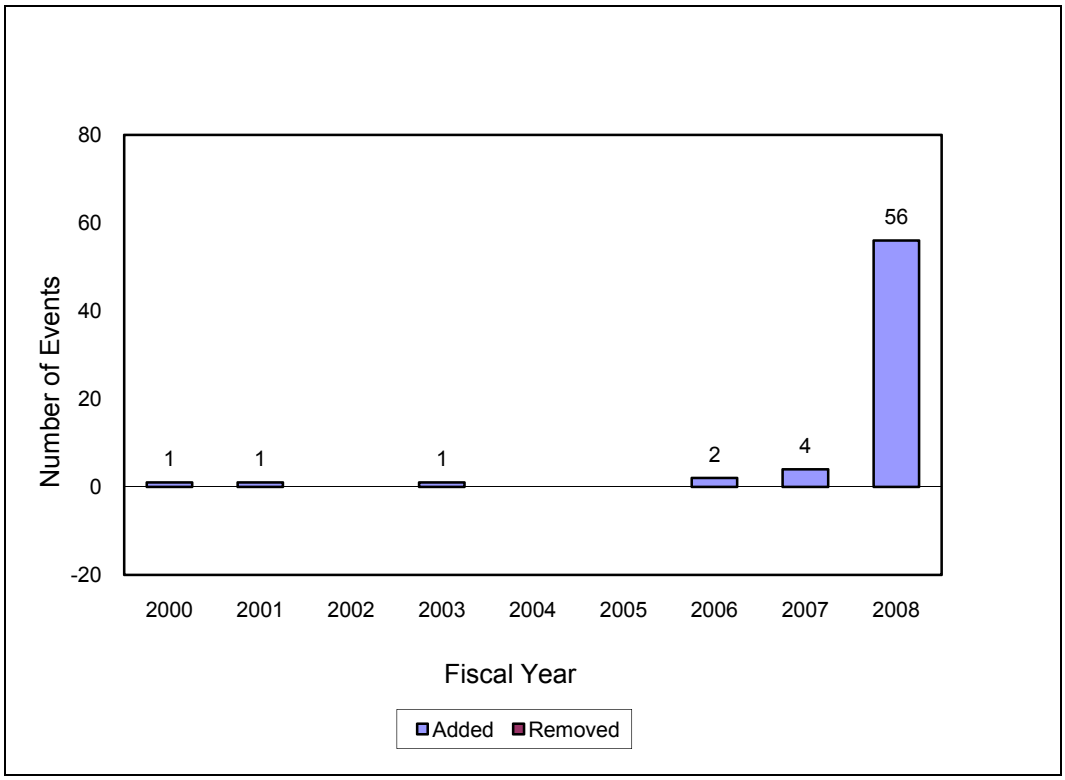


Figure D-2. Changes to LAS Data

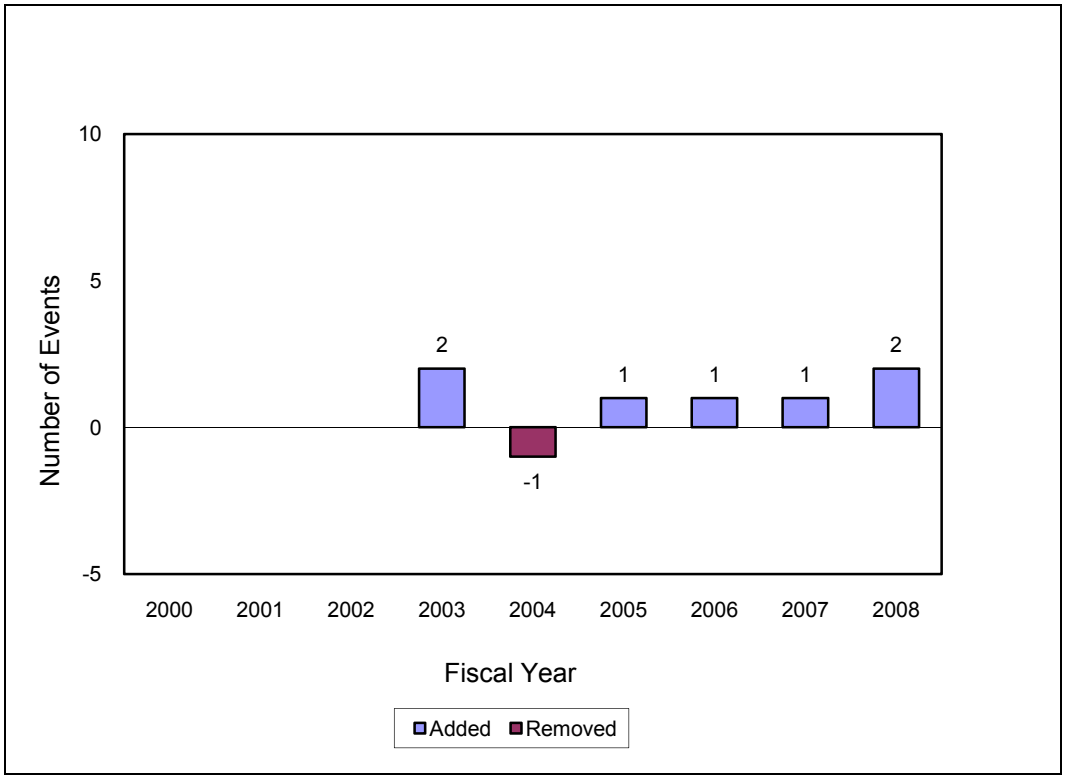


Figure D-3. Changes to MED Data

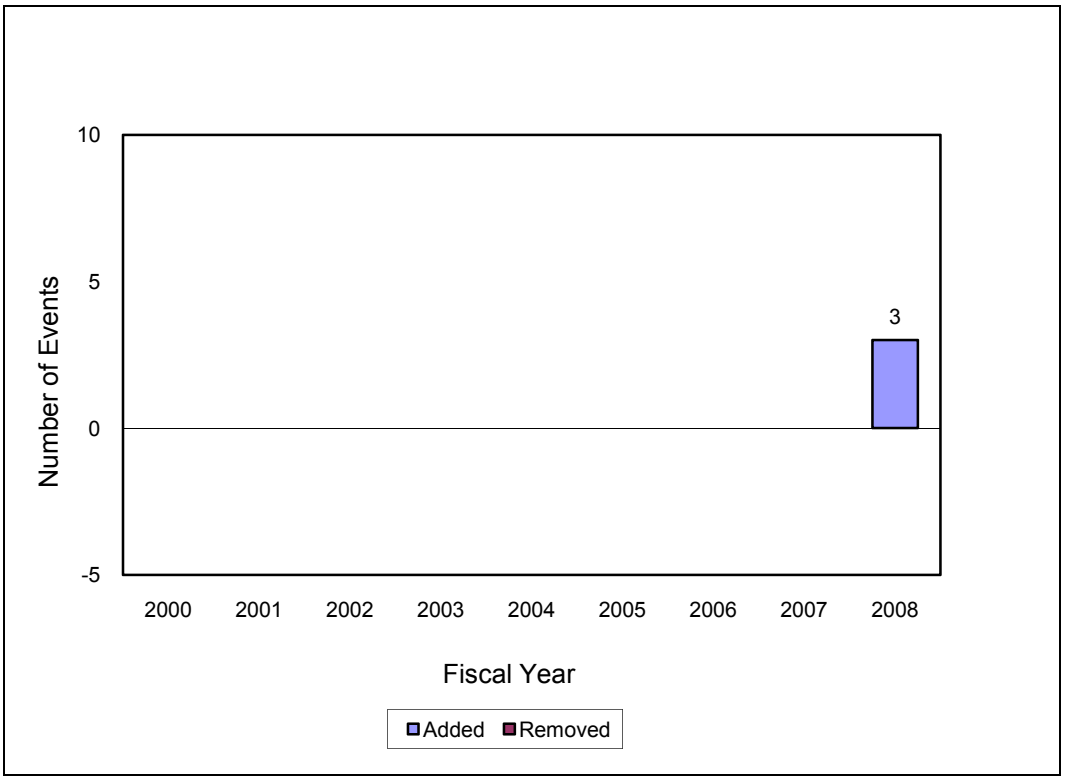


Figure D-4. Changes to EXP Data

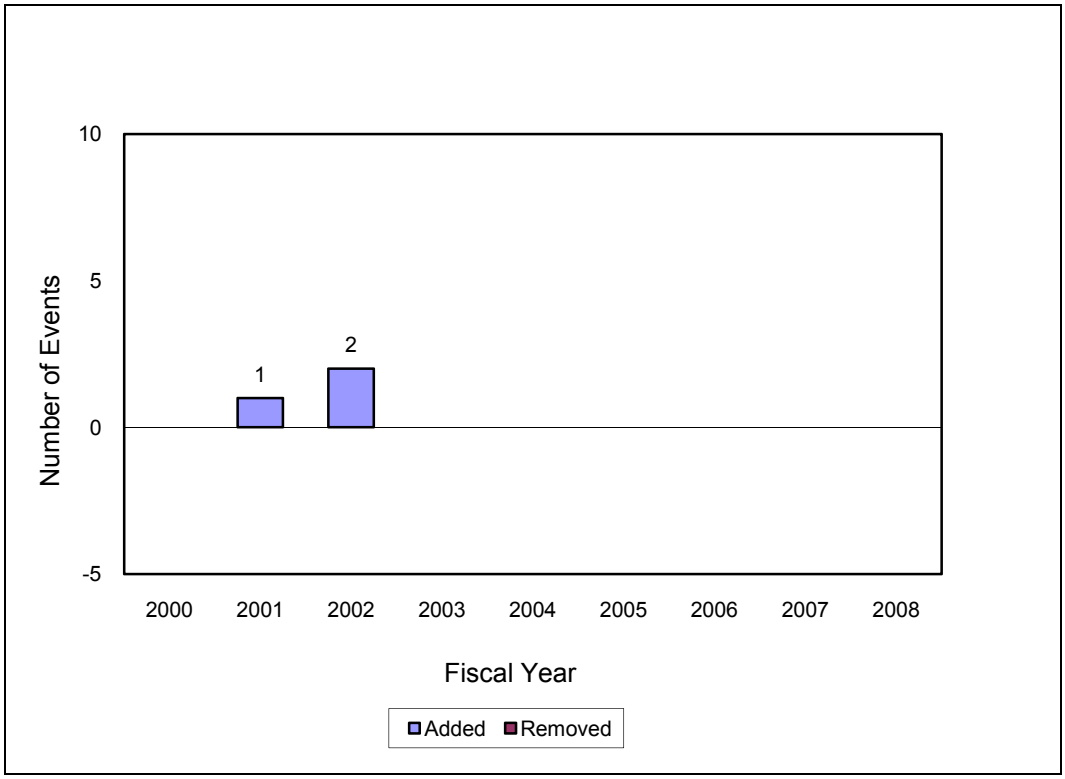


Figure D-5. Changes to RLM Data

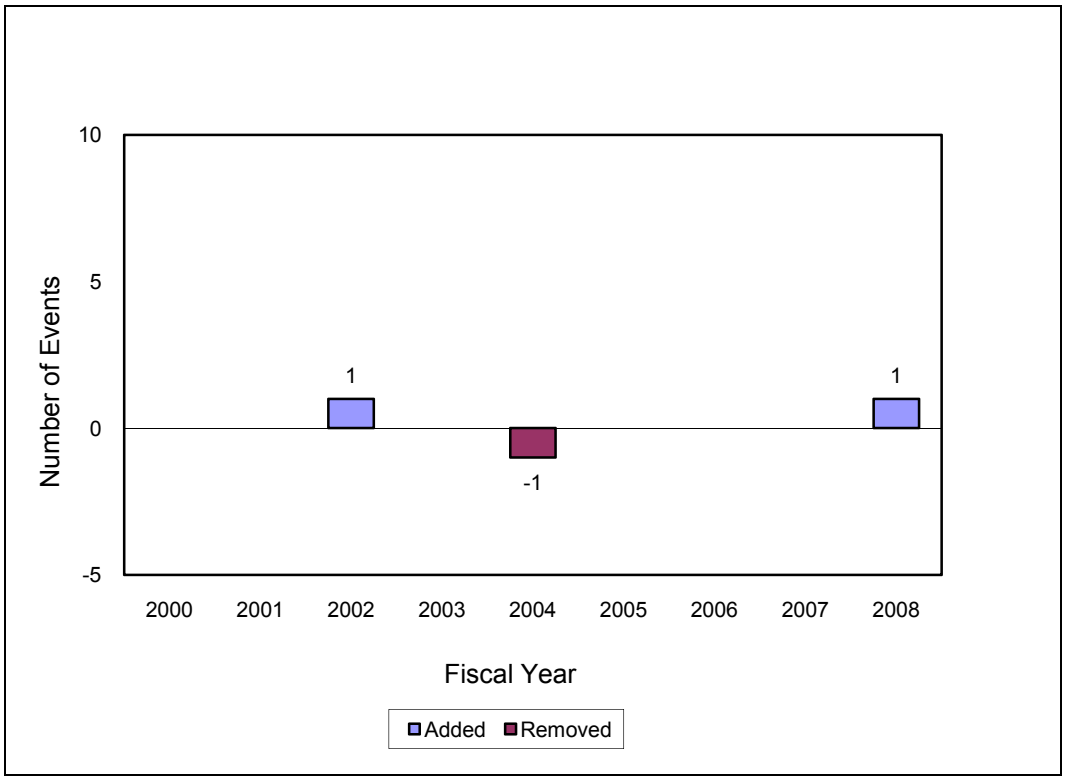


Figure D-6. Changes to LKS Data

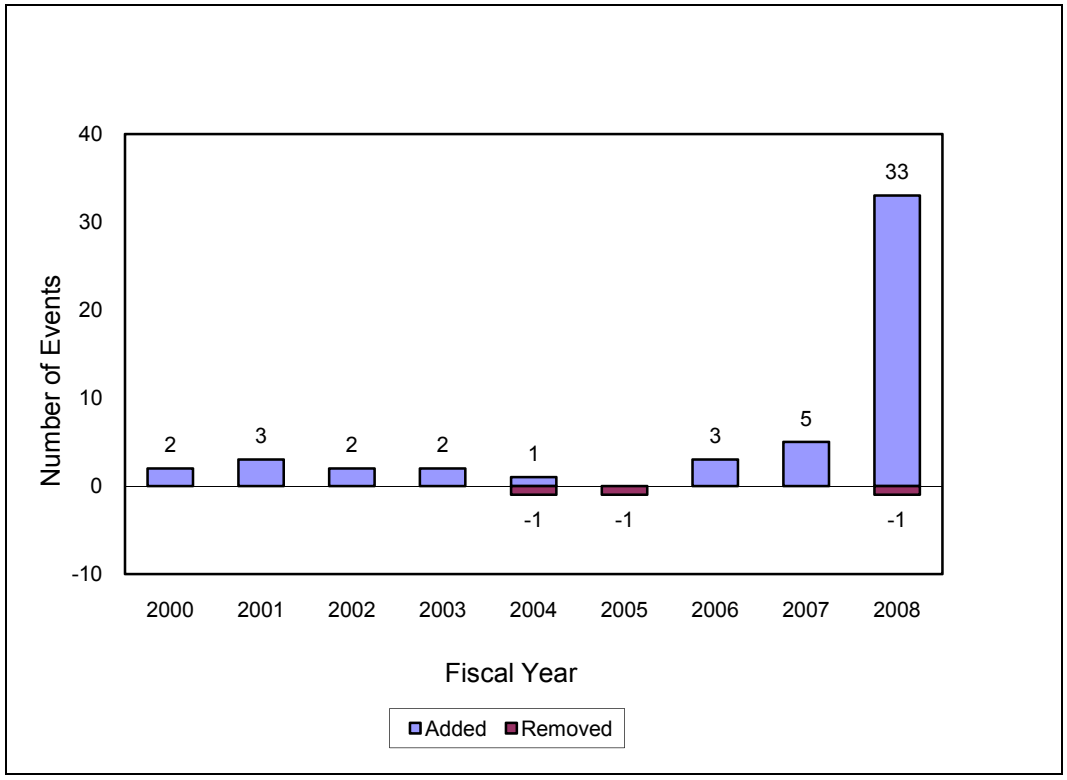


Figure D-7. Changes to EQP Data

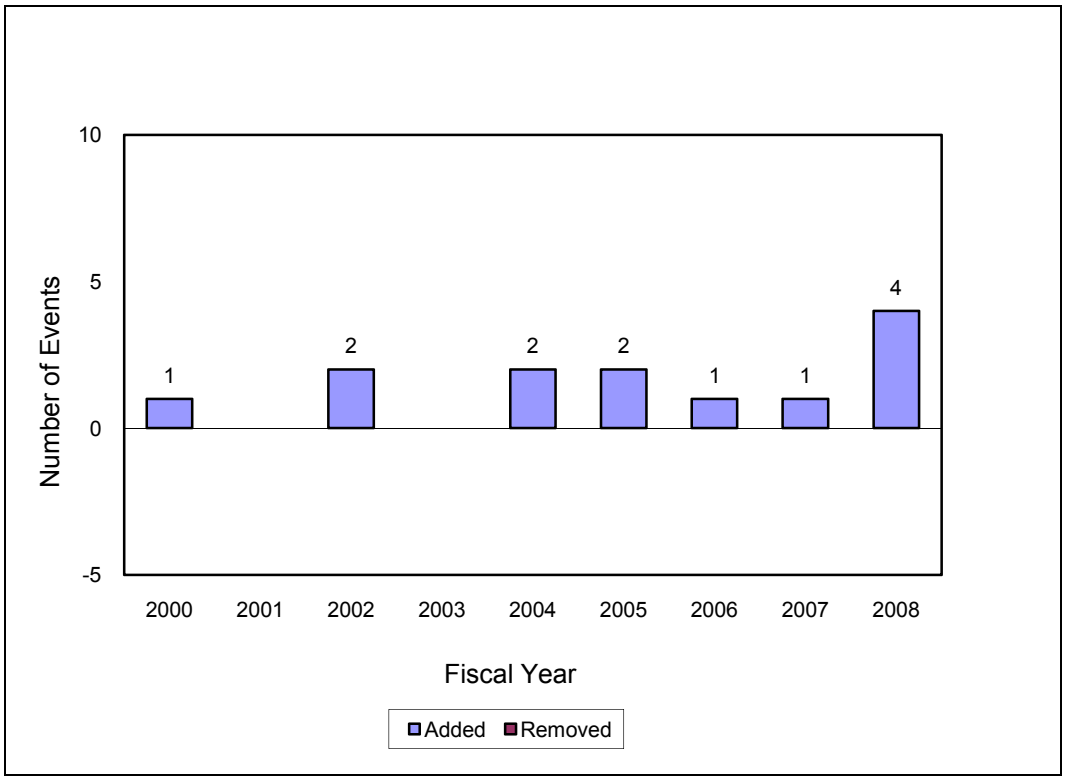


Figure D-8. Changes to TRS Data

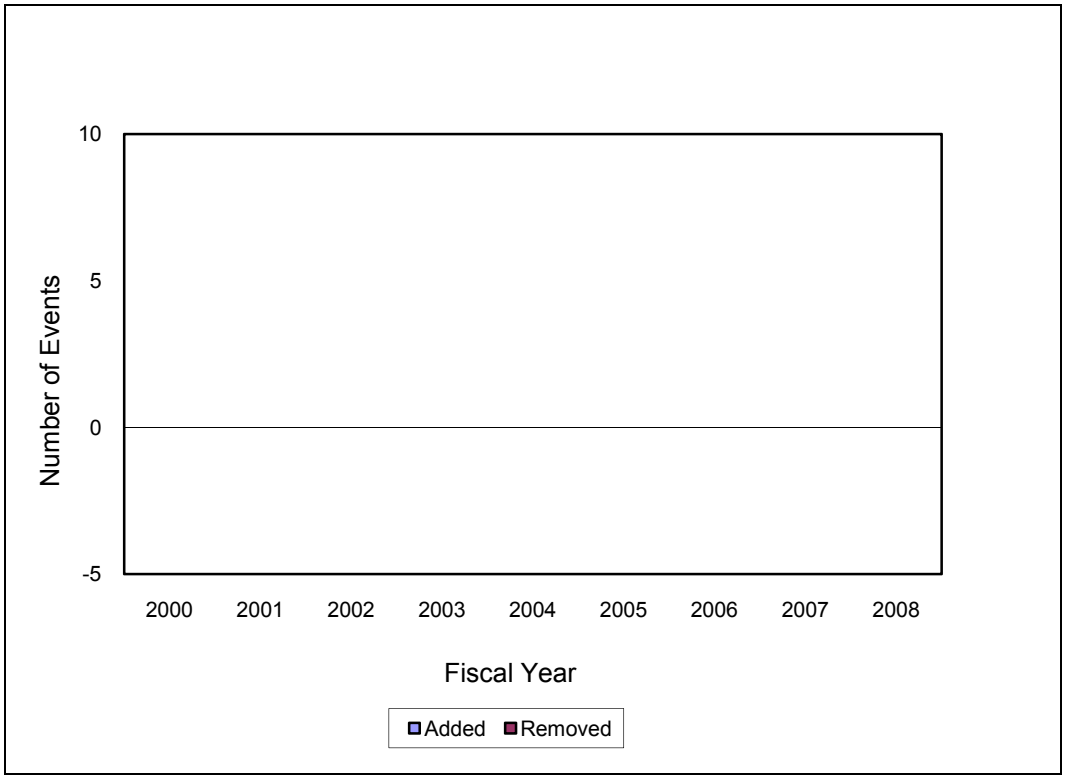
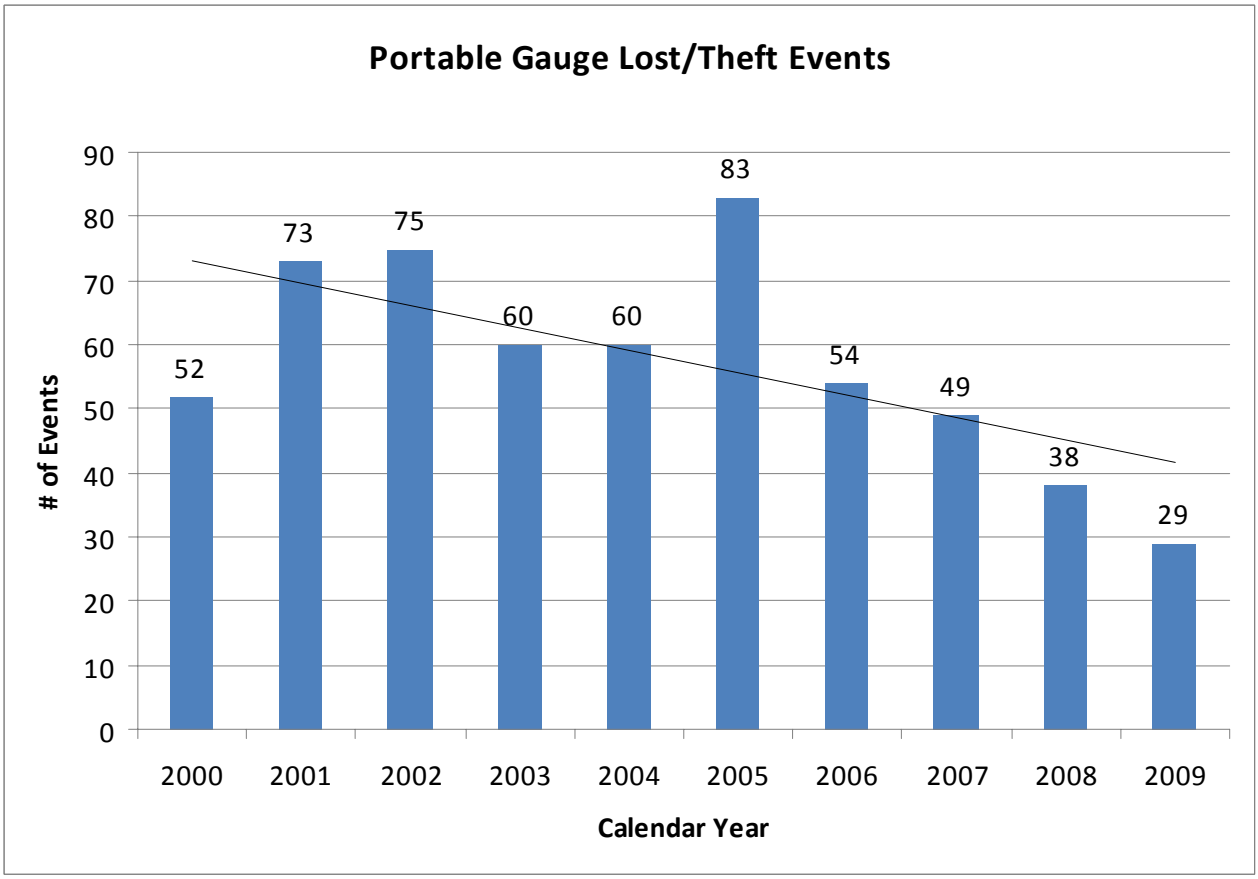


Figure D-9. Changes to OTH Data

Portable Gauge Events Trend Analysis for January 1, 2000 to December 31, 2009

The graph below displays the annual number of events due to losses and thefts of portable gauges for a 10 year period. The trend analysis indicates that the data does represent a statistically significant trend (indicated by the trend line).



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) continues to meet the performance trend criteria established in SECY-08-0135. Specifically, NFS had significant performance issues lasting more than one inspection period involving escalated enforcement actions and that warrant extraordinary NRC oversight (i.e., safety culture inspections and a second resident inspector). Two older enforcement cases resulted in four confirmatory orders in 2009 (i.e., fitness for duty and falsified medical exams). The orders implemented agreements reached during Alternative Dispute Resolution negotiations. During the negotiations, NRC agreed not to cite findings which likely would have resulted in Severity Level II and III violations.

Two Severity Level III violations were issued for security related issues. In addition, an Augmented Inspection Team identified significant performance issues that resulted in a Confirmatory Action Letter. The issues included inadequate evaluation of process changes, poor communication, lack of a questioning attitude, and lack of management oversight. The problems that led to the Confirmatory Action Letter are programmatic in nature and will require a sustained effort by the licensee to address the performance issues. Hence, a sustained period of heightened oversight by the U.S. Nuclear Regulatory Commission (NRC) is also warranted.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

Augmented Inspection Team

An Augmented Inspection Team (AIT) reviewed the circumstances associated with an unexpected exothermic reaction that occurred on October 13, 2009, within the Uranium Aluminum processing portion of the downblending facility at NFS. The preliminary insights from the AIT, combined with a review of recent operations and performance, led the staff to conclude that additional regulatory action was needed. On January 7, 2010, a Confirmatory Action Letter (CAL) was issued to confirm NFS commitments to 1) suspend processing operations in specific areas, 2) complete specific actions required before restart of operations, and 3) provide NRC sufficient time to inspect the actions taken. The AIT report was issued on March 19, 2010. NRC authorized restart of the Navy fuel process line on March 23, 2010, following a multi-week restart readiness inspection. Inspection coverage will be augmented during restart activities. Over the next year, we expect NFS to notify Region II when it is prepared to restart other process lines. Restart readiness inspections will be conducted to confirm fulfillment of CAL actions and other criteria established by NRC.

NFS Safety Culture and Configuration Management Improvement Oversight Panel

The Panel was formed after the February 2007 Order was issued to provide specific oversight of NFS's implementation of the Order. The Panel reviewed the qualifications, plan, and schedule of the independent third party performing the initial safety culture assessment. The Panel's review prompted the licensee to augment their initial assessment strategy, which resulted in NRC granting a 90 day extension for its implementation. The Panel then reviewed the initial assessment report and assessed NFS's plans to address the safety culture issues identified in the assessment. As before, the Panel's review prompted the licensee to clarify and improve its implementation plan. Follow-up inspections have noted progress, but have also identified failures to implement new procedures and raised concerns about the slow pace of improvements. The second safety culture assessment required by the order is in progress. The Panel will review the results when the second assessment is completed.

New Ownership

On December 31, 2008, Amendment 85 to License SNM-124 was issued to reflect an indirect transfer of control of the license from NFS Services, LLC, to NOG-Erwin Holdings, Inc. (a subsidiary of Babcock and Wilcox (B&W)). On January 1, 2009, David Kudsin became the President of NFS. On February 2, 2010, Luis Reyes, Bill Borchardt and Mike Weber met with B&W to discuss its efforts to enhance performance at NFS. On March 1, 2010, David Amerine replaced Mr. Kudsin as President of NFS. In addition, Mark Elliot was appointed the Director of a new Safety and Security Department on March 1. The safety and security organizations had reported to the Vice-President of Operations. Now they report to the Director of the Safety/Security Department.

Department of Veterans Affairs Philadelphia VA Medical Center

1. IDENTIFICATION

Location: Philadelphia, Pennsylvania
License No.: 03-23853-01VA
Docket No.: 030-34325
License Status: Active

2. STATUS SUMMARY

The Department of Veterans Affairs (DVA) holds a master materials license (MML), which was issued in March 2003. An MML is a material (byproduct, source, and/or special nuclear material) license issued to a Federal organization, authorizing the use of material at multiple sites. The MML authorizes the DVA to issue permits for the possession and use of licensed material, and ties the licensee to a framework of oversight consistent with NRC regulations and inspection and enforcement policies, procedures, and guides. The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP). The NHPP is responsible for issuing permits, conducting inspections and event follow-up,

investigating incidents, allegations, and enforcement. The Philadelphia VA Medical Center (PVAMC) is one of approximately 115 permits issued by the DVA.

On May 16, 2008, the NHPP notified the NRC of a possible medical event at the PVAMC that involved a prostate brachytherapy treatment in which the total dose delivered differed from the prescribed dose by more than 20 percent. The treatment was performed using iodine-125 seeds of a lower radioactivity than intended. Specifically, iodine-125 seeds were inadvertently ordered and implanted with the wrong radioactivity. As a result, the patient received a dose to the prostate that was less than 80 percent of the prescribed dose.

An expanded review of the program identified additional patients who received doses to the prostate that were less than 80 percent of the prescribed dose. The PVAMC identified that the circumstances for the additional medical events were unrelated to the initial medical event in that these treatments were performed using iodine-125 seeds of the correct radioactivity. However, based on the placement of the seeds by the physician, the treatment site (prostate) received a dose that was less than 80 percent of the prescribed dose. Based on these findings, the PVAMC expanded the review to include all of the patients who received prostate brachytherapy treatments (114) performed since the inception of the brachytherapy program (February 2002). The PVAMC prostate brachytherapy program was suspended on June 11, 2008, with no plans to restart the program.

Between May 16, 2008 and October 2, 2008, the licensee reported 92 medical events that involved I-125 prostate brachytherapy implants that occurred between February 25, 2002, and May 12, 2008 (one of these medical events was reported twice). Six additional medical events were reported to the NRC on August 12, 2009. The PVAMC reported 97 medical events between May 16, 2008 and August 12, 2009. On October 19, 2009, the PVAMC submitted their final dose assessments for the 114 patients that received permanent prostate implants at the medical center. After a comprehensive assessment of patient dose data, the staff identified 17 cases that met the current NRC Abnormal Occurrence (AO) criteria. In all cases the prescribed dose to the prostate was 160 Gy (16,000 rad) and the dose actually delivered to the prostate was in the range of 39 Gy (3,900 rad) to 111 Gy (11,100 rad). The doses to the periprostatic tissues and rectum, which should have received the same dose as the dose prescribed to the prostate (160 Gy (16,000 rad))**,** ranged between 248 Gy (24,800 rad) and 588 Gy (58,800 rad).

Each of the 17 AO cases were considered medical events because: (1) the region of the patient's periprostatic tissue or rectum where the seeds were placed received a dose that was greater than 0.5 Gy (50 rad) and was 50 percent greater than the expected dose the area would have received if the treatment had been administered in accordance with the written directive and treatment plan; and (2) the prostate received 20 percent less than the prescribed dose of 160 Gy (16,000 rad).

An NRC medical consultant reviewed a total of 39 medical events. During the consultants' onsite assessment, he reviewed numerous written directives and treatment plans with the inspectors and the licensee's consulting medical physicist. The medical consultant reviewed the permittee's spreadsheet summarizing the treatments and he provided a statistical analysis of the data. The consultant generally agreed with the licensee's dose estimates to the patients. However, he indicated that erratic seed placement caused a number of patients to have elevated doses to the rectum, bladder,

or periprostatic tissue. The consultant identified specific patients with rectal bleeding where the increased dose to the patients' colon, which resulted from erratic seed placement, may have been a contributing factor to the condition. Five of the 114 patients treated had expired; however, the inspectors confirmed that the cause of death for these 5 patients was not related to their prostate brachytherapy treatments. The PVAMC offered to refer 18 of its patients to the VA Puget Sound Health Care System, Seattle facility for re-implantation. Eight patients received re-implants. The remaining ten patients, who declined a re-implant, received additional follow up through other treatment modalities that did not involve any form of radiation therapy.

NRC Region III Office issued their inspection reports on March 30, 2009 and November 17, 2009. Based on the results of the inspections, eight apparent violations of NRC requirements were identified. The apparent violations involved inadequate procedures, training, and reporting requirements for medical events. A pre-decisional enforcement conference was held on December 17, 2009. The final enforcement action was issued on March 17, 2010.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

The major issues are:

a. 97 medical events occurred between February 2002 and May 2008, which were not identified and reported to the NRC until May 16 through October 2, 2008 and August 12, 2009. Of these 97 medical events, 17 of them met the abnormal occurrence criteria;

b. The authorized user physician and medical physicists failed to take appropriate corrective action when the post treatment plans demonstrated that the administered dose was not in accordance with the written directive and pre-treatment plan;

c. The licensee's written policies and procedures did not provide a procedure to adequately verify that the final treatment plan was in accordance with the written directive;

d. There was inadequate program oversight of the brachytherapy program by the PVAMC's Radiation Safety Officer and Radiation Safety Committee;

e. There was inadequate management oversight and no peer review of the physicians and physicists working under contract to provide brachytherapy services for the PVAMC;

f. The PVAMC failed to provide adequate training to the contractor physicians and physicists that provided brachytherapy services regarding identification and reporting requirements for medical events; and

g. The PVAMC lacked a safety culture for reporting radiation concerns to the appropriate individuals. As an example, interviews of two medical physicists indicated that they had concerns about the quality of an authorized physician user's implants being "suboptimal," but their concerns were never reported to the Radiation Safety Officer or licensee management.