POLICY ISSUE
INFORMATION

April 3, 2009 SECY-09-0052

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS FISCAL YEAR 2008

PURPOSE:

This paper provides the seventh 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) 2008. 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 2008, there was one nuclear material licensee, Nuclear Fuel Services, Inc., who met the criteria for identifying nuclear materials licensees for discussion at the Agency Action Review Meeting (AARM).

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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 (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 is based on aggregated information on operating experience associated with reportable events and generic issues affecting the industry. As committed to in SECY-02-0216, 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 issues that were identified based on significant issues criteria.

The following sections represent an evaluation of the significant adverse performance issues and performance trends followed by overall conclusions of performance in Materials and Waste Programs.

(1) Abnormal Occurrence Data:

The staff determined that 10 of the events reported to NRC in FY 2008, involving the Materials and Waste Programs, met the criteria for AO events. These AO events include 5 events at NRC-licensed facilities and 5 events at facilities licensed in Agreement States. All of the AO events were medical events (including 2 involving a dose 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 1998 through FY 2008 data. The "Report to Congress on Abnormal Occurrences - FY 2008" is scheduled to be published in April 2009.

The staff's analysis and evaluation of these AO events resulted in the finding that human error was a main contributor to the root causes of these AO events. For these 11 medical events; (1) 4 of the events involved not following or lack of procedures; (2) 3 of the events involved improper setup of equipment; (3) 2 of the events involved providing the incorrect radioactive material or dose to a patient; and, (4) 1 event involved misidentification of the organ to be treated.

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., 17 to 19 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 2008 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero, and there were no events reported during FY 2008 that met any of the strategic outcomes. Also, the safety and security goals for the performance measures were not exceeded in FY 2008.

(3) Data Derived Through Escalated Enforcement Actions:

For the 2008 calendar year (CY) period (January 1, 2008, through December 31, 2008), NRC issued 118 escalated enforcement actions involving NRC materials licensees (some of these actions involved multiple violations grouped together and issued as a problem). Escalated enforcement 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 2008 include 94 Severity Level II and III actions, 23 Orders, and one DFI.

In the past, the average for Severity Level I or II NOVs have been about three per year. In CY 2008, there were two cases involving Severity Level II violations, as described in the summaries provided in Enclosure 2. No significant performance trends were identified.

(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 are analyzed for the main event types, and are presented in an annual summary report, in which historical data are aggregated for evaluation of potential trends. A copy of the FY 2008 NMED Annual Report is available in Enclosure 3 of this paper.

In order to eliminate the random fluctuations in the event data from year to year and to assess an average trend of the data, we look at the last 10 years of data. For the 10 year period covering October 1, 1999, through September 30, 2008, a total of 5227 events (1867 NRC and 3360 Agreement State) associated with materials licensees were reported to NRC, versus a total of 5,053 events that were reported for the previous 10 year period, covering October 1, 1998, through September 30, 2007. 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, change in NRC regulations and 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 2008, 31 of the 640 total reportable events were considered safety significant events as described in the FY 2008 NMED Annual Report. There were 5 lost/abandoned/stolen radioactive material (LAS) events, 10 medical (MED) events, 3 radiation overexposure (EXP) events, 9 release of material or contamination (RLM) events, 2 leaking sealed source (LKS) events, 1 equipment failure (EQP) event, 2 transportation (TRS) events, and 2 "other" (OTH) events. For the 5 significant LAS events, there were 11 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 was classified as a Category 3 source. All of these sources were recovered. For the 10 MED events, 8 of these events were considered abnormal occurrences for FY 2008. One of the significant MED events involving prostate brachytherapy procedures was actually a compilation of 92 medical procedures at the same facility. All of the significant EXP events involved radiographers and, 1 of these events resulted in a 236 rem extremity dose. For the 9 RLM events, 2 of the events involved sources that were breached during removal from gauges and, 2 events involved the transportation of

contaminated individuals from a nuclear power plant to offsite medical facilities. The other 5 RLM significant events involved the cremation of a body containing brachytherapy seeds, 2 spill/release incidents at laboratories, a contaminated waste package at a gaseous diffusion plant, and an event at a uranium hexafluoride production facility. The 2 significant LKS events involved sources that were breached during removal from a gauge. These 2 events were also considered significant RLM events. There was 1 significant EQP event that involved a radiography equipment failure that resulted in an occupational radiation overexposure. This EQP event was also considered a significant EXP event. The 2 TRS significant events involved sources becoming unshielded during shipment. The OTH significant events involved 2 fetal doses resulting from treatments administered to pregnant patients. These 2 fetal dose events were classified as AO for FY 2008.

(5) Generic and Special Event Study Results:

General licenses (GLs) are established by the regulations[1] and grant authority to a person for a certain named activity or product involving licensed material. A GL is provided by regulation and is effective without the filing of an application with the regulatory authority (e.g., NRC or Agreement State) or the issuance of a licensing document to a person. NRC developed a General License Tracking System (GLTS) in 2001 to implement an annual registration program for certain 10 CFR Part 31 general licensed devices (GLDs) with the goal of improving the tracking and accountability of the GLs and GLDs containing radioactive sealed sources. The GLTS contains information from approximately 40,350 GLs, possessing approximately 513,000 devices. Of these, approximately 90 percent of GLDs in the GLTS are tritium exit signs that do not require an annual registration. Approximately 1,100 NRC-authorized GLs require annual registration and, these licenses cover approximately 7,600 GLDs.

In 2009, the staff evaluated events involving GLDs, which contain byproduct material. The data was reviewed to determine the type of general licensed events that have been reported to NMED and, to determine if there are any trends. Data was taken from NMED for the period covering January 1, 1998, to December 31, 2008. The data was downloaded from NMED on February 3, 2009. The data indicated that there were 546 events that involved GLDs during this time period. There were 7,776 GLDs involved in the 546 events. Tritium exit signs accounted for 93 percent (7,267 devices) of the total number of GLDs involved in these events, which is in line with the fact that approximately 90 percent of the devices in GLTS are tritium exit signs. Static eliminators were the next largest type of device involved in the GLD events. Static eliminators accounted for three percent (251 devices) of the total number of GLDs involved in these events. A breakdown of the type of GLDs and the number of GLDs by event type that have been involved in events for this time period may be found in Enclosure 4.

[1] Title 10, Part 31, “General Domestic Licenses for Byproduct Material,” of the *Code of Federal Regulations* (10 CFR Part 31) describes GLs for byproduct materials. The regulations for GLs for source material appear in 10 CFR Part 40, “Domestic Licensing of Source Material,” Sections 40.2 through 40.28, and those for GLs for special nuclear material are in Subpart C, “General Licenses,” of 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.”

We also looked at the isotopes and the activity that was involved in the GL events for the period January 1, 1998, to December 31, 2008. The study indicated that approximately 99 percent of the activity involved in these general licensed events was from Tritium (approximately 111,572 Ci). The majority of this tritium has been lost due to the large number of tritium exit signs and other GL devices containing tritium that have been lost or damaged. The activity of tritium is also higher than the other isotopes because 10 to 20 curies (Ci) of tritium is generally present in each exit sign while the activity of isotopes in other GLDs tend to be in the millicurie range. A breakdown of the type of isotopes and the amount of activity by event type that was involved in these GL events may also be found in Enclosure 4.

After analyzing the GL event data, the staff found that for the three most numerous devices (e.g., tritium exit signs, static eliminators, and gauges) that were involved in the GL events for this time period, the tritium exit sign events involved the least amount of general licensees. For the 250 events that involved 7,267 tritium exit signs there were only 74 general licensees involved in these events. For the 127 static eliminator and 119 gauge events there were 113 and 115 general licensees, respectively, involved in these events. The NRC is investigating the cause for the large number of tritium exit signs involved in these events. No other trends were found during this study.

The NRC is currently working on several actions that relate to GLDs. The staff has developed a proposed rulemaking for "Limiting the Quantity of Radioactive Materials in a Generally Licensed Device," which is currently being reviewed by the Commission. This rule would limit the quantity of byproduct material allowed in a GLD to below one-tenth (1/10) of the IAEA Category 3 threshold levels. Also, in regards to general licensed tritium exit signs, in January 2009, the NRC released a DFI request to general licensees that possess at least 500 tritium exit signs. This DFI was developed after a general licensee indicated that they may have a large number of lost or unaccounted for exit signs. The DFI will allow NRC to evaluate whether other general licensees with tritium exit signs have the same issue and to determine if additional actions will be required.

(6) Significant Issues Identified Based on Significant Issues Criteria:

SECY-08-0135 defines the criteria used to identify those 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 2008, there was one nuclear material licensee that met the criteria.

The nuclear material licensee that met the significant issues criteria as described in SECY-08-0135 was Nuclear Fuel Services, Inc. The staff's analysis regarding this licensee may be found in Enclosure 5. The staff's analysis outlines the issues and describes the regulatory actions being taken to improve licensee performance.

OVERALL PERFORMANCE CONCLUSIONS:

Based on the review of events data and assessment of key events, the staff concludes that the Materials and Waste Programs are functioning effectively to protect public health and safety. Based on the significant-issues criteria, there was one licensee that was identified as having significant performance issues during FY 2008. NRC staff is addressing the issues surrounding this licensee.

COORDINATION:

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

/RA Martin J. Virgilio Acting For/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. Annual Trend in AO Events from FYs 1998-2008
2. Summary of Severity Level I and II Enforcement Actions for CY 2008
3. FY 2008 Nuclear Material Events Database Annual Report
4. General License Event Summary for January 1, 1998, to December 31, 2008
5. Nuclear Fuel Services, Inc.

ANNUAL TREND IN ABNORMAL OCCURRENCE EVENTS FROM FY 1998 - 2008

Table 1 shows the number of events reported annually that were determined to meet the Abnormal Occurrence (AO) criteria. A total of 108 events were found to meet the AO criteria for the period FY 1998 - 2008. Of these 108 events, 39 of the events were by U.S. Nuclear Regulatory Commission (NRC) licensees and 69 of the events were by Agreement State licensees. Eighty percent of the AO events 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 1998 through 2008 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 11 years that met the AO criteria. The average number of AOs per year over the last 11 years is 9.8.

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
1998	0	0	3	1	1	0	1	0	**5**	**1**
1999	0	0	3	7	0	2	1	0	**4**	**9**
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**
Totals	**0**	**1**	**30**	**58**	**4**	**10**	**5**	**0**	**39**	**69**

*Include events involving a dose to embryo/fetus.

SUMMARY OF LEVEL I AND II ENFORCEMENT ACTIONS FOR CY 2008

Alaska Industrial X-Ray, Inc. **Severity Level II**
Anchorage, AK
EA-07-325; EA-08-196
Docket No. 030-10346

On August 20, 2008, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $20,800 was issued to Alaska Industrial X-Ray, Inc. for a willful Severity Level II problem involving (1) performing radiography at a location other than a permanent radiographic installation without the presence of two qualified individuals, in violation of 10 CFR 34.41(a), and (2) failing to provide the NRC with information that was complete and accurate in all material respects, in violation of 10 CFR 30.9(a). The NRC also issued an immediately effective Order Modifying License to require additional actions by the licensee to provide reasonable assurance that the health and safety of the public will be protected.

Source Production and Equipment Co., Inc. **Severity Level II**
St. Rose, LA
EA-08-039
Docket No. 71-0102

On July 14, 2008, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $9,600 was issued to Source Production and Equipment Co., Inc. (SPEC) for a deliberate Severity Level II problem of 10 CFR 71.3. Two violations were identified involving the transport of NRC licensed material without a license because SPEC did not comply with NRC Certificate of Compliance (CoC) No. 5979 requirements. Specifically, on July 15, 2003, December 4, 2003, and May 20, 2004, SPEC shipped licensed material to Mexico and 1) the end caps of the package were physically and dimensionally different from those approved in the CoC, and 2) the package was not inspected prior to the shipments as required by the CoC. There are no known actual health and safety consequences associated with the shipments. The Notice also included a Severity Level IV violation of 10 CFR 71.105(d) involving the failure to provide required training to individuals performing pre-shipping inspections of the Model No. 5979 transportation package. This Severity Level IV violation was not subject to a Civil Penalty.

February 2009

Nuclear Material Events Database

Annual Report

Fiscal Year 2008

Prepared for the U.S. Nuclear Regulatory Commission
by the Idaho National Laboratory (INL/EXT-09-15284)

Enclosure 3

INL/EXT-09-15284 (FY 2008)

Nuclear Material Events Database

Annual Report

Fiscal Year 2008

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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.

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The Nuclear Regulatory Commission's 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 safety significant events.

The safety significant events that occurred in Fiscal Year 2008 are summarized below. Note that a single event may be listed in more than one event type category.

Lost/Abandoned/Stolen Radioactive Sources/Material

Five 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)*. Zero Category 1 sources, 11 Category 2 sources, and one Category 3 source were lost, all of which were subsequently recovered. The 11 Category 2 sources were lost in four events; one source was contained within a radiography exposure device that fell from the back of a truck and the other 10 sources were lost during manufacturer shipments (three separate shipments) to international customers. The Category 3 source event involved a lost cardiac pacemaker from a deceased individual.

Medical Events

Ten significant events occurred, all of which were classified as potential Abnormal Occurrences. One of these events involved 92 prostate brachytherapy procedures performed at a single facility. Of the remaining nine events, four involved radiopharmaceutical misadministrations, four involved incorrect placement of brachytherapy sources, and one involved a gamma knife treatment to the wrong location.

Radiation Overexposure Events

Three significant events occurred, all involving exposures to radiographers. One of the events resulted in a 236 cSv (rem) extremity dose, which is just below the 250 cSv (rem) Abnormal Occurrence criteria.

Release of Licensed Material or Contamination Events

Nine significant events occurred. Two of these events involved sources that were breached while being removed from gauges for disposal. Two events involved the transportation of potentially contaminated individuals from commercial nuclear power plants to offsite medical facilities. The other five events involved the cremation of a body containing brachytherapy seeds, two spill/release incidents at laboratories, a contaminated waste package from a gaseous diffusion plant, and an event at a uranium hexafluoride production facility.

Leaking Sealed Source Events

Two significant events occurred. Both of these events involved sources that were breached while being removed from gauges for disposal. These two events were also classified as significant Release of Licensed Material or Contamination events.

Equipment Failure Events

One significant event occurred. This event involved a radiography equipment failure that resulted in an occupational overexposure. This event was also classified as a significant Radiation Overexposure event.

Transportation Events

Two significant events occurred, both of which involved sources becoming unshielded during shipping. In one of these events, the lid of a cask containing brachytherapy seeds became loose, resulting in an elevated package radiation level. In the other event, a source fell from a damaged cask.

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 2008

1. INTRODUCTION

1.1 Overview and Objectives

Nuclear material event reports are evaluated to identify statistically significant trends and safety 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 19,000 records of material events submitted to the NRC from approximately January 1990 through December 2008.

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; multiple events can result from a single occurrence report.

The data presented in this report are limited to reportable events that occurred between October 1, 1998, and September 30, 2008. The data were downloaded from the NMED on January 15, 2009. 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 NRC and Agreement State staff at https://nmed.inl.gov.

For assistance on searches or other questions, contact Duane White (Duane.White@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 (FY99-08).

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.

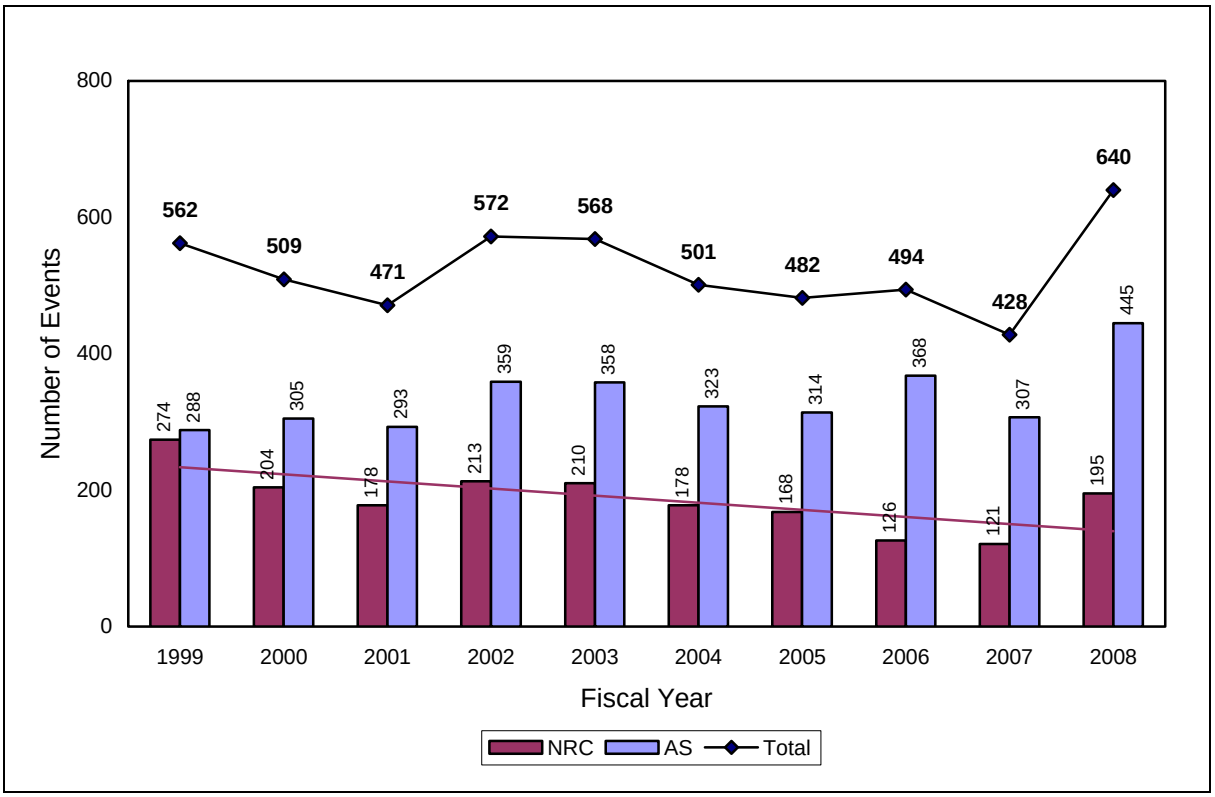

Figure 1. All NMED Events (5,227 total)

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

1. The FY08 data include 209 events that resulted from Wal-Mart's one-time review of their tritium exit sign inventory.
2. 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).
3. 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.
4. 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 do not represent statistically significant trend in the Total 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 NRC-regulated events represent a statistically significant decreasing trend, while the Agreement State-regulated events represent a statistically significant increasing trend (indicated by the trend lines).

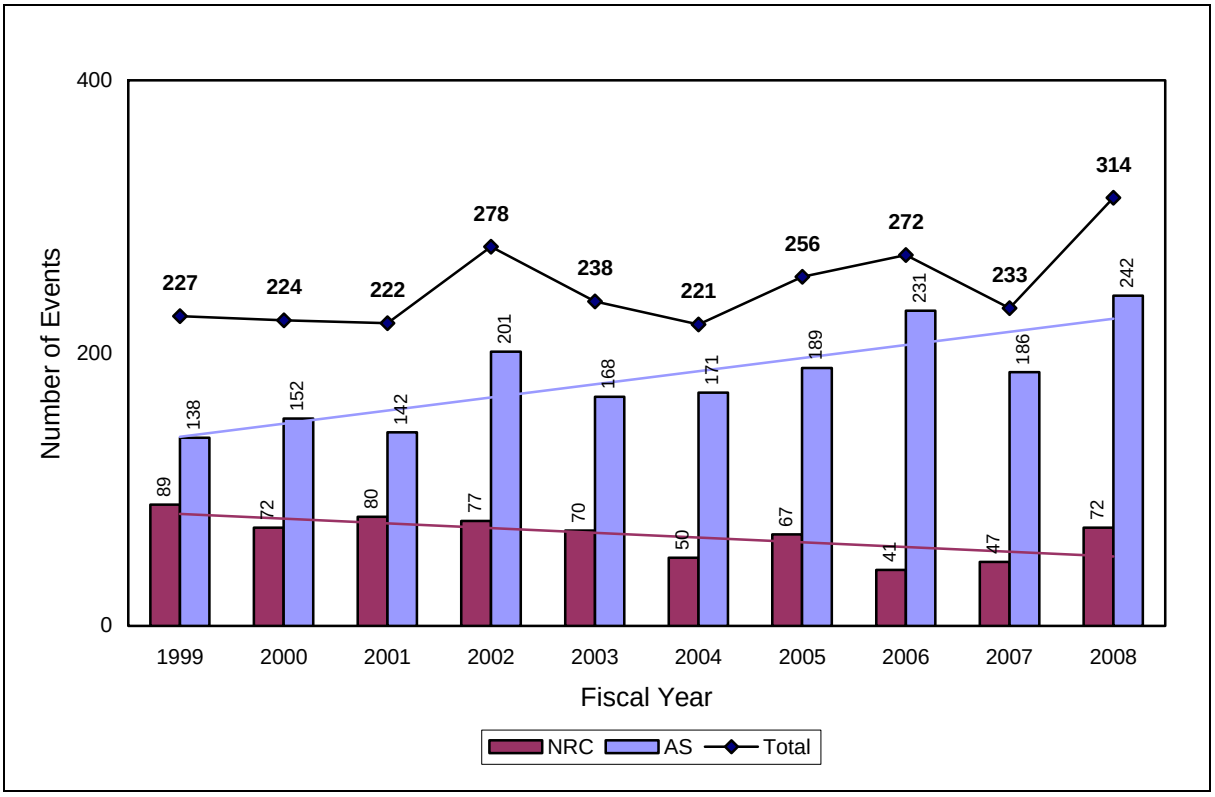

Figure 2. Lost/Abandoned/Stolen Material Events (2,485 total)

The FY08 data include 106 LAS events 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 thru 3 are considered safety significant.

The 2,485 LAS events that occurred during the ten-year period involved the loss of approximately 4,615 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, 57 Category 2 sources, and 17 Category 3 sources were lost. All of these sources were recovered, with the exception of three Category 2 and three Category 3 sources.

Table 2. Number of Sources Lost/Abandoned/Stolen (LAS) and Sources not Recovered (NRec)

Category		Fiscal Year 1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
1	LAS[4]	0	0	0	0	0	0	0	0	0	0	**0**
	NRec[5]	0	0	0	0	0	0	0	0	0	0	**0**
2	LAS	10	3	7	3	5	5	8	3	2	11	**57**
	NRec	1	0	1	0	0	0	1	0	0	0	**3**
3	LAS	0	1	0	3	0	1	6	4	1	1	**17**
	NRec	0	1	0	0	0	0	2	0	0	0	**3**
4	LAS	74	72	83	82	86	76	108	95	56	57	**789**
	NRec	38	26	32	30	28	30	34	48	20	29	**315**
5	LAS	99	90	131	123	137	107	149	108	69	110	**1123**
	NRec	54	39	62	52	60	36	56	42	21	41	**463**
< 5	LAS	1	2	2	4	2	4	7	0	2	0	**24**
	NRec	1	2	2	2	1	4	4	0	0	0	**16**
Activity Not Known[1]	LAS	8	2	3	15	1	8	3	7	3	8	**58**
	NRec	7	0	2	6	0	3	0	1	0	1	**20**
Nuclide Not Known[2]	LAS	2	1	1	1	1	0	3	0	0	1	**10**
	NRec	0	0	0	0	1	0	0	0	0	0	**1**
Other[3]	LAS	196	252	149	307	264	249	223	253	259	385	**2537**
	NRec	123	180	92	200	160	170	136	128	129	317	**1635**
Total	**LAS**	**390**	**423**	**376**	**538**	**496**	**450**	**507**	**470**	**392**	**573**	**4615**
	NRec	**224**	**248**	**191**	**290**	**250**	**243**	**233**	**219**	**170**	**388**	**2456**

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 thru 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 thru 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 thru 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 thru 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 321 IAEA Category 1 thru 4 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 fiscal year.

Table 3. Summary of IAEA Category 1 thru 4 Sources Not Recovered (Fiscal Years 1999 thru 2008)

Radionuclide	Half Life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Aggregate IAEA Category[5]
Am-241	432.7 years	48	4.38788	4.33934	3
Am-Be	432.7 years	245	13.99530	13.85802	3
Cm-244	18.1 years	4	0.29000	0.23984	4
Cs-137	30.07 years	18	3.09700	2.69491	4
Ir-192	73.83 days	5	189.30000	0.00021	5
Sr-90	28.78 years	1	0.99700	0.83265	4
Total		**321**	**212.06718**	**21.96497**	**2**

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). For Table 3, only the Category 1 thru 3 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). For Table 3, only the Category 1 thru 3 source counts were corrected for the "partially recovered"
4. The source activities were decayed from the event date to 01/15/2009 (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 thru 4 Sources Not Recovered (Fiscal Year 2008)

Radionuclide	Half Life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Aggregate IAEA Category[5]
Am-241	432.7 years	10	0.34500	0.34457	4
Am-Be	432.7 years	17	0.70200	0.70108	4
Cs-137	30.07 years	2	0.20000	0.19675	4
Total		**29**	**1.24700**	**1.24240**	**4**

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity). For Table 3, only the Category 1 thru 3 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). For Table 3, only the Category 1 thru 3 source counts were corrected for the "partially recovered"
4. The source activities were decayed from the event date to 01/15/2009 (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 FY08 Data

Three hundred fourteen LAS events occurred in FY08, involving the loss of approximately 573 sources, 388 of which have not been recovered. Of the 573 lost sources, none were Category 1, 11 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 070738 - A licensee reported the loss and recovery of a radiography exposure device that contained an 888 GBq (24 Ci) Ir-192 source. On 12/3/2007, a radiography crew left a temporary jobsite north of Saginaw, Texas, with the device on the tailgate. The crew drove approximately 15 minutes towards Justin, Texas, prior to remembering that the device was on the tailgate of the truck. It was then noticed that the device was missing. The crew retraced their route, but did not locate the device. A member of the public found the device on Blue Mound Road in Saginaw on the evening of 12/3/2007 and took it to their home, storing it there overnight. A Texas Department of State Health Services inspector traveled to the residence on 12/4/2007 and noted that the device was not damaged and the source was retracted in the shielded position. A leak test was performed on 12/5/2007 and no leakage was identified. The licensee took possession of the device. Corrective actions included personnel reprimanded, personnel received additional and new training, and new personnel were hired.

Item Number 080005 - A source manufacturer reported that a shipment containing seven Ir-192 sources with a total activity of 28.86 TBq (780 Ci) bound for Argentina was missing but subsequently found. The shipment left the manufactures' facility on 12/5/2007. A trucking carrier was to deliver the shipment to an air cargo carrier at the Miami International Airport. However, a sub-broker had cancelled the

Argentina shipment due to incomplete permitting requirements, without notifying anyone except the air cargo carrier. When the trucking carrier delivered the shipment to the air cargo carrier, they would not accept it. During the subsequent search for the missing shipment, it was determined that the air cargo carrier had inadvertently signed some paperwork indicating that they had accepted the shipment on 12/11/08. The shipment was eventually located at the trucking carrier's receiving bay in Miami on 12/23/2007. The source manufacturer's corrective actions included retraining distribution staff to immediately notify the regulatory department if a shipment does not arrive on time, not using a carrier until all appropriate documentation is obtained and reviewed, obtaining after hours contact numbers of appropriate carrier representatives, affixing a highly visible label on radioactive material shipments, and integrating other shipment quality management policies.

Item Number 080115 - A source manufacturer reported that a shipment containing two Ir-192 sources bound for Hong Kong was missing but subsequently found. One source contained an activity of 2.9 TBq (77.5 Ci) and the other source contained an activity of 2.1 TBq (57.2 Ci). The source manufacturer was advised on 2/19/2008 that the shipment was declared missing. The package was eventually located at the shipping carrier's facility in Newark, New Jersey, on 2/21/2008. The cause was that the shipment's paperwork became separated from the shipment itself; only the paperwork was sent to Hong Kong.

Item Number 080283 - A source manufacturer reported that a shipment containing a 5.52 TBq (149.2 Ci) Ir-192 source bound for Trinidad was missing but subsequently found. The source was shipped on 5/7/2008. It arrived in Miami, Florida, and was transferred to an air cargo carrier. On 5/8/2008, the carrier reported that the shipment could not be found at the time of its originally scheduled flight to Trinidad. The carrier eventually located the missing shipment in their Miami facility on 5/12/2008.

Significant Events—Category 3 Source Events

Item Number 080147 - A health care facility reported the loss and recovery of a cardiac pacemaker containing between 74 and 148 GBq (2 and 4 Ci) of Pu-238. The health care facility attempted to contact the individual with the implanted pacemaker on 3/5/2008 for a checkup and discovered that the individual was deceased (the patient's family did not follow the protocol provided to them by the health care facility, which asked that the health care facility be notified of the death of the patient). The health care facility contacted the funeral home in an attempt to recover the pacemaker. They also contacted the pacemaker's manufacturer to determine if the funeral home had returned the pacemaker to them. The funeral home had explanted the pacemaker, but did not recognize that the device was still in their possession when contacted by the health care facility. The pacemaker had been kept with several non-nuclear devices, which were to be returned to various manufacturers. When the funeral home later noted that one of the devices met the description of the pacemaker in question, they contacted the health care facility. The pacemaker was properly disposed of through transfer to the Los Alamos National Laboratory. The health care facility indicated that this was their last nuclear pacemaker patient and that they will be terminating their special nuclear materials license.

Events of Interest

Item Number 080477 - A university reported the loss of 17 grams of elemental uranium enriched to 43% U-235. The cause of the incident was considered to be inadequate material accounting practices for the period since 1978. Apparently, records were not maintained for the day-to-day consumption of uranium for research and subsequent discard of uranium that occurred routinely. There were no records to indicate use. Therefore, the SNM is considered "material unaccounted for" and an ongoing investigation is in progress to determine the disposition of the material between 1994 and 1997.

Item Number 080598 - A surgical center reported that a patient implanted with I-125 seeds on 8/6/2008, died on 8/17/2008, and was cremated on 8/20/2008 without removing the seeds. The patient had been implanted with 63 seeds containing a total activity of 0.59 GBq (15.8 mCi). The surgical center's RSO responded to the funeral home and determined that the patient's ashes were in the pulverizer unit and a second person's ashes were in the crematory unit. The RSO obtained radiation readings of 1 mR/hour at

the opening of the crematory unit, with 100 mR/hour in the interior of the unit and 10 mR/hour on contact with the patient's ashes in the pulverizer unit. The deceased persons' ashes were placed in plastic bags and then in plastic containers. The patient's plastic container revealed 10 mR/hour and the second person's plastic container revealed 0.1 mR/hour. On 8/21/2008, radiation readings in the crematory unit ranged up to 20 mR/hour. On 8/22/2008, a Georgia Department of Natural Resources (GDNR) inspector visited the funeral home and determined that the patient's ashes had been transferred to a cherry wood urn and buried on 8/21/2008. The second person's ashes had been transferred to a nickel-plated steel urn that was given to the family with instructions to place the urn in a remote location. On 8/26/2008, the GDNR inspector again visited the funeral home. The highest radiation reading in the crematory unit on 8/26/2008 was 9 mR/hour. The inspector took smears in areas around the crematory office, the crematory unit frame casing, the crematory preparation room, and areas around the exhaust vent in the preparation room. On 9/10/2008, the inspector returned to the funeral home to collect vegetation and ground samples from the outside of the facility, which revealed background results. The funeral home hired a contractor to decontaminate their facility. Two funeral home personnel were potentially exposed during this event. They will receive thyroid scans and other tests. This event was classified as an EQP, LAS, LKS, and RLM event.

One hundred-six LAS events involved missing and/or damaged tritium exit signs at multiple Wal-Mart stores.

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 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 represent a statistically significant decreasing trend (indicated by the trend line).

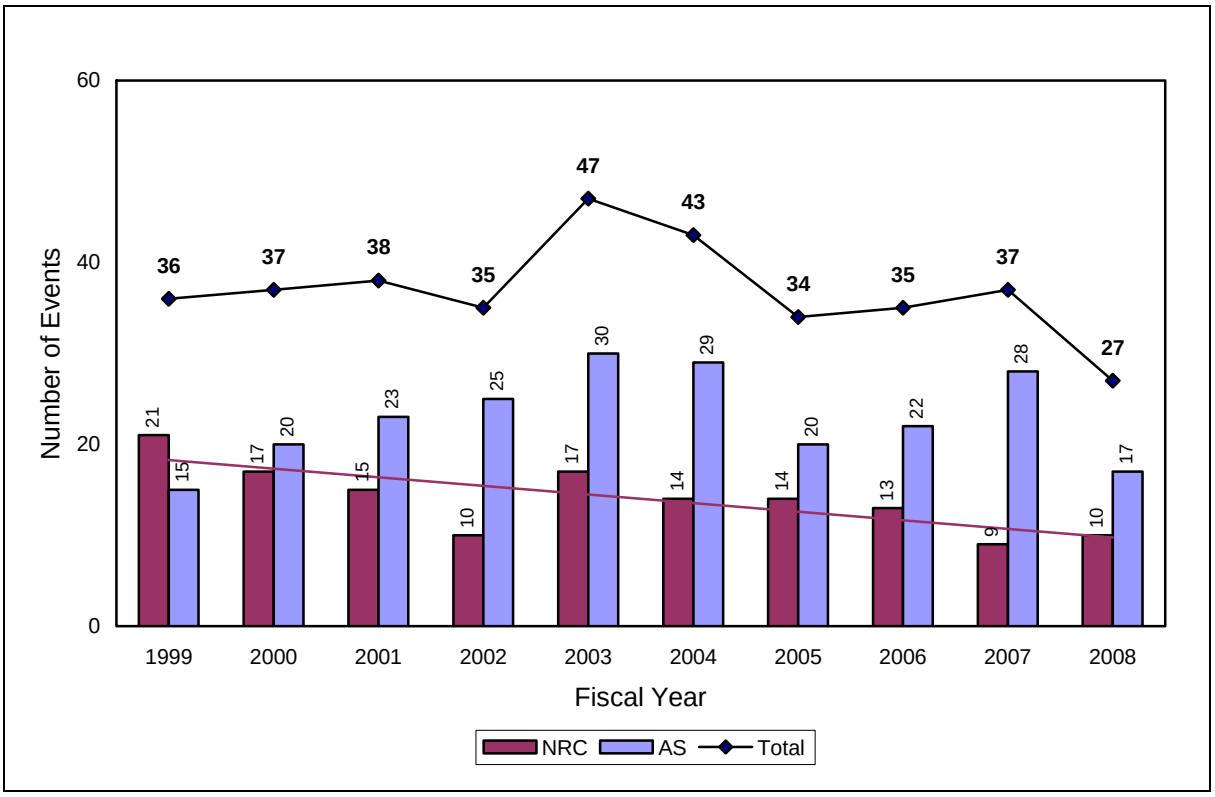

Figure 3. Medical Events (369 total)

A significant 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 FY08) are considered safety significant.

Table 5. Medical AO Events

	Fiscal Year										
	1999	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008[1]**	**Total**
Events	5	5	2	6	9	12	7	6	10	10	**72**

Notes:

1. Events in FY08 are currently marked as potential AOs, because the AO determination process has not yet been completed for this year. In 2009 (typically April or May), the final AO determination will be made and the events published in NUREG 0090.
2. NUREG 0090 reports AOs according to the report date of the event and not the actual event date, which is used in this NMED report. Therefore, the data for the two reports may appear different for a given fiscal year.
3. 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 FY08 Data

Twenty-seven MED events occurred in FY08, 10 of which were classified as significant events.

Significant Events—Potential AOs

Item Number 070672 - A gamma knife treatment was delivered to the wrong location of a patient's brain on 10/24/2007. The patient was being treated for a metastatic brain tumor in the right cerebellum. The gamma knife unit contained Co-60 sources with a total activity of 227.96 TBq (6,161 Ci). While taking an MRI image of the patient's brain in preparation for the treatment, the left and right sides of the brain were reversed in the image due to human error. This resulted in a treatment of 1,800 cGy (rad) being delivered to the wrong location. The left/right image reversal resulted in an 18-mm shift of the isocenter. The collimator size was 18-mm, resulting in some overlap of the delivered 50% isodose volume with the correct target lesion volume. Approximately 9% of the lesion volume received the prescribed dose of 1,800 cGy (rad), rather than the intended 95% of the lesion volume. The NRC hired a medical consultant to review the consequences of the event, who concluded that no significant deterministic effects were expected. Corrective actions included procedure modification, additional reviews of left/right alignment of MRI images, and personnel training.

Item Number 080007 - A patient was administered 81.4 MBq (2.2 mCi) of I-131 for a whole body scan instead of the intended I-123 for a thyroid uptake scan. The doctor ordered an iodine thyroid uptake and scan for the patient without specifying the radionuclide. The facility uses I-123 for that purpose. The administration occurred on 12/17/2007 and the error was discovered on 12/25/2007. Scheduling personnel were retrained to verify an order before scheduling patients for a procedure. The technician was also retrained to read the script prior to administering a patient.

Item Number 080053 - A wrong radionuclide was administered to a patient on 1/14/2008. A physician gave a verbal order to a nurse, who wrote the order for an I-123 uptake scan. The nurse incorrectly scheduled an I-131 uptake scan and the physician never reviewed the order. The patient was administered 173.9 MBq (4.7 mCi) of I-131. On 1/16/2008, the physician reviewed the results and realized that the wrong radionuclide had been administered. Corrective actions included policy and procedure modifications to require that physicians fill out all orders.

Item Number 080132 - On 2/27/2008, 37 I-125 brachytherapy seeds were implanted approximately 2 cm below a patient's prostate. Each seed contained an activity of 11.66 MBq (0.315 mCi). The patient was prescribed to receive a dose of 11,000 cSv (rem) through the placement of 62 seeds. After 37 seeds were

implanted, the location of the implanted seeds was verified to be below the prostate, and the procedure was terminated. A dose assessment determined that the region of the perineum where the seeds were implanted received a dose of 5,500 cSv (rem), while the prostate received a dose of 300 to 1,500 cSv (rem). This event was caused by misidentification of the patient's prostate due to inadequate procedures. The patient's prostate will be treated with external beam radiation therapy. The patient may develop complications including fibrosis and necrosis of the tissue in the perineum where the seeds were implanted. The NRC contracted a medical consultant, who generally agreed with the dose estimates. Corrective actions included revising the policy and procedure for prostate seed implants to ensure that the location of the needle in the prostate is verified prior to implanting seeds.

Item Number 080230 - An error occurred during a gynecological brachytherapy treatment using a high dose rate (HDR) unit with a 185 GBq (5 Ci) Ir-192 source. The patient was prescribed to receive five fractional treatments of 600 cGy (rad) each, for a total treatment of 3,000 cGy (rad). The treatments began on 12/11/2007 and were scheduled to occur over six days. Three fractional treatments were administered, but the patient did not return for the final two treatment fractions due to reasons not associated with the HDR treatments. On 3/25/2008, measurements of the tandem and ovoid applicators indicated that the length of the source wire entered into the treatment planning system should have been 128 cm; however, a length of 120 cm had been used. Further inspection revealed that the tandem catheter should have been used with a different applicator. These errors resulted in the dose for the three fractions being delivered 86 mm inferior to the intended treatment site. Therefore, only 470 cGy (rad) of the intended 600 cGy (rad) per fraction was received by the intended treatment site. The vaginal region inferior to the intended treatment site received an unintended dose of 1,300 cGy (rad). The patient is not expected to experience adverse health effects due to this event. This event was caused by the failure to measure the catheters. Corrective actions included checking all catheters for integrity and length prior to treatment, ordering and using a single set of catheters for the transfer tubes, better verification of the treatment plan and catheters prior to each treatment, and reviewing the existing quality assurance plan and modifying if needed to ensure accuracy. A full time certified medical physicist was also hired.

Item Number 080279 - Patient A was prescribed a dosimetric Bexxar I-131 dosage of 0.19 GBq (5 mCi) for a lymphatic cancer uptake study, but received an I-131 dosage of 1.65 GBq (44.5 mCi). The administered dose was actually intended for Patient B. Patient A had taken a thyroid blocking agent prior to the administration. The State of Kentucky Radiation Health Department conducted an investigation and determined that the cause was oversight by the technologist. The administered dose was received for Patient B on 4/25/2008. However, Patient B's treatment was canceled and the dose was placed in the hot laboratory to be returned to the radiopharmacy. The intended dose for Patient A was not received from the radiopharmacy. The mistake occurred when the call was received to dose Patient A on 4/28/2008. The technologist took the dose from the container left from the cancelled procedure. The hospital changed their process of receiving, handling, and returning doses to the radiopharmacy. A labeling system was instituted on the dose and canister to let staff know the status of the dose. The technologist and nurse are responsible for performing checks. Patient A was subsequently administered a therapeutic dose of I-131 for lymphatic cancer.

Item Number 080296 – An NRC Master Materials Licensee (MML) reported 92 medical events involving patients that received permanent implant prostate brachytherapy procedures at a medical center in Philadelphia, Pennsylvania. Of these 92 medical events, 57 involved doses less than 80% of the prescribed dose and 35 involved doses to an organ or tissue other than the intended treatment site (the rectum, perineum, and/or the bladder). Each patient was prescribed a dose of 160 Gy (16,000 rad) using I-125 seeds with standard seed strengths of 14.06 MBq (0.38 mCi) per seed or, in one case, 18.69 MBq (0.509 mCi) per seed. This problem was initially identified when the medical center performed an implant on 5/5/2008 using seeds of a lower apparent activity than prescribed because the wrong seeds were ordered. The MML then reviewed all 112 procedures performed since the inception of the cancer treatment program on 2/25/2002. The prostate cancer treatment program was suspended by the MML

director in June 2008 pending an investigation. The NRC contracted a medical consultant to review a sample of these medical events. These medical events were caused by a failure to follow procedures, human error on the part of the physician inserting the needles, and inadequate procedures to ensure that the administered dose was in accordance with the written directives. This event remains under investigation.

Item Number 080337 - A patient received doses differing from prescribed during a breast cancer treatment using high dose rate (HDR) mammosite balloon brachytherapy on 5/1/2008. The patient was prescribed 10 fractions using a 165.4 GBq (4.47 Ci) Ir-192 source. The target site was prescribed to receive 340 cGy (rad) during each fraction, for a total dose of 3,400 cGy (rad). During administration of the first fraction, the physicist received an error message from the HDR computer indicating friction or obstruction in the HDR catheter. The cause of the error message was not investigated and the physicist attempted to resolve the problem by incorrectly changing the catheter length value at the treatment console by 20 mm instead of the intended 2 mm. This event was identified during a subsequent review of the first treatment and the cause of the error message. The displacement of the source by 20 mm put it at the skin entry point of the catheter, resulting in an underdose to the target site and an overdose to the skin. The actual dose to some areas of the target site was 86 cGy (rad). The doses administered during the ninth and tenth fractions were adjusted so that the total dose to the target site was 3,400 cGy (rad). Dose to the unintended site was prescribed as 148 cGy (rad) for the first fraction, but 1,142 cGy (rad) was administered. The intended dose to that unintended site for all ten fractions was 1,484 cGy (rad), but the site actually received 2,370 cGy (rad). The doctor will monitor the patient's skin for ill effects. An NRC medical consultant concluded that no significant adverse health effect to the patient was expected due to this event. Corrective actions included procedure changes and training to personnel on those changes. The authorized use and authorized medical physicist are to be physically present during the procedure and upon receipt of an error message they will investigate and determine the cause prior to continuing the treatment.

Item Number 080555 - A patient prescribed to receive 0.74 GBq (20 mCi) of I-131 was administered 2.78 GBq (75 mCi) of I-131 on 7/17/2008. Two patients were scheduled for different I-131 therapy doses and the doses got switched. The patient was given a blocking agent of 130 mg SSKI approximately one hour after the I-131 administration. The next day, measurements indicated a 74 MBq (2 mCi) uptake to the patient's thyroid and a 370 MBq (10 mCi) whole body retention. Corrective actions included procedure modifications.

Item Number 080694 - A patient received 3,400 cGy (rad) to unintended tissue during several breast cancer therapy treatments from 9/10 to 9/17/2008. The patient was being treated with an Ir-192 high dose rate (HDR) afterloader unit. Symptoms of erythema were identified by the patient. The medical physicist reviewed the records and determined that the HDR afterloader was wrongly programmed such that the source stopped 10 cm short of the intended tumor site in the right breast. As a result, the entire dose intended for the tumor was administered to the left breast, which was not intended to be treated. The Commonwealth of Florida will dispatch an inspector to the facility to investigate the incident.

Events of Interest

Item Number 080171 - A hospital reported that an implanted I-125 brachytherapy seed was leaking. The seed contained less than 12.95 MBq (350 uCi). On 3/10/2008, the patient was implanted with 102 seeds. On 3/11 or 3/12/2008, the patient complained of pain and difficulty urinating. A cauterization was performed via the urethra. Upon removal of the cauterization equipment, some seeds also exited the urethra. One seed was visibly different from the rest. Upon closer observation, the seed was noted to be shorter than the others and had been damaged. The cause of the damage was not definitely determined. However, it is believed to have occurred as a result of the cauterization procedure. Surveys revealed contamination of the equipment and bodily fluids, and an external reading directly over the thyroid showed levels above background. A CT scan performed on 3/19/2008 revealed that 92 seeds remained in the patient. Wipes of the remaining seeds showed contamination levels up to 18.5 kBq (500 nCi). It is

believed that those seeds were cross-contaminated while in storage. Bioassays of the patient on 3/19/2008 revealed a thyroid burden of 29.6 kBq (0.8 uCi) and a dose of less than 1 cSv (rem) to the thyroid. The hospital stated that while extremely rare, they would consider doing the same cauterization procedure again but with greater screening of the need for that particular procedure as opposed to another, presumably less hazardous procedure, to accomplish the same goal. This event was classified as an EQP and LKS event. Note that this event was not classified as an MED event and is listed in this section for reference only.

Item Number 080262 - A patient was administered 0.37 GBq (10 mCi) of I-131 for treatment of a hyperactive thyroid on 2/7/2008, instead of the prescribed 0.37 MBq (10 uCi). The incident was not discovered until 4/25/2008 during a review of written directives administered. The written directive incorrectly prescribed 0.37 MBq (10 uCi). The authorized user realized his error in prescribing 0.37 MBq (10 uCi) and telephoned the nuclear medicine technician to change the activity to the correct dosage of 0.37 GBq (10 mCi). However, neither a new or revised written directive was issued. Corrective actions included counseling the technician on following procedures, revising the written directive form to exclude a choice of units, and enforcing that no telephone requests from an authorized user will be carried out until a new or revised written directive is issued.

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 FY08, both of which are classified as potential AOs.

Item Number 080514 - A pregnant patient received a 5.52 GBq (149.2 mCi) I-131 dose on 6/4/2008. The patient was tested for pregnancy on 6/2/2008 prior to receiving the ablative dose. The qualitative serum screening result was negative and the dose was administered with no complications. On 8/13/2008, the patient was informed that she was pregnant. The NRC first learned of the incident during an unannounced inspection conducted on 9/5/2008. Follow-up consultation with the Radiation Emergency Assistance Center/Training Site (REAC/TS) and calculations determined that the dose to the fetus was approximately 31.5 cGy (rad). However, since the incident occurred early in the zygote phase of development, there are no anticipated adverse consequences. The NRC obtained the services of a medical consultant to assist in the ongoing special inspection of the incident. The consultant reviewed the case and calculated a slightly higher embryo/fetus dose of 32.5 cGy (rad). Corrective actions taken by the hospital included advising abstinence from intercourse for a period of 14 days prior to I-131 treatment or the use of an effective method of contraception for a period of 30 days prior to treatment. The hospital initially decided on a corrective action of using only quantitative serum test for detecting pregnancy instead of qualitative testing. The consultant stated that the difference in sensitivity between the two tests would not justify the increased expense and longer turnaround time. Either test would fail to detect early pre-implantation pregnancies.

Item Number 080550 - A pregnant patient received a 4.96 GBq (134 mCi) I-131 dose for thyroid carcinoma on 4/11/2008. The patient had two negative pregnancy tests on 4/6 and 4/10/2008. Following treatment, the patient suspected she was pregnant and returned to the hospital on 4/28/2008. Subsequent testing indicated she became pregnant approximately four to six days following treatment. The calculated whole body exposure to the fetus was 35 cGy (rad). The cause of the incident was that the patient did not follow the contraceptive plan outlined in the procedure she signed prior to treatment. Hospital staff followed all procedures. Corrective actions included procedure modifications to over-emphasize the risks associated with becoming pregnant following administration of radioiodine.

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 NRC-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 Agreement State-regulated events represent statistically significant decreasing trends (indicated by the trend lines).

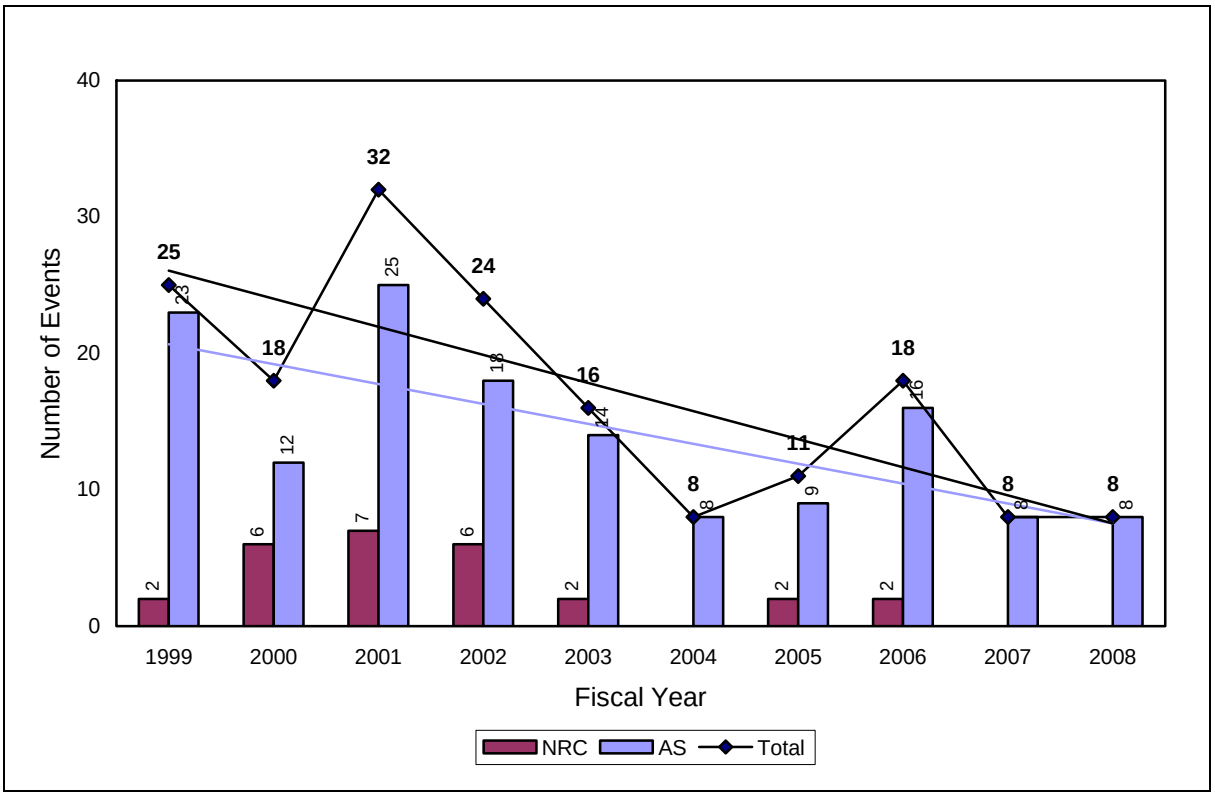

Figure 4. Radiation Overexposure Events (168 total)

The safety 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 safety 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										
	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
Immediate	2	1	2	1	2	1	0	1	1	0	**11**
24-Hour	11	1	1	0	1	1	1	3	1	3	**23**
30-Day	12	16	29	23	13	6	10	14	6	5	**134**
Total	**25**	**18**	**32**	**24**	**16**	**8**	**11**	**18**	**8**	**8**	**168**

2.4.2 FY08 Data

Eight EXP events occurred in FY08, three of which were classified as significant events.

Significant Events—Immediate Reports

None.

Significant Events—Within 24-Hour Reports

Item Number 080158 - A radiographer was overexposed while performing operations at a facility in Nebraska City, Nebraska, under reciprocity. The radiographer was using an exposure device with a 1.22 TBq (33.1 Ci) Ir-192 source. While at the job site on 3/4 and 3/5/2008, the radiographer noticed that his direct-reading pocket dosimeter was off-scale. He reported the reading to the RSO on 3/7/2008 and was directed to send his TLD to Landauer Laboratories for processing. On 3/10/2008, Landauer informed the RSO that the TLD indicated that the radiographer received 7.753 cSv (rem) deep dose equivalent. The radiographer was restricted from radiation areas while the State of Nebraska investigated the incident. It was determined that the radiographer had performed operations alone on 3/4 and 3/5/2008. The most probable scenario was that the radiographer did not fully retract the source following a shot and failed to properly conduct a complete survey around the exposure device and guide tube prior to repositioning. Corrective actions included reprimanding the involved radiographer and requiring that he be requalified and recertified as an industrial radiographer. He must also retake the 40-hour radiation safety course and all radiographers will receive refresher training, including a review of the incident. As of 3/13/2008, this was classified as an International Nuclear Event Scale level 2 event.

Item Number 080526 - An occupational radiation overexposure occurred due to a stuck 4.11 TBq (111 Ci) Ir-192 radiography source. Three radiographers were performing pipeline weld testing near Ardmore, Oklahoma, under reciprocity on 9/2/2008. The radiographers were traveling along the pipeline testing the welds. One radiographer had the exposure device balanced behind him on the seat of a 4-wheeled all terrain vehicle (ATV), positioning the device to take shots at each weld. The other two radiographers were walking ahead of the ATV placing and positioning film on the pipeline. The device and guide tube were not disassembled between shots. At approximately 1000 hours, the device fell off the ATV and the guide tube was bent where it attached to the device. After straightening the guide tube, the source was cranked in and out with increased resistance. They continued working with the damaged guide tube, even though another guide tube was available. At approximately noon, the radiographer on the ATV decided the terrain near the next weld was too rugged, so he dismounted and disassembled the device and guide tube to carry them to the next weld. When he unscrewed the guide tube, he saw the cable inside and realized the source was not retracted. The crew was able to retract the source. The radiographer that was always near the device had a pocket dosimeter that was reading off-scale. When his alarming rate meter was tested, it did not work; the utilization log stated that it did work when checked that morning, but state investigators could not get it to work. The radiography crew stated that the radiographer on the ATV was the only person who worked with the exposure device from the time the guide tube was damaged until the overexposure was discovered. The radiographer had a survey meter, but was not using it at the time of the incident. The radiographer's badge was sent for emergency processing. The badge provider reported

a whole body dose of 16 cSv (rem). The radiographer stated that the distance between his body and the device was about one foot. The radiographer does not remember whether his badge was on his front or back pocket. If it was worn on his front pocket, the dose reported from his badge will probably be lower than his actual dose. Two different sets of blood samples were obtained, one to be processed locally and the other to be processed by REAC/TS. The radiographer saw an occupational physician on 9/9/2008. No symptoms were observed. REAC/TS stated that their Cytogenic dosimetry estimate for the exposed individual was 0 to 30 cSv (rem), with a most likely result of 11 cSv (rem). That estimate is consistent with the 16 cSv (rem) already reported. An exposure of 11 cSv (rem) was assigned to the individual's dose record. Corrective actions included requiring the radiographer to re-take the 40 hour radiation safety class. This event was classified as an EQP and EXP event. As of 9/9/2008, this was classified as an International Nuclear Event Scale level 2 event.

Item Number 080624 - A radiographer received an estimated extremity dose of 235.65 cSv (rem). On 9/29/2008, the radiographer moved an exposure device to perform the next shot. He removed the safety plug from the device to attach the guide tube and his electronic dosimeter began to alarm. He then noted that the 3.15 TBq (85 Ci) of Ir-192 source had moved out of the exposure device approximately 0.75 inches. The radiographer attempted to push the source back into the device using the safety plug. After that attempt failed, he used the crank assembly to return the source to the shielded position. The radiographer's pocket dosimeter had gone off scale. His TLD was sent for processing and results revealed 9.46 mSv (946 mrem) deep dose equivalent. The RSO had the radiographer reenact his actions taken during the incident. Two dose estimates revealed extremity exposures of 66.5 cSv (rem) and 282.2 cSv (rem), the higher exposure was based on possible contact with the source. The RSO stated that there have been no observable effects to the radiographer's hand. The radiographer was removed from duties involving radiation exposure. The Texas Department of State Health Services conducted an investigation and estimated that the dose to the radiographer's right hand was 235.65 cSv (rem). The individual's TEDE dose was measured at 2.74 cSv (rem) for the 2008 calendar year. As of 10/9/2008, this was classified as an International Nuclear Event Scale level 2 event.

Events of Interest

None.

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 NRC-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 Agreement State-regulated events represent statistically significant decreasing trends (indicated by the trend lines).

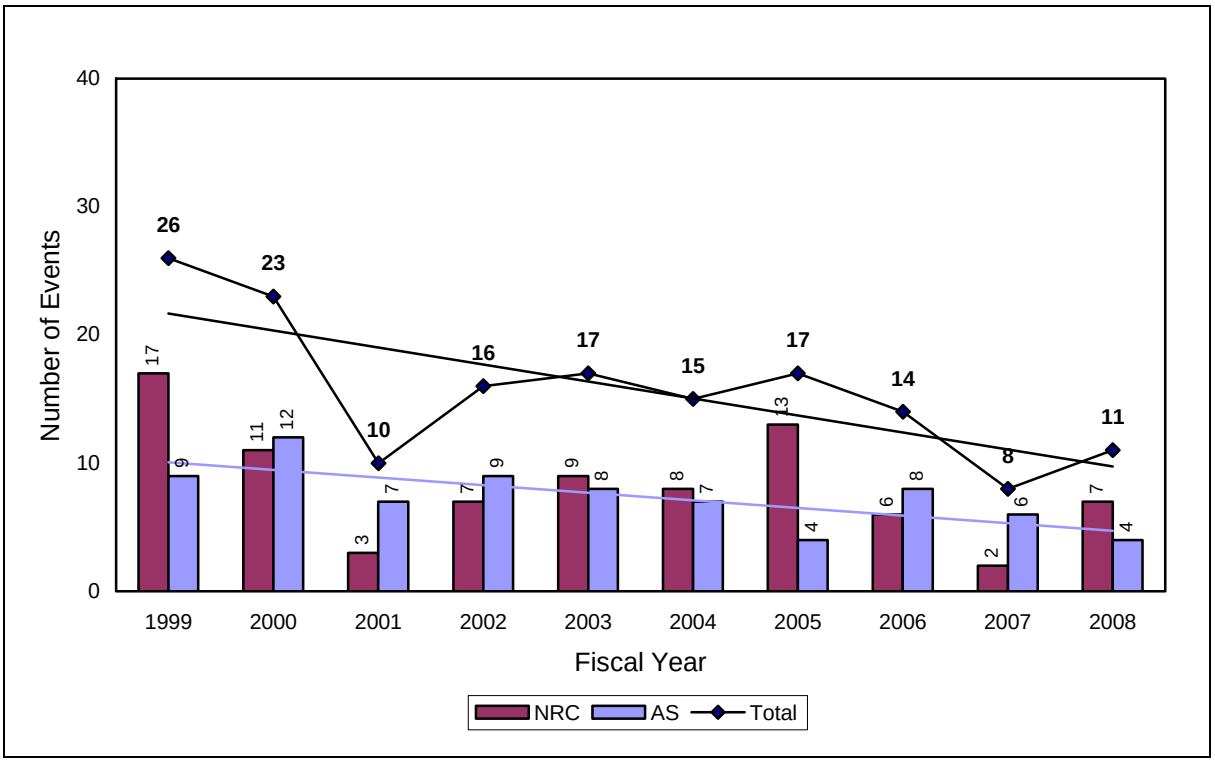

Figure 5. Release of Licensed Material or Contamination Events (157 total)

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 safety 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										
	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
Immediate	1	1	0	0	0	2	0	0	0	2	**6**
24-Hour	25	19	9	13	16	13	17	12	8	7	**139**
30-Day	0	3	1	3	1	0	0	2	0	2	**12**
Total	**26**	**23**	**10**	**16**	**17**	**15**	**17**	**14**	**8**	**11**	**157**

2.5.2 FY08 Data

Eleven RLM events occurred in FY08, nine of which were classified as significant events.

Significant Events—Immediate Reports

Item Number 080128 - A Sr-90 source was breached during removal from a fixed industrial gauge on 2/29/2008. The source's original activity was 3.7 GBq (100 mCi) on 8/9/1984; the activity at the time of the event was approximately 2.29 GBq (62 mCi). Personnel were disassembling industrial gauges in preparation for source disposal without adequate training procedures or supervision. The work area and the worker performing the task were contaminated. The worker was contaminated on his hands, face, and clothing, and inhaled some of the material. He was taken to a local health care facility where medical officials consulted with the Oak Ridge Radiation Emergency Assistance Center/Training Site (REAC/TS) regarding exposure. REAC/TS estimated that the dose received by the worker was below regulatory limits. A subsequent dose assessment based on bioassay results revealed a total effective dose equivalent of 14.4 mSv (1.44 rem). Three other workers were also contaminated to a lesser extent. Extensive radiation surveys performed by the NRC, the DOE Radiological Assistance Program, and the State of Idaho confirmed that no Sr-90 contamination had spread outside of the facility. Decontamination of the facility was completed on 5/16/2008. NRC inspectors conducted a confirmatory survey on 6/5/2008 and concluded that the facility was effectively remediated. Corrective actions included procedure modification and personnel training. This event was classified as an EQP, LKS, and RLM event.

Item Number 080598 - A surgical center reported that a patient implanted with I-125 seeds on 8/6/2008, died on 8/17/2008, and was cremated on 8/20/2008 without removing the seeds. The patient had been implanted with 63 seeds containing a total activity of 0.59 GBq (15.8 mCi). The surgical center's RSO responded to the funeral home and determined that the patient's ashes were in the pulverizer unit and a second person's ashes were in the crematory unit. The RSO obtained radiation readings of 1 mR/hour at the opening of the crematory unit, with 100 mR/hour in the interior of the unit and 10 mR/hour on contact with the patient's ashes in the pulverizer unit. The deceased persons' ashes were placed in plastic bags and then in plastic containers. The patient's plastic container revealed 10 mR/hour and the second person's plastic container revealed 0.1 mR/hour. On 8/21/2008, radiation readings in the crematory unit ranged up to 20 mR/hour. On 8/22/2008, a Georgia Department of Natural Resources (GDNR) inspector visited the funeral home and determined that the patient's ashes had been transferred to a cherry wood urn and buried on 8/21/2008. The second person's ashes had been transferred to a nickel-plated steel urn that was given to the family with instructions to place the urn in a remote location. On 8/26/2008, the GDNR inspector again visited the funeral home. The highest radiation reading in the crematory unit on 8/26/2008 was 9 mR/hour. The inspector took smears in areas around the crematory office, the crematory unit frame casing, the crematory preparation room, and areas around the exhaust vent in the preparation room. On 9/10/2008, the inspector returned to the funeral home to collect vegetation and ground samples from the outside of the facility, which revealed background results. The funeral home hired a contractor to decontaminate their facility. Two funeral home personnel were potentially exposed during this event.

They will receive thyroid scans and other tests. This event was classified as an EQP, LAS, LKS, and RLM event.

Significant Events—Within 24-Hour Reports

Item Number 070605 - A commercial nuclear power plant reported that a contaminated worker was transported offsite to a medical facility on 10/3/2007. The individual was working in the upper containment in support of the reactor vessel closure head replacement project. The individual's injuries were the result of being struck when a rigging clevis dropped from an elevated position. Site emergency medical technicians responded to the scene and transported the individual to the hospital via ambulance. At the time of transport, the individual was considered potentially contaminated because complete radiation surveys could not be performed while in transit due to immobilization. Following arrival at the hospital, radiation protection personnel verified the presence of low levels of contamination on the individual's outer protective clothing. NRC inspectors reviewed the circumstances involving the incident. They verified that personnel performed adequate radiological surveys of the individual, ambulance, and any affected areas of the hospital. The power plant also implemented adequate measures to ensure that radioactive material was not released into the public domain.

Item Number 080046 - A contamination event occurred at a radioactive waste processing facility on 1/16/2008. In preparation for concrete encapsulation work on 1/16/2008, a package received from a gaseous diffusion uranium enrichment plant was opened to physically inspect its contents. The contents were manifested as being a sealed source (metal disc) containing 52.9 MBq (1.43 mCi) of U-232 and 33.3 MBq (0.9 mCi) of Th-229. It was later determined that the package also contained 814 MBq (22 mCi) of U-233. High levels of loose contamination were measured on the exterior surfaces of an inner container (400,000 dpm/100 cm2 beta/gamma and 100,000 dpm/100 cm2 alpha). Inspection work was halted and the package was secured. However, the immediate work area and several individuals had already been contaminated. Although the inner container was not opened and its contents inspected, the waste generator reviewed the waste processor's photos of the labeling on the inner container and believed its contents to be uranium oxide powder, formerly used in preparation of laboratory standards. Personnel were decontaminated and received lung counts, which were negative for elevated intake. Fecal bioassays were ordered for each of the potentially exposed individuals. TEDE exposures for six individuals were 27.83, 0.32, 0.3, 0.22, 0.15, and 0 mSv (2783, 32, 30, 22, 15, and 0 mrem). The individual opening and subsequently securing the source package had the highest intake. Additional samples were collected from that individual (no regulatory limits were exceeded). The work area was decontaminated and returned to operable conditions. Corrective actions included revised training for workers engaged in source handling and more prescriptive work conditions.

Item Number 080123 - An 11.1 GBq (300 mCi) Cs-137 source was breached during removal from a source holder on 2/22/2008. The event involved two employees working in the source disposal room of a gauge manufacturer. No contamination occurred outside of the source disposal room. Personnel contamination was limited primarily to the clothing worn by the two individuals, who were successfully decontaminated. Lung bioassays of the individuals revealed 162.8 Bq (4.4 nCi) for one and 203.5 Bq (5.5 nCi) for the other. Urine samples showed no uptake for either individual. The Ohio Bureau of Radiological Protection (BRP) dispatched two inspectors to the Ohmart facility on 2/25/2008. The inspectors verified that Ohmart had secured ventilation and sealed off the source disposal room to prevent the spread of contamination. Decontamination activities and removal of all waste was completed on 4/3/2008. Corrective actions taken included procedure revisions and training for removal of sealed sources from gauges. The BRP lifted the Emergency Adjudication Order on 4/18/2008. This event was classified as an EQP, LKS, and RLM event.

Item Number 080191 - A commercial nuclear power plant transported a radioactively contaminated person to an offsite medical facility for treatment. Initial onsite surveys for radioactive contamination were unable to be performed prior to transport. Surveys conducted at the hospital identified low levels of contamination on the individual's clothing and skin. A maximum radiation reading of 600 cpm above

background was located on the right hand. Other locations ranged from 20 to 100 cpm above background. The individual was decontaminated with no remaining contamination above background identified. Radiation Protection personnel took control of the radioactive material and returned it to trhe power plant 2 in accordance with DOT guidelines. Radiation Protection personnel surveyed the ambulance and emergency room and no contamination was identified.

Item Number 080499 - A contamination event occurred at a uranium hexafluoride production facility on 8/27/2008. The contamination occurred while using the prepared feed mill. An average air sample revealed approximately 6.7 E-11 uCi/ml of natural uranium ore concentrates in the physical form of light dusty material.

Item Number 080500 - A contamination event occurred at a pharmacy on 8/28/2008. Six vials containing 55.5 GBq (1,500 mCi) of Tc-99m Cardiolite each were incubating in the iodine room. The sixth vial broke when a technician removed it from the incubator. The pharmacist was contacted and cleanup was initiated. The contamination was contained within the iodine room. The pharmacist's laboratory coat and the technician's laboratory coat, shirt, and dosimeter were contaminated. Personnel surveys performed by the RSO showed that the technician had a small amount of contamination on her hands and her hair was reading 10 mR/hour on contact. The RSO instructed the technician to go home, shower, bag her clothes and return to work. Upon returning to work, the employee was cleared of contamination. Her bagged clothing read above background. The iodine room was allowed to decay to background. The incident was attributed to failed equipment; the glass vial separated at the neck, probably due to an unnoticed crack or other imperfection. Corrective actions included examining vials, aluminum crimps, and septa for cracks or imperfections prior to use, examining vials after heating while still in the heating block, and training personnel to use caution when removing vials from the heating block.

Item Number 080652 - A pharmaceutical company reported the release of 8.51 GBq (230 mCi) of C-14 acetylene. A chemist was using 10.36 GBq (280 mCi) of C-14 acetylene, in a 24-hour reaction, to make C-14 ethylene. A plastic clamp used to hold the reaction equipment together became loose, allowing the C-14 to be released. Two potential causes of the release were identified; the receptacle may not have been at least four times the volume of the reaction, or chemistry in the receptacle produced pressure and the ground glass joints were not hard wired with copper wiring. The chemist recovered 1.85 GBq (50 mCi) of the product from the reaction equipment over the weekend. Radiological surveys of the fume hood revealed that some material was released through the stack. Urinalysis revealed no personnel exposure. Corrective actions included providing additional training for the chemist and discussions with the radio group to determine preventative measures in the future. This event was classified as an LAS and RLM event

Events of Interest

Item Number 080326 - A small glass vial containing standard reference material was discovered broken in a government laboratory on 6/9/2008. The reference material contained between 0.52 and 0.63 GBq (14 and 17 mCi) of plutonium powder of various isotopes (mixture of Pu-238, 239, 240, 241, and 242). Low levels of radioactive contamination spread outside the laboratory into an adjoining hallway. Surveys beyond the hallway were conducted, with no contamination detected. The laboratory's parent organization sent health physics personnel to assist with the event. Subsequent surveys found two minor contamination spots in a stairwell, which were easily cleaned up with soap and water. One office that had been identified as contaminated from the earliest survey was sealed pending future decontamination. Air monitoring equipment was installed in the adjacent hallway as a precaution in the unlikely event of air leakage from the contaminated laboratory. Bioassays were initiated on personnel known to have trace external contamination or determined to be potentially contaminated. Dose analyses and lifetime risk estimates indicated that the small number of personnel internally exposed to plutonium are not expected to suffer any clinically significant impact on either their short or long-term health. Health physicists made entries to the contaminated laboratory on 6/14 and 6/15/2008 to investigate the cause and extent of the spill. They found contamination in the laboratory sink and subsequently learned that a researcher who

worked directly with the plutonium sample had used that sink to wash his hands during the incident. City wastewater officials were notified of a potential plutonium discharge from the sink to the sanitary sewer system. For help in determining what might have been released to the sanitary sewer, the laboratory requested help from the DOE Radiological Assistance Program (RAP). The RAP team arrived 6/20/2008. It was determined that at least 76 to 87% of the spilled material could be accounted for. Because many smaller areas of contamination had not been analyzed, more of the material will be accounted for during future entries and testing. No evidence of releases to the atmosphere were found. The NRC dispatched a special inspection team to the facility to independently assess the event. The cause of the incident was human error; the vial of plutonium was handled inappropriately. Corrective actions included immediately halting the use of nuclear materials until better radioactive material use guidelines can be established. This event was classified as an EQP and RLM event.

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 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).

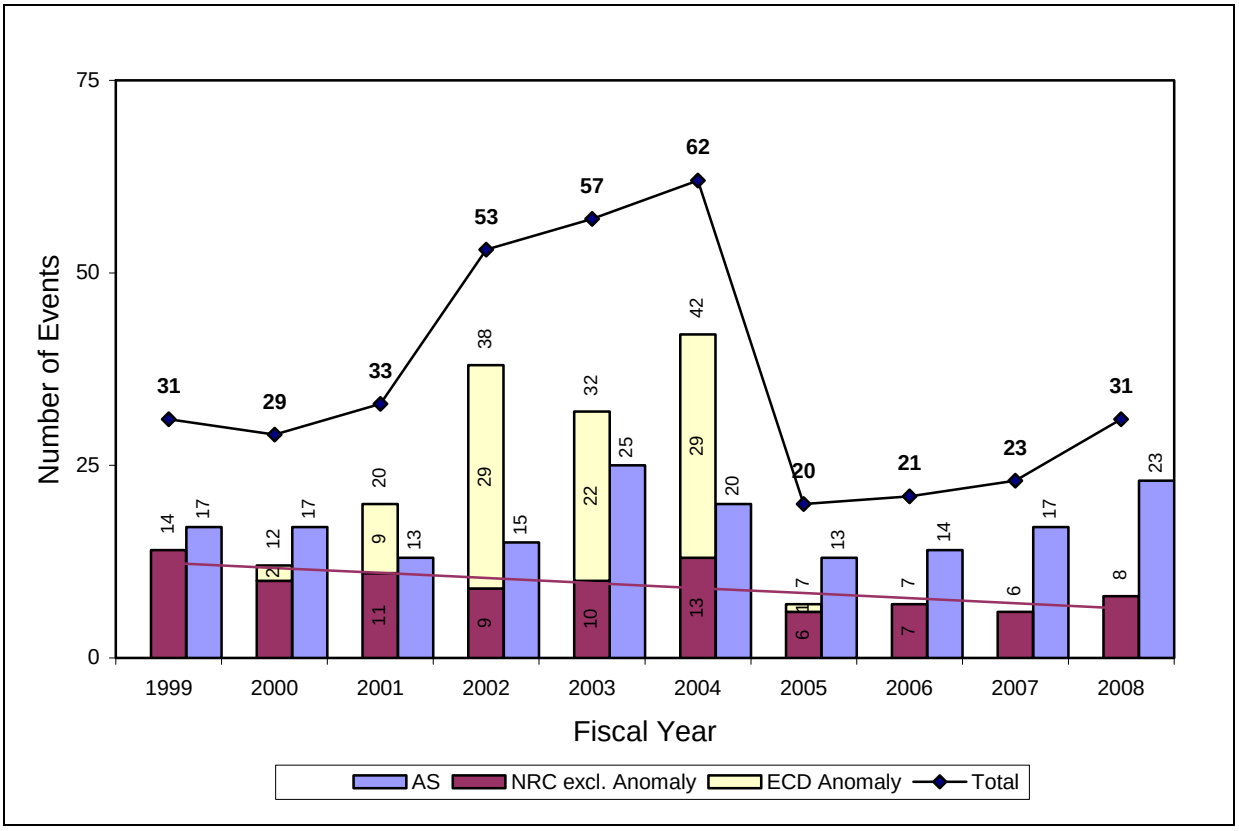

Figure 6. Leaking Sealed Source Events (360 total)

It is not possible to discern the significance of these events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). There are essentially no immediate or 24-hour reporting requirements for leaking sources. The exception is 39.77(a), which is an immediate report to the NRC Regional office of a ruptured well logging source.

2.6.2 FY08 Data

Thirty-one LKS events occurred in FY08, two of which were classified as significant events.

Significant Events

Item Number 080123 - An 11.1 GBq (300 mCi) Cs-137 source was breached during removal from a source holder on 2/22/2008. The event involved two employees working in the source disposal room of a

gauge manufacturer. No contamination occurred outside of the source disposal room. Personnel contamination was limited primarily to the clothing worn by the two individuals, who were successfully decontaminated. Lung bioassays of the individuals revealed 162.8 Bq (4.4 nCi) for one and 203.5 Bq (5.5 nCi) for the other. Urine samples showed no uptake for either individual. The Ohio Bureau of Radiological Protection (BRP) dispatched two inspectors to the Ohmart facility on 2/25/2008. The inspectors verified that Ohmart had secured ventilation and sealed off the source disposal room to prevent the spread of contamination. Decontamination activities and removal of all waste was completed on 4/3/2008. Corrective actions taken included procedure revisions and training for removal of sealed sources from gauges. The BRP lifted the Emergency Adjudication Order on 4/18/2008. This event was classified as an EQP, LKS, and RLM event.

Item Number 080128 - A Sr-90 source was breached during removal from a fixed industrial gauge on 2/29/2008. The source's original activity was 3.7 GBq (100 mCi) on 8/9/1984; the activity at the time of the event was approximately 2.29 GBq (62 mCi). Personnel were disassembling industrial gauges in preparation for source disposal without adequate training procedures or supervision. The work area and the worker performing the task were contaminated. The worker was contaminated on his hands, face, and clothing, and inhaled some of the material. He was taken to a local health care facility where medical officials consulted with the Oak Ridge Radiation Emergency Assistance Center/Training Site (REAC/TS) regarding exposure. REAC/TS estimated that the dose received by the worker was below regulatory limits. A subsequent dose assessment based on bioassay results revealed a total effective dose equivalent of 14.4 mSv (1.44 rem). Three other workers were also contaminated to a lesser extent. Extensive radiation surveys performed by the NRC, the DOE, and the State of Idaho confirmed that no Sr-90 contamination had spread outside of the facility. Decontamination of the facility was completed on 5/16/2008. NRC inspectors conducted a confirmatory survey on 6/5/2008 and concluded that the facility was effectively remediated. Corrective actions included procedure modification and personnel training. This event was classified as an EQP, LKS, and RLM event.

Events of Interest

Item Number 080087 – A 318.9 GBq (8.62 Ci) Ir-192 brachytherapy source was damaged during testing at an oncology center on 2/9/2009. A manufacturer's field engineer was testing a high dose rate (HDR) unit when an emergency retraction of the source occurred. During the retraction, the vault door closed on the tip of the source, resulting in a source disconnect and the loss of the top part of the source capsule. The source was then manually retracted to the inner vault. The inner vault/spool cartridge (containing the source) was shipped to the manufacturer, who received it on 2/26/2008. The loss of the source capsule tip was not known until the inner vault was inspected on 3/18/2008. A wipe of the tip of the cap/wire where the capsule was missing (the source would have direct contact with this piece) had a count of 327 cpm (background was 37 cpm). The back end of the cable had a count of 101 cpm. Survey results on the side of the vault were 200 mR/hour, with 100 mR/hour at the end of the vault. When the inner vault was disassembled, the bare Ir-192 pellet was found, but the source capsule was not. The shipping package was re-surveyed, but the capsule was not found. A field engineer later traveled to the oncology center, but could not locate the capsule. The Ir-192 activity in the missing capsule was not determined. Initial corrective actions included software changes to ensure the vault door doesn't close until the source capsule is in the appropriate location. This event was classified as an EQP and LKS event.

Item Number 080160 - A metal recycling facility reported that a barge of scrap metal from a recycling facility in Vancouver, British Columbia, Canada, set off their radiation monitor alarms. The load of metal contained two gauges with Cs-137 sources. One gauge had been sheared apart with scrap steel equipment and the source was leaking. Neither gauge contained labeling. One is believed to be manufactured by Kay-Ray and the Cs-137 source is marked with K57. The other gauge is believed to be manufactured by Ohmart, but no attempt has been made to identify markings on the leaking source. Oregon Radiation Protection Services personnel, a U.S. EPA Duty Officer, and an Oregon 102nd Civil Support Team

assisted with final radiation surveys and decontamination evaluations. The Canadian authorities were informed. This event was classified as an EQP, LAS, and an LKS event.

Item Number 080171 - A hospital reported that an implanted I-125 brachytherapy seed was leaking. The seed contained less than 12.95 MBq (350 uCi). On 3/10/2008, the patient was implanted with 102 seeds. On 3/11 or 3/12/2008, the patient complained of pain and difficulty urinating. A cauterization was performed via the urethra. Upon removal of the cauterization equipment, some seeds also exited the urethra. One seed was visibly different from the rest. Upon closer observation, the seed was noted to be shorter than the others and had been damaged. The cause of the damage was not definitely determined. However, it is believed to have occurred as a result of the cauterization procedure. Surveys revealed contamination of the equipment and bodily fluids, and an external reading directly over the thyroid showed levels above background. A CT scan performed on 3/19/2008 revealed that 92 seeds remained in the patient. Wipes of the remaining seeds showed contamination levels up to 18.5 kBq (500 nCi). It is believed that those seeds were cross-contaminated while in storage. Bioassays of the patient on 3/19/2008 revealed a thyroid burden of 29.6 kBq (0.8 uCi) and a dose of less than 1 cSv (rem) to the thyroid. The hospital stated that while extremely rare, they would consider doing the same cauterization procedure again but with greater screening of the need for that particular procedure as opposed to another, presumably less hazardous procedure, to accomplish the same goal. This event was classified as an EQP and LKS event.

Item Number 080598 - A surgical center reported that a patient implanted with I-125 seeds on 8/6/2008, died on 8/17/2008, and was cremated on 8/20/2008 without removing the seeds. The patient had been implanted with 63 seeds containing a total activity of 0.59 GBq (15.8 mCi). The surgical center's RSO responded to the funeral home and determined that the patient's ashes were in the pulverizer unit and a second person's ashes were in the crematory unit. The RSO obtained radiation readings of 1 mR/hour at the opening of the crematory unit, with 100 mR/hour in the interior of the unit and 10 mR/hour on contact with the patient's ashes in the pulverizer unit. The deceased persons' ashes were placed in plastic bags and then in plastic containers. The patient's plastic container revealed 10 mR/hour and the second person's plastic container revealed 0.1 mR/hour. On 8/21/2008, radiation readings in the crematory unit ranged up to 20 mR/hour. On 8/22/2008, a Georgia Department of Natural Resources (GDNR) inspector visited the funeral home and determined that the patient's ashes had been transferred to a cherry wood urn and buried on 8/21/2008. The second person's ashes had been transferred to a nickel-plated steel urn that was given to the family with instructions to place the urn in a remote location. On 8/26/2008, the GDNR inspector again visited the funeral home. The highest radiation reading in the crematory unit on 8/26/2008 was 9 mR/hour. The inspector took smears in areas around the crematory office, the crematory unit frame casing, the crematory preparation room, and areas around the exhaust vent in the preparation room. On 9/10/2008, the inspector returned to the funeral home to collect vegetation and ground samples from the outside of the facility, which revealed background results. The funeral home hired a contractor to decontaminate their facility. Two funeral home personnel were potentially exposed during this event. They will receive thyroid scans and other tests. This event was classified as an EQP, LAS, LKS, and RLM 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 (indicated by the absence of a trend line). Therefore, variations within the annual values represent random fluctuation around the average of the data.

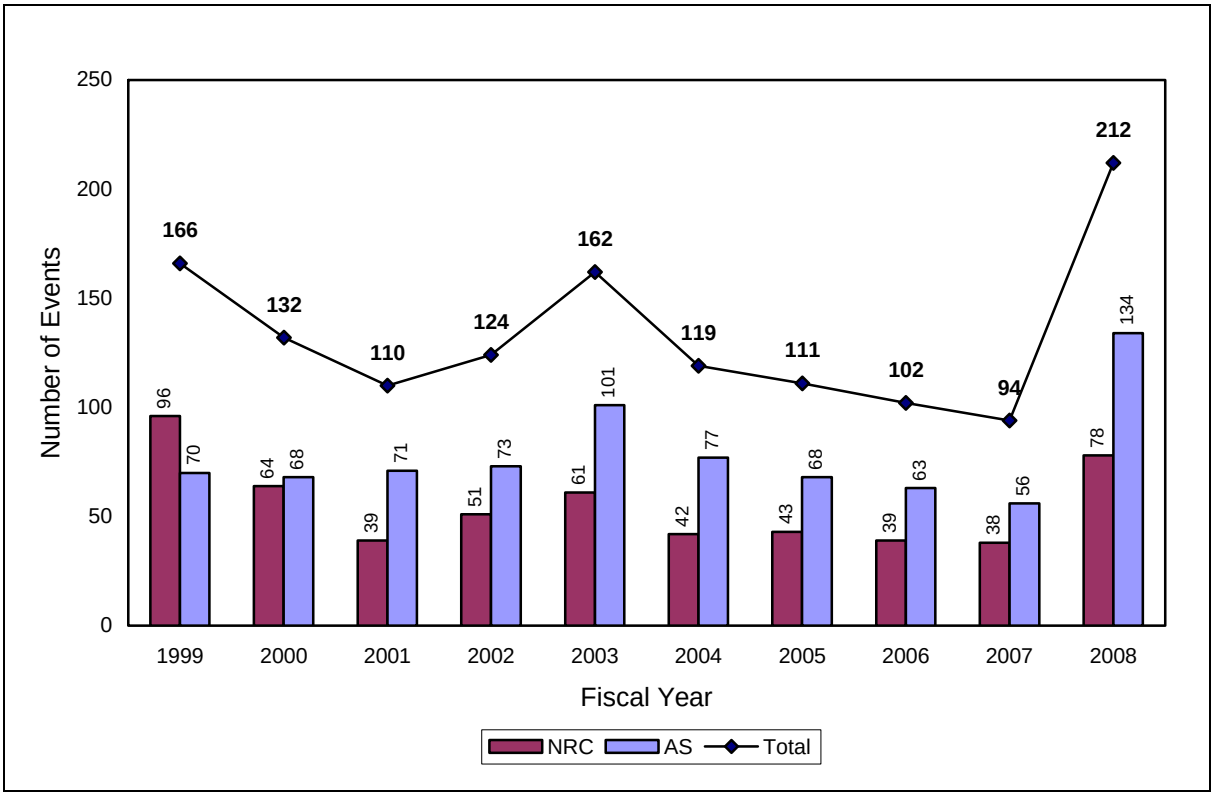

Figure 7. Equipment Events (1,332 total)

The FY08 data include 103 EQP events that 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 10/01/06 (Fiscal Quarter 07-1), 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 (RAI) 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.

2.7.2 FY08 Data

Two hundred-twelve EQP events occurred in FY08, one of which was classified as a significant event.

Significant Events

Item Number 080526 - An occupational radiation overexposure occurred due to a stuck 4.11 TBq (111 Ci) Ir-192 radiography source. Three radiographers were performing pipeline weld testing near Ardmore, Oklahoma, under reciprocity on 9/2/2008. The radiographers were traveling along the pipeline testing the welds. One radiographer had the exposure device balanced behind him on the seat of a 4-wheeled all terrain vehicle (ATV), positioning the device to take shots at each weld. The other two radiographers were walking ahead of the ATV placing and positioning film on the pipeline. The device and guide tube were not disassembled between shots. At approximately 1000 hours, the device fell off the ATV and the guide tube was bent where it attached to the device. After straightening the guide tube, the source was cranked in and out with increased resistance. They continued working with the damaged guide tube, even though another guide tube was available. At approximately noon, the radiographer on the ATV decided the terrain near the next weld was too rugged, so he dismounted and disassembled the device and guide tube to carry them to the next weld. When he unscrewed the guide tube, he saw the cable inside and realized the source was not retracted. The crew was able to retract the source. The radiographer that was always near the device had a pocket dosimeter that was reading off-scale. When his alarming rate meter was tested, it did not work; the utilization log stated that it did work when checked that morning, but state investigators could not get it to work. The radiography crew stated that the radiographer on the ATV was the only person who worked with the exposure device from the time the guide tube was damaged until the overexposure was discovered. The radiographer had a survey meter, but was not using it at the time of the incident. The radiographer's badge was sent for emergency processing. The badge provider reported a whole body dose of 16 cSv (rem). The radiographer stated that the distance between his body and the device was about one foot. The radiographer does not remember whether his badge was on his front or back pocket. If it was worn on his front pocket, the dose reported from his badge will probably be lower than his actual dose. Two different sets of blood samples were obtained, one to be processed locally and the other to be processed by REAC/TS. The radiographer saw an occupational physician on 9/9/2008. No symptoms were observed. REAC/TS stated that their Cytogenic dosimetry estimate for the exposed individual was 0 to 30 cSv (rem), with a most likely result of 11 cSv (rem). That estimate is consistent with the 16 cSv (rem) already reported. An exposure of 11 cSv (rem) was assigned to the individual's dose record. Corrective actions included requiring the radiographer to re-take the 40 hour radiation safety class. This event was classified as an EQP and EXP event. As of 9/9/2008, this was classified as an International Nuclear Event Scale level 2 event.

Events of Interest

Item Number 070642 - A moisture density gauge containing a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 fell out of the back of a truck onto a highway in Houston, Texas , on 10/18/2007. The RSO retraced the technician's route, found pieces of the gauge including the Cs-137 source, but could not find the Am-Be source. The Texas Department of State Health Services (DSHS) responded to the site. Law enforcement officials temporarily closed the highway to search for the Am-Be source, which was not found. The City of Houston performed road sweeping between 11/26 and 11/28/2007. The sweeper's hoppers were surveyed, but no radioactive material was identified. This event was classified as an EQP and LAS event.

Item Number 080070 - A health care facility reported an equipment failure involving a gamma knife unit containing a 82.84 TBq (2,239 Ci) of Co-60. On 1/31/2008, a patient was receiving the first of three treatment fractions. After the normal termination time of that fraction, the couch retracted fully and the patient's head was withdrawn from the unit. However, the shielding doors on the unit did not close. An

authorized medical physicist entered the treatment room, walked behind the unit, and manually closed the shielding doors. The physicist received an estimated exposure of no more than 0.083 uSv (8.3 urem) while closing the doors. The patient was removed from the treatment room and a radiation survey was conducted to verify that the shielding doors had closed completely. The manufacturer's representative completed an evaluation of the gamma knife unit and replaced some parts. The patient's remaining two exposure fractions were successfully completed. The radiation dose received by the patient did not deviate from the written directive.

Item Number 080087 - A 318.9 GBq (8.62 Ci) Ir-192 brachytherapy source was damaged during testing at an oncology center on 2/9/2009. A manufacturer's field engineer was testing a high dose rate (HDR) unit when an emergency retraction of the source occurred. During the retraction, the vault door closed on the tip of the source, resulting in a source disconnect and the loss of the top part of the source capsule. The source was then manually retracted to the inner vault. The inner vault/spool cartridge (containing the source) was shipped to the manufacturer, who received it on 2/26/2008. The loss of the source capsule tip was not known until the inner vault was inspected on 3/18/2008. A wipe of the tip of the cap/wire where the capsule was missing (the source would have direct contact with this piece) had a count of 327 cpm (background was 37 cpm). The back end of the cable had a count of 101 cpm. Survey results on the side of the vault were 200 mR/hour, with 100 mR/hour at the end of the vault. When the inner vault was disassembled, the bare Ir-192 pellet was found, but the source capsule was not. The shipping package was re-surveyed, but the capsule was not found. A field engineer later traveled to the oncology center, but could not locate the capsule. The Ir-192 activity in the missing capsule was not determined. Initial corrective actions included software changes to ensure the vault door doesn't close until the source capsule is in the appropriate location. This event was classified as an EQP and LKS event.

Item Number 080101 - A trailer load of waste set off the radiation alarms at a landfill in Northeast Pennsylvania on 1/7/2008. A health physicist located a source that was segregated, placed in a cask, and then placed into a locked office building. The dose rate at approximately one inch from the cask was 470 uR/hour and 3.5 mR/hour on contact. On 1/8/2008, it was identified that the source contained 0.3 GBq (8 mCi) of Cs-137 and was from a moisture/density gauge. The gauge owner was identified, however, their license had expired on 3/31/1999. The source was properly disposed of. This event was classified as an EQP and LAS event.

Item Number 080123 - An 11.1 GBq (300 mCi) Cs-137 source was breached during removal from a source holder on 2/22/2008. The event involved two employees working in the source disposal room of a gauge manufacturer. No contamination occurred outside of the source disposal room. Personnel contamination was limited primarily to the clothing worn by the two individuals, who were successfully decontaminated. Lung bioassays of the individuals revealed 162.8 Bq (4.4 nCi) for one and 203.5 Bq (5.5 nCi) for the other. Urine samples showed no uptake for either individual. The Ohio Bureau of Radiological Protection (BRP) dispatched two inspectors to the Ohmart facility on 2/25/2008. The inspectors verified that Ohmart had secured ventilation and sealed off the source disposal room to prevent the spread of contamination. Decontamination activities and removal of all waste was completed on 4/3/2008. Corrective actions taken included procedure revisions and training for removal of sealed sources from gauges. The BRP lifted the Emergency Adjudication Order on 4/18/2008. This event was classified as an EQP, LKS, and RLM event.

Item Number 080128 - A Sr-90 source was breached during removal from a fixed industrial gauge on 2/29/2008. The source's original activity was 3.7 GBq (100 mCi) on 8/9/1984; the activity at the time of the event was approximately 2.29 GBq (62 mCi). Personnel were disassembling industrial gauges in preparation for source disposal without adequate training procedures or supervision. The work area and the worker performing the task were contaminated. The worker was contaminated on his hands, face, and clothing, and inhaled some of the material. He was taken to a local health care facility where medical officials consulted with the Oak Ridge Radiation Emergency Assistance Center/Training Site (REAC/TS) regarding exposure. REAC/TS estimated that the dose received by the worker was below regulatory

limits. A subsequent dose assessment based on bioassay results revealed a total effective dose equivalent of 14.4 mSv (1.44 rem). Three other workers were also contaminated to a lesser extent. Extensive radiation surveys performed by the NRC, the DOE, and the State of Idaho confirmed that no Sr-90 contamination had spread outside of the facility. Decontamination of the facility was completed on 5/16/2008. NRC inspectors conducted a confirmatory survey on 6/5/2008 and concluded that the facility was effectively remediated. Corrective actions included procedure modification and personnel training. This event was classified as an EQP, LKS, and RLM event.

Item Number 080160 - A metal recycling facility reported that a barge of scrap metal from a recycling facility in Vancouver, British Columbia, Canada, set off their radiation monitor alarms. The load of metal contained two gauges with Cs-137 sources. One gauge had been sheared apart with scrap steel equipment and the source was leaking. Neither gauge contained labeling. One is believed to be manufactured by Kay-Ray and the Cs-137 source is marked with K57. The other gauge is believed to be manufactured by Ohmart, but no attempt has been made to identify markings on the leaking source. Oregon Radiation Protection Services personnel, a U.S. EPA Duty Officer, and an Oregon 102nd Civil Support Team assisted with final radiation surveys and decontamination evaluations. The Canadian authorities were informed. This event was classified as an EQP, LAS, and an LKS event.

Item Number 080171 - A hospital reported that an implanted I-125 brachytherapy seed was leaking. The seed contained less than 12.95 MBq (350 uCi). On 3/10/2008, the patient was implanted with 102 seeds. On 3/11 or 3/12/2008, the patient complained of pain and difficulty urinating. A cauterization was performed via the urethra. Upon removal of the cauterization equipment, some seeds also exited the urethra. One seed was visibly different from the rest. Upon closer observation, the seed was noted to be shorter than the others and had been damaged. The cause of the damage was not definitely determined. However, it is believed to have occurred as a result of the cauterization procedure. Surveys revealed contamination of the equipment and bodily fluids, and an external reading directly over the thyroid showed levels above background. A CT scan performed on 3/19/2008 revealed that 92 seeds remained in the patient. Wipes of the remaining seeds showed contamination levels up to 18.5 kBq (500 nCi). It is believed that those seeds were cross-contaminated while in storage. Bioassays of the patient on 3/19/2008 revealed a thyroid burden of 29.6 kBq (0.8 uCi) and a dose of less than 1 cSv (rem) to the thyroid. The hospital stated that while extremely rare, they would consider doing the same cauterization procedure again but with greater screening of the need for that particular procedure as opposed to another, presumably less hazardous procedure, to accomplish the same goal. This event was classified as an LAS and EQP event.

Item Number 080173 - A package containing a 4.55 GBq (123 mCi) Co-60 source was damaged during shipping, leaving the source unshielded. The source rod (the source was on the end of a 3-inch rod) was shipped in a Type A package from a temporary jobsite in Washington to the owner's office in Paramount, California. The Type A container was constructed of steel, with an inner lead storage pig, and secured to a wooden pallet. The cover of the lead pig was secured by a rod that fits through a steel collar. The rod was secured in place by a lock. Upon arrival, the wooden pallet was missing, the locking rod was out of position with the lock missing, and, although the inner lead pig cover was in place, the source rod was lying on top of the lead pig inside the collar. It is possible that someone noticed the damage and manually placed the loose source rod on top of the lead pig. Calculated radiation levels for the source were approximately 170 mR/hr at one meter, 1.8 R/hr at one foot, and 1,700 R/hr at one centimeter. An owner's employee reinserted the source rod into the lead pig before removing the package from the carrier's truck. He did this by handling the non-source end of the source rod with his bare fingers while wearing extremity dosimetry. The calculated extremity dose for this employee was 1 to 2 mSv (100 to 200 mrem). The owner requested that the carrier determine how the damage occurred and to evaluate exposures to carrier personnel. The DOT investigated the incident. The investigation did not identify any personnel overexposures. Corrective actions included equipping the package with a secondary padlock positioned through a hole in the T-bar, located on the interior of the protective collar and in an unexposed

position. Additionally, a protective nipple will be welded to the exterior of the collar, around the T-bar exit hole. That nipple will protect the T-bar in the event the package is dropped. This event was classified as an EQP and TRS event.

Item Number 080218 - On or about 2/21/2008, a scrap metal shipment from Preston, Idaho, triggered the portal radiation monitor at a recycling facility in Plymouth, Utah. A gauge containing a Cs-137 source with an original activity of 3.7 GBq (100 mCi) in May 1978 was located. The gauge was secured in a locked metal box and stored in an isolated area. On 2/29/2008, an inspector from the Idaho Department of Environmental Quality determined that the gauge's shutter was open and measured 0.2 mSv/hr (20 mrem/hr) at the surface of the open end of the gauge. Surveys for removable contamination were negative. The gauge owner was not identified. A health physics consulting firm was contracted to assist with disposal of the gauge. This event was classified as an EQP and LAS event.

Item Number 080326 - A small glass vial containing standard reference material was discovered broken in a government laboratory on 6/9/2008. The reference material contained between 0.52 and 0.63 GBq (14 and 17 mCi) of plutonium powder of various isotopes (mixture of Pu-238, 239, 240, 241, and 242). Low levels of radioactive contamination spread outside the laboratory into an adjoining hallway. Surveys beyond the hallway were conducted, with no contamination detected. The laboratory's parent organization sent health physics personnel to assist with the event. Subsequent surveys found two minor contamination spots in a stairwell, which were easily cleaned up with soap and water. One office that had been identified as contaminated from the earliest survey was sealed pending future decontamination. Air monitoring equipment was installed in the adjacent hallway as a precaution in the unlikely event of air leakage from the contaminated laboratory. Bioassays were initiated on personnel known to have trace external contamination or determined to be potentially contaminated. Dose analyses and lifetime risk estimates indicated that the small number of personnel internally exposed to plutonium are not expected to suffer any clinically significant impact on either their short or long-term health. Health physicists made entries to the contaminated laboratory on 6/14 and 6/15/2008 to investigate the cause and extent of the spill. They found contamination in the laboratory sink and subsequently learned that a researcher who worked directly with the plutonium sample had used that sink to wash his hands during the incident. City wastewater officials were notified of a potential plutonium discharge from the sink to the sanitary sewer system. For help in determining what might have been released to the sanitary sewer, the laboratory requested help from the DOE Radiological Assistance Program (RAP). The RAP team arrived 6/20/2008. It was determined that at least 76 to 87% of the spilled material could be accounted for. Because many smaller areas of contamination had not been analyzed, more of the material will be accounted for during future entries and testing. No evidence of releases to the atmosphere were found. The NRC dispatched a special inspection team to the facility to independently assess the event. The cause of the incident was human error; the vial of plutonium was handled inappropriately. Corrective actions included immediately halting the use of nuclear materials until better radioactive material use guidelines can be established. This event was classified as an EQP and RLM event.

Item Number 080364 - A recycling facility reported that a truckload of recyclable metal set off their radiation monitor alarms on 6/20/2008. The truck read 20 uSv/hour (2 mrem/hour) at a distance of five feet and about 0.3 uSv/hour (30 urem/hour) at a distance of 20 feet. A moisture/density gauge source rod, index rod, and handle were separated from the load. The 0.3 GBq (8 mCi) Cs-137 source was placed in a lead pig and transferred to the California Health and Human Services Agency's southern radioactive material storage area. Surveys revealed no source leakage or contamination. The associated Am-Be source was not found. The NRC Registry of Radioactive Sealed Sources and Devices indicates that this device contains an Am-Be source with a maximum activity of 1.63 GBq (44 mCi). The gauge owner had previously reported that the device was stolen on 3/5/1993. This event was classified as an EQP and LAS event.

Item Number 080518 - A steel manufacturing company reported an incident on 7/7/2008 that damaged the shielding of four fixed gauges, each containing a 48.1 GBq (1.3 Ci) Cs-137 source. A lightning strike

caused a loss of power while a steel pour was in progress on several billet caster lines. All but one of the lines were shutdown in time to avert a spill. However, the final line overloaded and several tons of molten steel spilled over a steel cabinet holding eight fixed gauges. An inspector responded to the plant on 7/7/2008 and identified an exposure rate of 200 mR/hour near the gauge bank. One gauge was recovered by the gauge manufacturer from that bank. A puddle of lead was identified outside the source holder. Radiation readings were less than 500 mR/hour near the surface of the source holder. Subsequently, three more gauges on another production line were determined to be adversely affected. There was no evidence that the lead in the housings had become molten to a point of escaping the housings, but each had deformed to affect shutter operation. No Cs-137 contamination was identified. The damaged gauges will be refurbished or replaced. The company plans to upgrade equipment to prevent future spills during a power failure.

Item Number 080598 - A surgical center reported that a patient implanted with I-125 seeds on 8/6/2008, died on 8/17/2008, and was cremated on 8/20/2008 without removing the seeds. The patient had been implanted with 63 seeds containing a total activity of 0.59 GBq (15.8 mCi). The surgical center's RSO responded to the funeral home and determined that the patient's ashes were in the pulverizer unit and a second person's ashes were in the crematory unit. The RSO obtained radiation readings of 1 mR/hour at the opening of the crematory unit, with 100 mR/hour in the interior of the unit and 10 mR/hour on contact with the patient's ashes in the pulverizer unit. The deceased persons' ashes were placed in plastic bags and then in plastic containers. The patient's plastic container revealed 10 mR/hour and the second person's plastic container revealed 0.1 mR/hour. On 8/21/2008, radiation readings in the crematory unit ranged up to 20 mR/hour. On 8/22/2008, a Georgia Department of Natural Resources (GDNR) inspector visited the funeral home and determined that the patient's ashes had been transferred to a cherry wood urn and buried on 8/21/2008. The second person's ashes had been transferred to a nickel-plated steel urn that was given to the family with instructions to place the urn in a remote location. On 8/26/2008, the GDNR inspector again visited the funeral home. The highest radiation reading in the crematory unit on 8/26/2008 was 9 mR/hour. The inspector took smears in areas around the crematory office, the crematory unit frame casing, the crematory preparation room, and areas around the exhaust vent in the preparation room. On 9/10/2008, the inspector returned to the funeral home to collect vegetation and ground samples from the outside of the facility, which revealed background results. The funeral home hired a contractor to decontaminate their facility. Two funeral home personnel were potentially exposed during this event. They will receive thyroid scans and other tests. This event was classified as an EQP, LAS, LKS, and RLM event.

Item Number 080599 - A paper manufacturing facility reported that the screws on a thickness gauge had backed out and a shielding plate fell off, leaving a 37 GBq (1 Ci) Kr-85 source exposed on 9/17/2008. The operator roped off the area around the paper machine to prevent access and exposure. A service technician responded to the facility on 9/17/2008.

Item Number 080625 - On 10/3/2008, a radiography equipment manufacturer reported a 10 CFR 21 defect potentially involving 659 Ir-192 and six Co-60 radiography source wires that were sold with defective connectors. An Ir-192 source disconnection incident on 8/21/2008 (NMED Item Number 080494) prompted the manufacturer to perform an investigation that identified the defective component (a female source connector). The defect could result in inadequate connection between the source and drive cable. Affected customers were advised to inspect their devices and return any defective source wires for replacement. The manufacturer will inspect their inventory and evaluate the component manufacturing process. In addition to the source disconnection event reported in NMED Item number 080494, this defect may also have been responsible for the source disconnection events reported in NMED Item Numbers 080382 and 080566.

Item Number 080675 - On 10/13/2008, a radiography equipment manufacturer reported a second 10 CFR 21 defect involving radiography source wire connectors. An Ir-192 source disconnection incident that occurred on 9/30/2008 (NMED Item Number 080639) prompted the manufacturer to perform an

investigation that identified the another source wire connector defect. This defect involves 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. Affected customers were advised to inspect their devices and return any defective source wires for replacement. The manufacturer will inspect their inventory and evaluate the component manufacturing process.

One hundred-three EQP events involved damaged tritium exit signs at multiple Wal-Mart stores.

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.

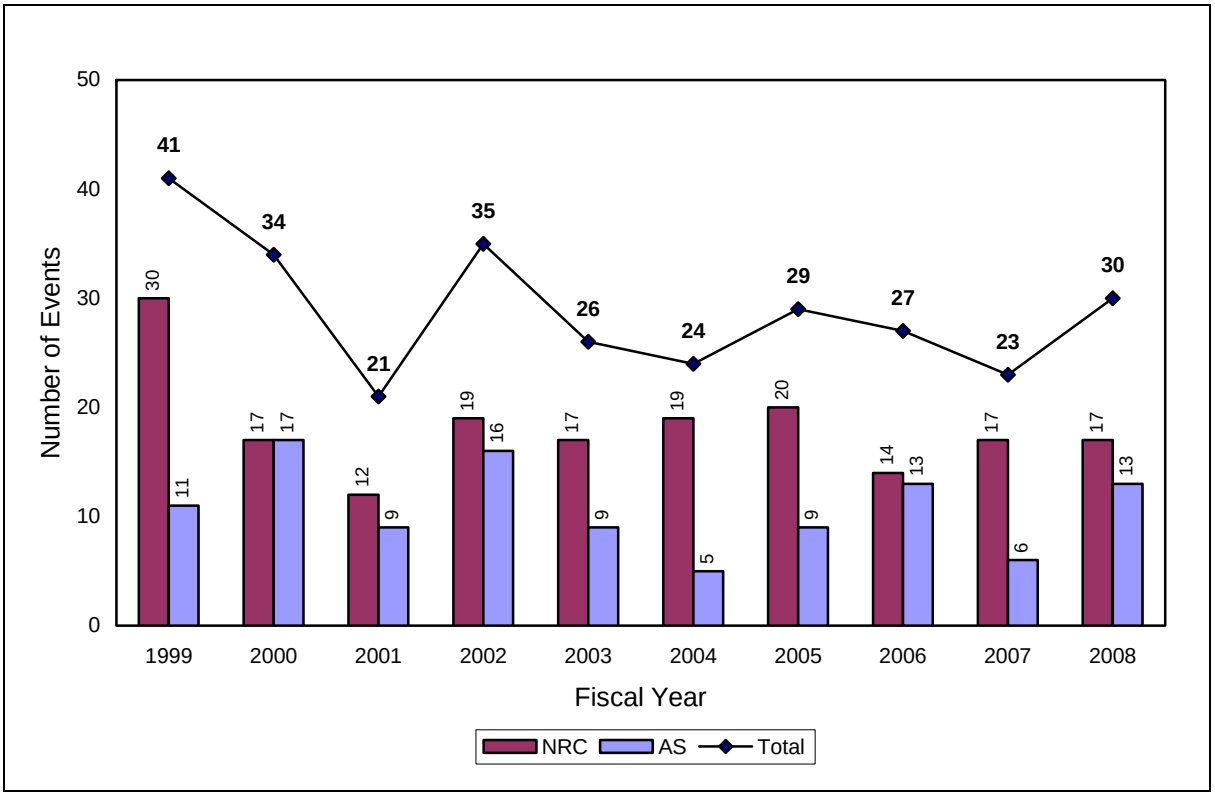

Figure 8. Transportation Events (290 total)

2.8.2 FY08 Data

Thirty TRS events occurred in FY08, two of which were classified as significant events.

Significant Events

Item Number 070691 - A brachytherapy product company reported that a package of 51 I-125 seeds, containing a total activity of 1.41 GBq (38 mCi), had been returned from a health care facility on 11/9/2007. The package had a radiation level of 600 mR/hour on contact and 1.4 mR/hour at one meter. The lid to the cask containing the seeds had become loose during transit due to the failure to properly secure it. The vial containing the seeds was intact with no signs of radioactive contamination or loss of integrity. The receiving RSO contacted the medical facility and courier. No personnel overexposures were suspected. The health care facility believed that the incident was due to abuse during shipment. All future shipments to clients will include more tape for sealing the lid and updated repackaging instructions to tape the lid closed.

Item Number 080173 - A package containing a 4.55 GBq (123 mCi) Co-60 source was damaged during shipping, leaving the source unshielded. The source rod (the source was on the end of a 3-inch rod) was shipped in a Type A package from a temporary jobsite in Washington to the owner's office in Paramount, California. The Type A container was constructed of steel, with an inner lead storage pig, and secured to a wooden pallet. The cover of the lead pig was secured by a rod that fits through a steel collar. The rod

was secured in place by a lock. Upon arrival, the wooden pallet was missing, the locking rod was out of position with the lock missing, and, although the inner lead pig cover was in place, the source rod was lying on top of the lead pig inside the collar. It is possible that someone noticed the damage and manually placed the loose source rod on top of the lead pig. Calculated radiation levels for the source were approximately 170 mR/hr at one meter, 1.8 R/hr at one foot, and 1,700 R/hr at one centimeter. The source owner's employee inserted the source rod into the lead pig before removing the package from the carrier's truck. He did this by handling the non-source end of the source rod with his bare fingers while wearing extremity dosimetry. The calculated extremity dose for this employee was 1 to 2 mSv (100 to 200 mrem). The owner requested that the carrier determine how the damage occurred and to evaluate exposures to carrier personnel. The DOT investigated the incident. The investigation did not any personnel overexposures. Corrective actions included equipping the package with a secondary padlock positioned through a hole in the T-bar, located on the interior of the protective collar and in an unexposed position. Additionally, a protective nipple will be welded to the exterior of the collar, around the T-bar exit hole. That nipple will protect the T-bar in the event the package is dropped. This event was classified as an EQP and TRS event.

Events of Interest

None.

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.

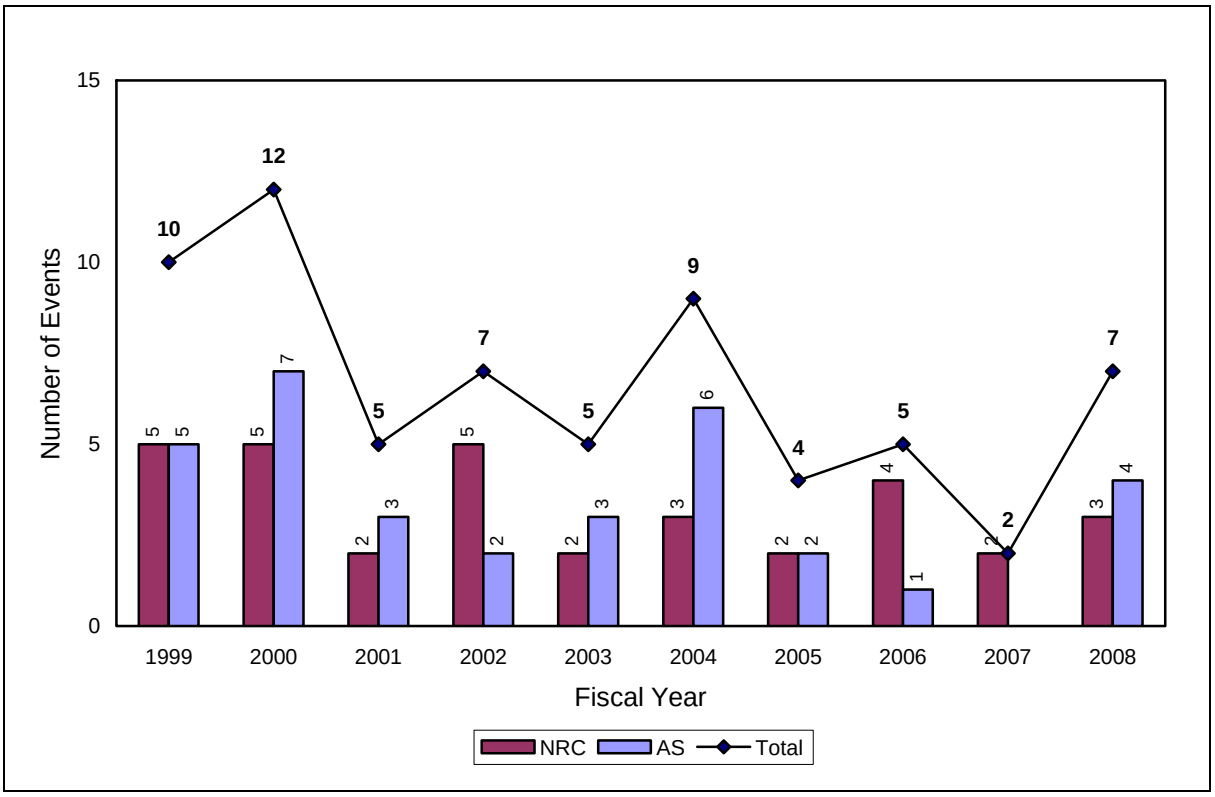

Figure 9. Other Events (66 total)

2.9.2 FY08 Data

Seven OTH events occurred in FY08, two of which were classified as significant events.

Significant Events

Item Number 080514 - A pregnant patient received a 5.52 GBq (149.2 mCi) I-131 dose on 6/4/2008. The patient was tested for pregnancy on 6/2/2008 prior to receiving the ablative dose. The qualitative serum screening result was negative and the dose was administered with no complications. On 8/13/2008, the patient was informed that she was pregnant. The NRC first learned of the incident during an unannounced inspection conducted on 9/5/2008. Follow-up consultation with the Radiation Emergency Assistance Center/Training Site (REAC/TS) and calculations determined that the dose to the fetus was approximately 31.5 cGy (rad). However, since the incident occurred early in the zygote phase of development, there are no anticipated adverse consequences. The NRC obtained the services of a medical consultant to assist in the ongoing special inspection of the incident. The consultant reviewed the case and calculated a slightly higher embryo/fetus dose of 32.5 cGy (rad). Corrective actions taken by the hospital included advising abstinence from intercourse for a period of 14 days prior to I-131 treatment or the use of an effective method of contraception for a period of 30 days prior to treatment. The hospital initially decided on a corrective action of using only quantitative serum test for detecting pregnancy instead of qualitative testing. The consultant stated that the difference in sensitivity between the two tests would not justify the increased expense and longer turnaround time. Either test would fail to detect early pre-implantation pregnancies. This event was classified as a potential AO.

Item Number 080550 - A pregnant patient received a 4.96 GBq (134 mCi) I-131 dose for thyroid carcinoma on 4/11/2008. The patient had two negative pregnancy tests on 4/6 and 4/10/2008. Following treatment, the patient suspected she was pregnant and returned to the hospital on 4/28/2008. Subsequent testing indicated she became pregnant approximately four to six days following treatment. The calculated whole body exposure to the fetus was 35 cGy (rad). The cause of the incident was that the patient did not follow the contraceptive plan outlined in the procedure she signed prior to treatment. Hospital staff followed all procedures. Corrective actions included procedure modifications to over-emphasize the risks associated with becoming pregnant following administration of radioiodine. This event was classified as a potential AO.

Events of Interest

Item Number 080359 - The Oklahoma Department of Environmental Quality (DEQ) reported visiting a facility on 6/19/2008 to verify the security of radioactive material. The facility held a radioactive material license, which expired on 1/31/2005, authorizing possession of portable soil moisture/density gauges containing Am-Be and Cs-137. They retained their gauges and continued to operate after the license expired. DEQ initiated enforcement action, leading to issuance of a consent order in late 2007, which involved payment of a penalty spread over three payments and submission of a new application, following which DEQ would issue a new license. The company stopped making the penalty payments and their RSO did not respond to DEQ attempts at telephone contact. Therefore, the DEQ visited the site on 6/19/2008. The inspector could not locate anyone at the facility office and investigated the property to find an employee to assist him. He found an unlocked door and opened it. Inside he found a wooden chest with a Yellow II radioactive material transportation label. The outside of the chest revealed a radiation reading of 0.1 mSv/hour (10 mrem/hour). The chest was not chained, locked, or secured in any way. He called the RSO, but she was unavailable and arranged for another employee to contact the inspector for assistance. When the employee arrived, they opened the chest and found a portable gauge that contained a 70.3 MBq (1.9 mCi) Ra-Be source. Radiation levels outside the shutter were approximately 0.5 mSv/hour (50 mrem/hour). Measurements of a wipe of the closed shutter did not reveal any removable contamination. The gauge was not listed on the previous license, nor on the new license application. Facility staff denies any prior knowledge of the gauge's presence. The gauge manufacturer stated that the gauge was sold to a different engineering consulting firm in 1973, who also no longer has a radioactive material license. There is no known connection between that firm and the present facility. It is not known how or when the gauge ended up in possession of the facility. The inspector verified that the previously-known Am-Be and Cs-137 gauges were still present and chained in the storage area.

Item Number 080492 - A radiography equipment manufacturer reported that a potential personnel radiation overexposure occurred on 8/20/2008. A radiography source wire assembly and end plate are used to perform a radiation profile of all incoming exposure devices as part of the quality control test procedure. A technician operating the radiation profiler inadvertently removed an end plate and a 4.19 TBq (113.2 Ci) Ir-192 source wire assembly from a device that had just been profiled, thinking that only the end plate was attached. The high radiation alarms sounded at the facility, which caused an immediate evacuation of the building. Radiation surveys outside the building indicated a dose rate of approximately 3 mR/hour at a distance of 25 feet from the building exterior. A 2 mR/hour boundary was established outside the building and manned by radiation protection personnel. A source retrieval team recovered the source and placed it in a shielded container. The building was reoccupied approximately 30 minutes later. Preliminary investigation indicated that the technician's electronic dosimeter showed an exposure of 7.2 mSv (720 mrem). Dosimetry for both the technician and another employee that was nearby when the incident occurred was sent for immediate processing. The technician's collar TLD registered a whole body dose equivalent of 3.28 mSv (328 mrem) and his right ring TLD measured 7.19 mSv (719 mrem). His estimated left hand exposure was 19.68 mSv (1,968 mrem). The waist TLD whole body badge for the second employee in the laboratory read 1.49 mSv (149 mrem). Company radiation safety staff performed additional investigations and stated that no personnel overexposure occurred. It was

determined that the technician failed to maintain focus on the task at hand, while reviewing personal messages. Corrective actions included restricting the involved technician from performing source transfers for a month and requiring him to complete retraining. An additional employee was also assigned to perform quality control tasks to decrease the workload of the involved technician.

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 scrams per plant year, then we could use regression methods to study whether there is a relationship between time and scram 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,* 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*, 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 safety 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 thru 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 show the net numerical differences to the 10-year data previously published. A positive value indicates that the net value has increased from that published in the previous report, while a negative value indicates that the net value decreased from the previous report.

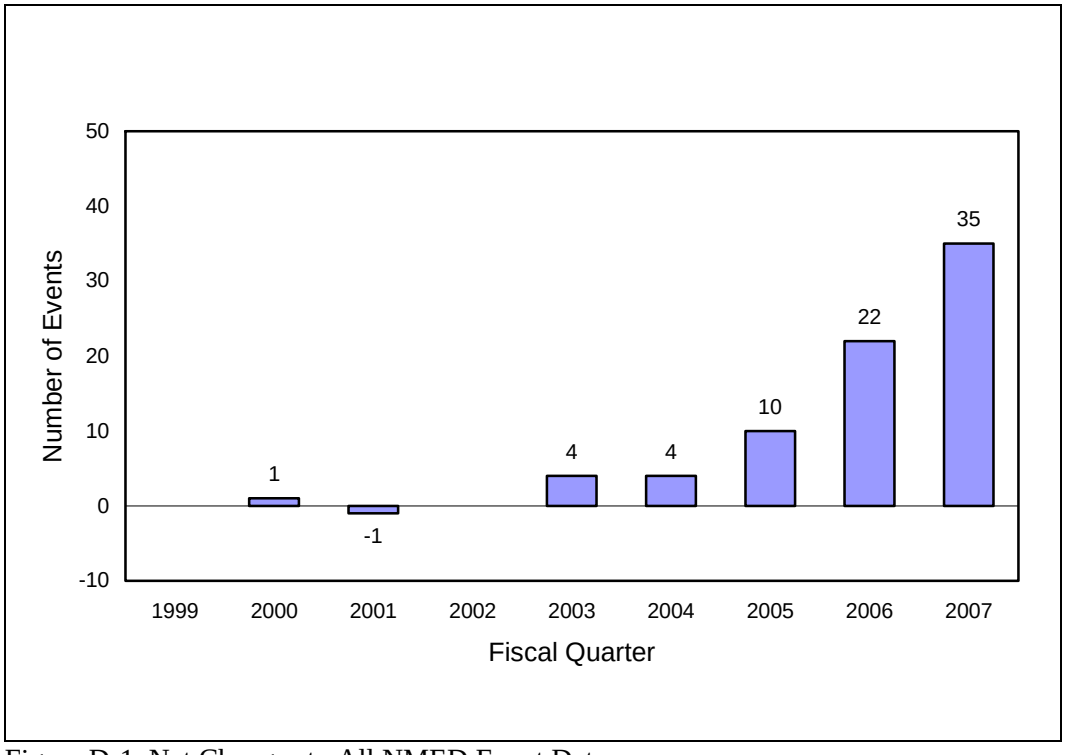

Figure D-1. Net Changes to All NMED Event Data

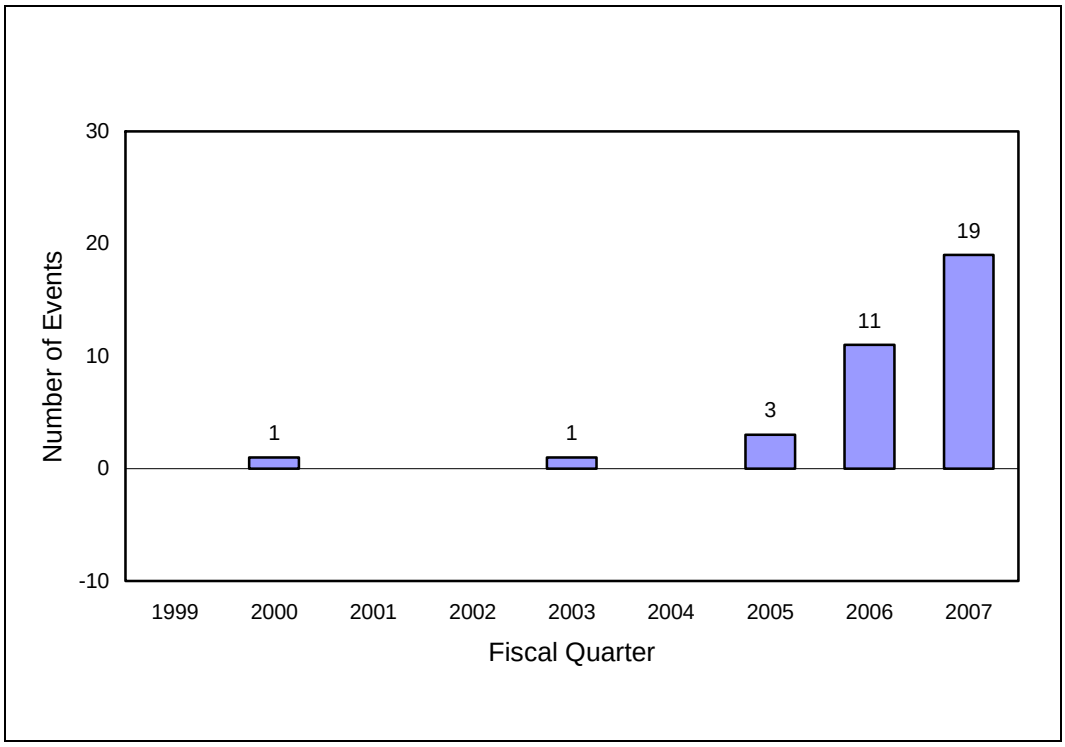

Figure D-2. Net Changes to LAS Data

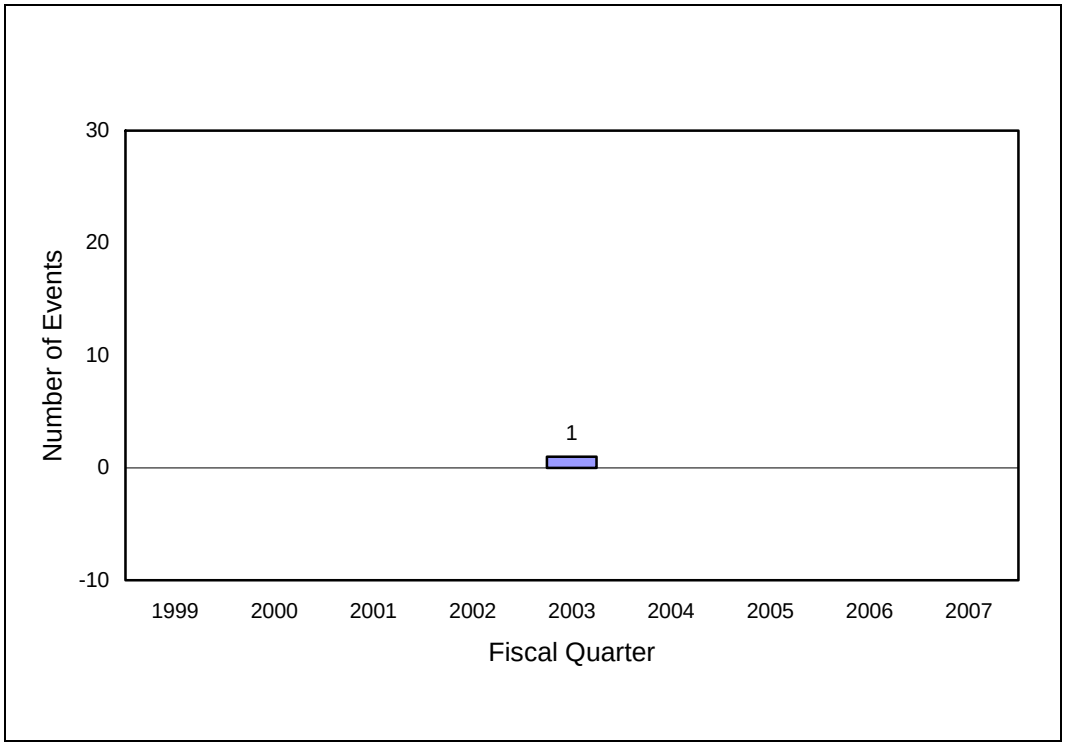

Figure D-3. Net Changes to MED Data

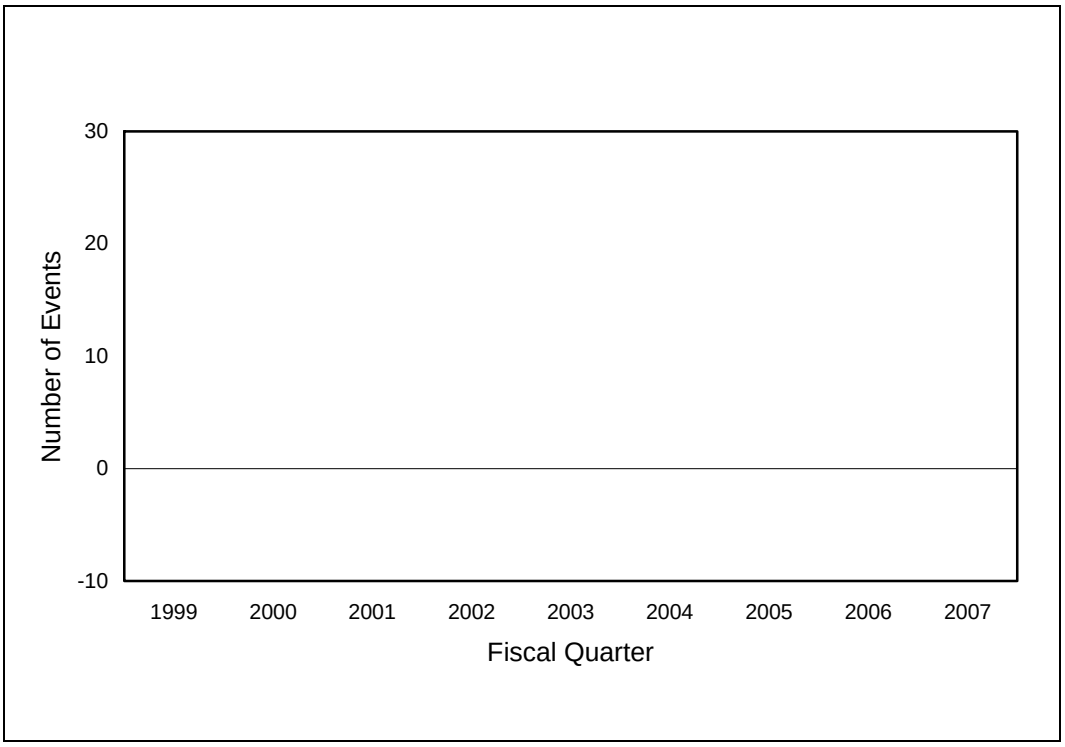

Figure D-4. Net Changes to EXP Data

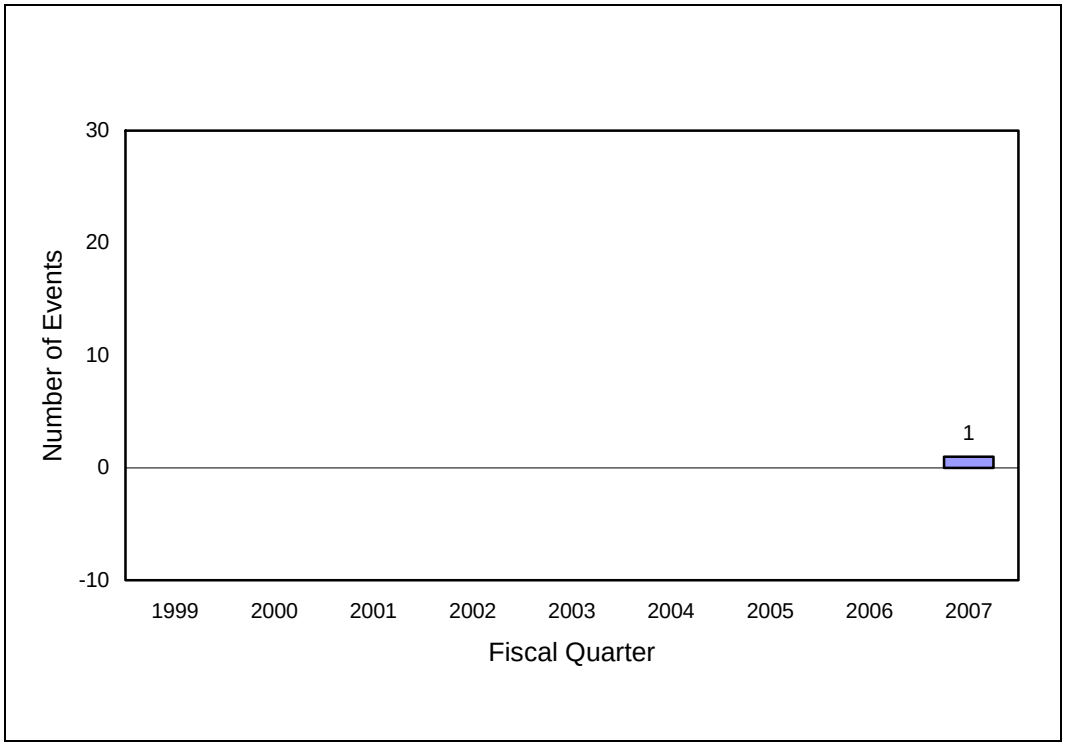

Figure D-5. Net Changes to RLM Data

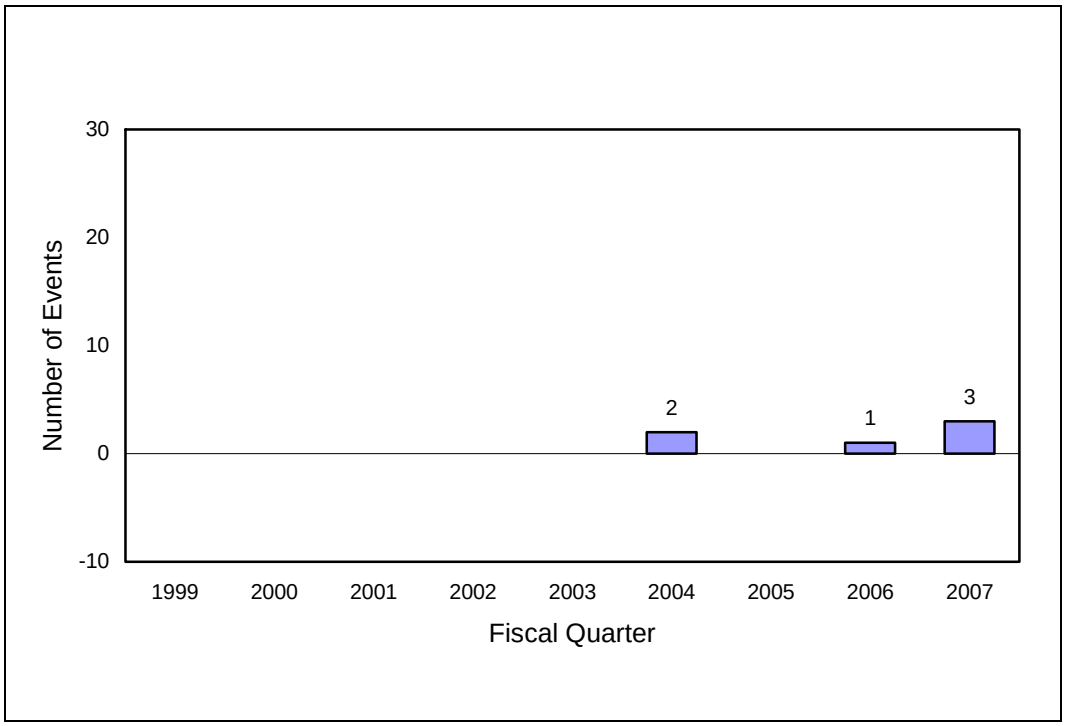

Figure D-6. Net Changes to LKS Data

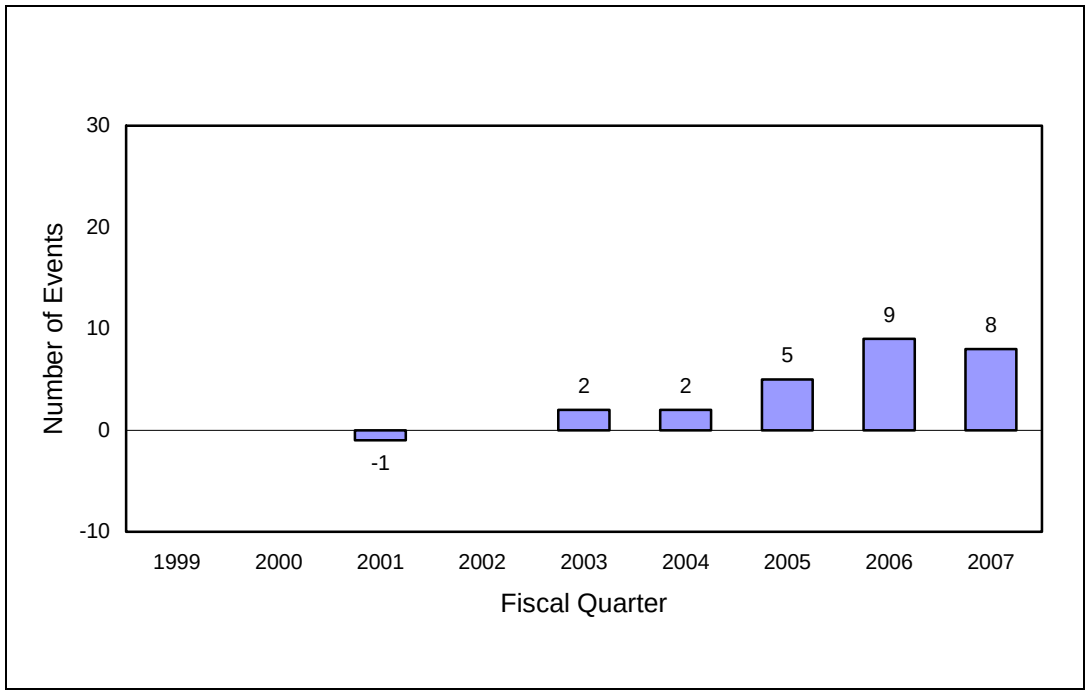

Figure D-7. Net Changes to EQP Data

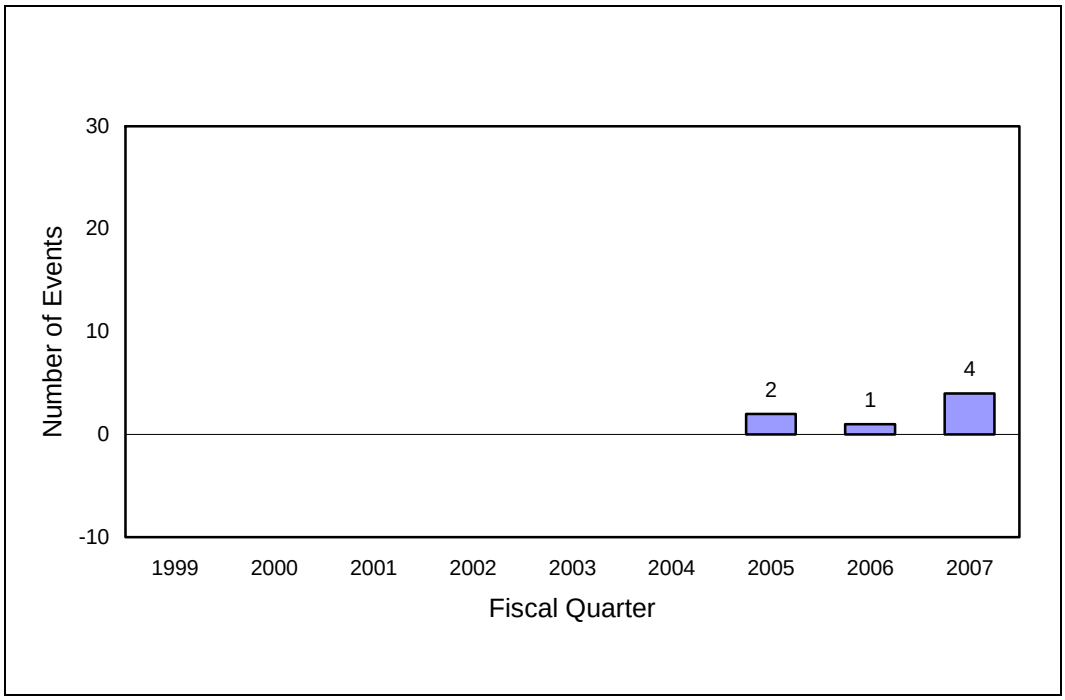

Figure D-8. Net Changes to TRS Data

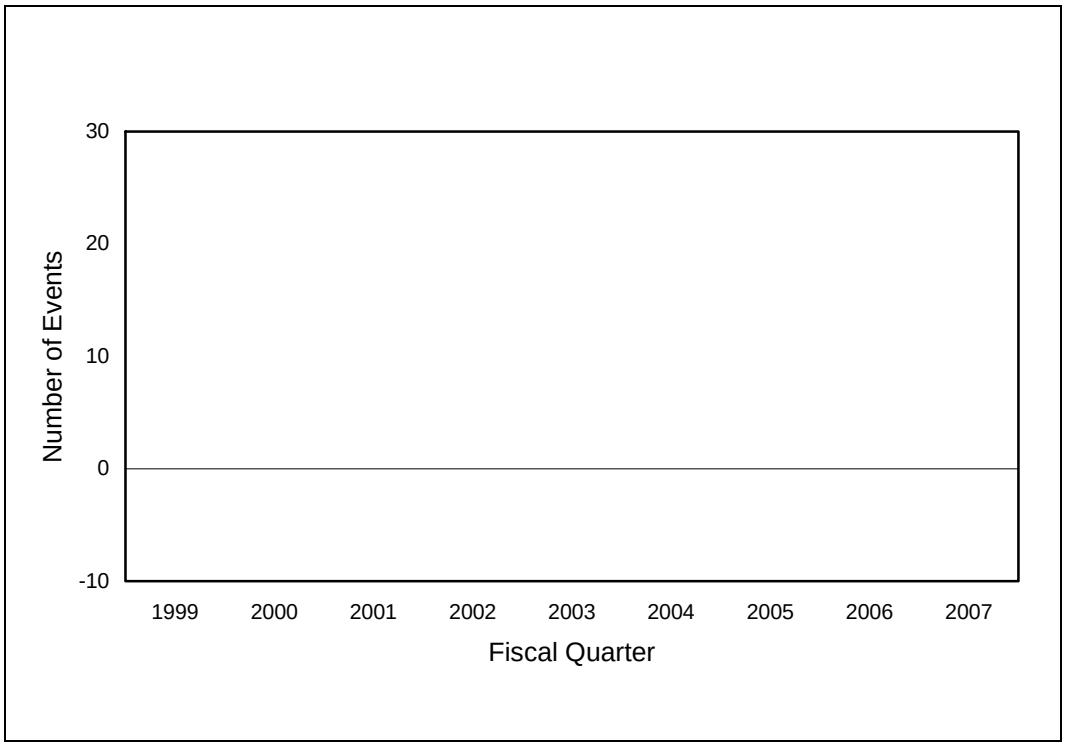

Figure D-9. Net Changes to OTH Data

General License Event Summary for January 1, 1998, to December 31, 2008

Events Involving General Licensed Devices								
			Number of Devices per Event Type**					
Devices	Number of Events*	Total Number of Devices	LAS	EQP	LKS	RLM	TRS	OTH
Tritium Exit Signs	250	7267	7249	252	0	1	0	0
Static Eliminator	127	251	241	14	11	0	2	0
Gauges (Fixed, Portable)	119	174	126	50	5	0	2	2***
Electron Capture Devices	22	33	24	0	9	0	0	0
Fluorescence Analyzers	21	23	20	4	0	0	0	0
Gas Chromatograph	7	7	4	0	3	0	0	0
Liquid Scintillation Counter	6	6	0	6	5	0	0	0
Radioluminescent Markers	1	12	12	0	0	0	0	0
Chemical Agent Monitor	1	2	2	0	0	0	0	0
Smoke Detector	1	1	1	0	0	0	0	0
Total	**555**	**7776**	**7679**	**326**	**33**	**1**	**4**	**2**

* Note that multiple types of devices may be involved in an event. Therefore, the total for the number of events per device will be greater than the total number of general licensed events.
** Note that a device event may meet multiple event types. Therefore, the sum of the devices per event type for a given device does not represent the total number for that type of device. Also, the event type descriptions and criteria may be found in Appendix A of the FY 2008 Nuclear Material Event Database Annual Report, which may be found in Enclosure 3 of this paper.
*** Note that these two "OTH" events involved radiation dose rates in unrestricted areas exceeding applicable dose limits set forth in 10 CFR Part 20. However, no individual received an over exposure.

Events Involving General Licensed Devices	
Devices	**Isotopes Used for Device***
Tritium Exit Signs	H-3
Static Eliminator	Am-241, H-3, Ni-63, Po-210
Gauges (Fixed, Portable)	Am-241, Am-Be, Ba-133, Cd-109, Cm-244, Cs-137, Fe-55, H-3, Kr-85, PM-147, Ra-226, Sr-90, Tl-204
Electron Capture Devices	H-3, Ni-63
Fluorescence Analyzers	Am-241, Cd-109, Cm-244, Co-57, Fe-55
Gas Chromatograph	Ni-63
Liquid Scintillation Counter	Cs-137
Chemical Agent Monitors	Ni-63
Smoke Detector	Am-241
Radioluminescent Safety Markers	H-3

* Note that the isotopes listed represent the isotopes for the devices involved in this general license event study.

Byproduct Material of General Licensed Devices						
	Activity (Ci) per Event Type**					
Isotope*	LAS	EQP	LKS	RLM	TRS	OTH
H-3	111551.72	3795.27	0	20	0	0
Cs-137	16.34509	2.23094	0.00015	0	1.2	1.02
Am-241	8.715511	8.80253	1.112	0	0	0
Kr-85	3.9284	0.668	0	0	0	0
Po-210	1.9656392	0.14763	0.1409	0	0.027	0
Sr-90	0.54780796	0.12	0.000005	0	0	0
Cm-244	0.403	0.01325	0.00025	0	0	0
Fe-55	0.370629	0.02	0	0	0	0
Ni-63	0.3685	0	0.14	0	0	0
Cd-109	0.19065	0.023	0	0	0	0
Pm-147	0.004933	0.003	0.0018	0	0	0
Tl-204	0.000085	0.00005	0.00005	0	0	0
Ra-226	0.000007	0	0	0	0	0
Am-BE	0	3	0	0	0	0
Ba-133	0	0.01	0.01	0	0	0
Co-57	0	0.0087	0	0	0	0
Total	**111584.5603**	**3810.3171**	**1.405155**	**20**	**1.227**	**1.02**

* Note that an event may be classified under multiple event types. Therefore, the sum of the activity per event type for a given isotope does not represent the total amount of activity for the isotope. Also, the event type descriptions and criteria may be found in Appendix A of the FY 2008 Nuclear Material Event Database Annual Report, which may be found in Enclosure 3 of this paper.

** In some cases, the activity was not reported for an event. For theses cases, the average activity for the type of source/device was used. If the activity was not reported and an average activity could not be determined the source was not included in this table.

Nuclear Fuel Services, Inc.

1. SITE IDENTIFICATION

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

2. SITE STATUS SUMMARY

Nuclear Fuel Services, Inc. (NFS) met the declining "performance trend" criteria established in SECY-08-0135 for Agency Action Review Meeting (AARM) consideration. Specifically, the U.S. Nuclear Regulatory Commission (NRC) inspections and events at NFS, prior to and during 2006, revealed significant performance issues that lasted more than one inspection period. The performance issues resulted in escalated enforcement actions that warranted extraordinary NRC actions (i.e., an Augmented Inspection Team Inspection in 2006, and issuance of a confirmatory order in February 2007). The Order required NFS to revise its configuration management (CM) programs and implement a comprehensive safety culture improvement initiative. The NRC response to the performance issues also included heightened NRC oversight at NFS (i.e., additional inspections, the assignment of a second resident inspector, and more frequent Licensee Performance Reviews).

Although the results of our more recent inspections indicate that NFS has made progress in improving its performance, the problems that led to issuance of the confirmatory order are deeply rooted, and a sustained effort will be required by the licensee as part of its safety culture improvement initiative to enhance its overall performance. In addition, the NRC will disposition several apparent violations extending from 2006 to the present with similarities to the performance issues that resulted in the 2007 confirmatory order, and that may result in escalated enforcement. Hence, a sustained period of heightened oversight by NRC is also warranted.

3. MAJOR TECHNICAL OR REGULATORY ISSUES

Oversight of Licensee Actions Regarding February 2007 Confirmatory Order

The NRC staff chartered the NFS Safety Culture and Configuration Management Improvement Oversight Panel (Panel) 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 (ISCA). 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 also reviewed NFS' May 15, 2008, submittal which included the report of the ISCA as well as NFS' safety culture improvement plan. In December 2008, the Panel issued a letter to NFS noting that NFS continued to meet the conditions of the February 2007 Order. The Panel further noted that NFS' plan contained only a high level overview of NFS planned actions and that onsite inspection would be needed to evaluate specific details on the implementation of the Plan.

The staff plans to conduct a series of at least five team inspections over and above the core inspection for the facility to examine implementation of the safety culture improvement plan. These five inspections, which are planned between January and August 2009, will include a two week Problem Identification and Resolution inspection. The planned inspections represent an additional fifty percent above the inspection normal core inspection resources budgeted for the facility.

In addition, the staff is currently developing a strategy to determine appropriate criteria for future modification or closure of the Confirmatory Order. It is anticipated that the strategy will include substantial inspection activities by NRC, including independent NRC assessment of safety culture at NFS through application and adaption of existing inspection tools such as Inspection Procedure 95003.

Pending Escalated Enforcement Actions

Three pending escalated enforcement actions currently exist at NFS. A fitness-for-duty case (EA-08-103) resulted in the identification of several apparent violations that could result in escalated enforcement, including individual actions. Apparent violations related to the processing of a weapon onto the site (EA-08-346) were identified that could result in escalated enforcement action. Finally, an apparent violation that involved the potential willful falsification of medical records (EA-08-321) could also result in escalated enforcement action.

New Ownership

On December 31, 2008, Amendment 85 to License SNM-124 was issued to reflect an indirect transfer of control of the licensee from NFS Services, LLC, to NOG-Erwin Holdings, Inc. (a subsidiary of Babcock and Wilcox). On January 1, 2009, David Kudsin became the President of NFS. This was the only personnel change at the site.