

**POLICY ISSUE**  
**(Information)**

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FOR: The Commissioners

FROM: Mark A. Satorius, Director */RA/*  
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and Environmental Management Programs

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE  
PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS  
FISCAL YEAR 2012

PURPOSE:

This paper provides the eleventh annual report on significant nuclear materials issues and licensee performance trends in the Materials and Waste Programs pursuant to Staff Requirements Memorandum (SRM) SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated February 25, 2003 (ML030560328). This report covers fiscal year (FY) 2012. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2012, the staff evaluated significant nuclear materials issues and performance trends based on aggregated information obtained from operating experience associated with reportable events and generic concerns 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 discernible performance trends or generic concerns and that public health and safety were protected.

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**BACKGROUND:**

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

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

On September 16, 2008, the staff issued SECY-08-0135 "Revision of the Criteria for Identifying Nuclear Materials Licensees for Discussion at the Agency Action Review Meeting" (ML082480564), which provided a revision to the criteria provided in Table 1 of SECY-02-0216 for determining nuclear materials licensees that warrant discussion at the AARM. The criteria were revised to provide additional clarity and incorporate NRC's current policies and procedures. In 2011, the criteria for identifying nuclear material licensees for discussion at the AARM was revised again to include an additional criterion to address licensees who previously were discussed at the AARM but their corrective actions were ineffective in correcting the underlying issues. The information regarding that revision to the criteria for identifying nuclear materials licensees for discussion at the AARM was provided to the Commission in SECY-11-0132, "Revision of the Criteria for Identifying Nuclear Material Licensees for Discussion at the Agency Action Review Meeting," dated September 20, 2011.

**DISCUSSION:**

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

The aggregated information used to evaluate significant adverse performance issues and performance trends was obtained through existing processes and systems and includes the following information: strategic outcomes and performance measures data; annual assessment of events reported to the Nuclear Material Events Database (NMED); Abnormal Occurrence (AO) data; data derived through escalated enforcement actions; and significant licensee performance issues that were identified based on the criteria described in SECY-11-0132. The following sections represent an evaluation of this information followed by overall conclusions of the licensee performance in the Materials and Waste Programs.

Typically generic and/or special event study results are included in this aggregated information; however, after review and analysis of the event data, it was determined that an event study was not warranted for FY 2012.

#### 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 2012 Performance and Accountability Report," related to nuclear materials events. The metric for the strategic outcomes is zero occurrences, and there were no occurrences related to nuclear materials that met any of the safety or security strategic outcomes for FY 2012. Also, the safety and security performance measure targets were met in FY 2012.

#### Assessment of Data Reported to NMED

The NMED contains records of events involving nuclear materials reported to NRC by its licensees, Agreement States, and non-licensees. These reported events are sorted by the event reporting requirements as defined in NRC regulations. The event reports are evaluated to identify any safety significant events and their causes. NMED data is analyzed for the main event types, is aggregated for evaluation of potential trends, and is presented in an annual summary report (NMED Annual Report). For the purposes of the NMED Annual Report data, it should be noted that a single occurrence/event report may be captured in multiple NMED event categories (e.g., a report may describe a loss of licensed material that also resulted in a radiation overexposure). It should also be noted that for the FY 2012 NMED Annual Report, Transportation (TRS) events involving fuel cycle process facilities are also coded as Fuel Cycle Process (FCP) events. A copy of the FY 2012 NMED Annual Report is available in [Enclosure 1](#). Copies of previous NMED Annual Reports may be found at <http://nmed.inl.gov/>.

In order to account for the potential random fluctuations in the event data from year to year and to assess an average trend of the data, the data from the last 10 FYs are reviewed. For the 10 year period covering October 1, 2002, through September 30, 2012 (i.e., FY 2003 through FY 2012), a total of 5,802 events (1,959 NRC and 3,843 Agreement State events) associated with materials licensees were reported to NRC, compared to 5,938 events that were reported for the previous 10 consecutive year period, covering October 1, 2001, through September 30, 2011 (i.e., FY 2002 through FY 2011).

For the current 10 year period, the review of the data did not indicate any significant performance trends. The NMED annual report indicated some statistically significant trends related to narrow sections of the data (See [Enclosure 1](#), page 4, Table 1. Summary of Trending Analysis). For example, the total number of NRC reportable events, NRC lost/abandoned/stolen materials events, and NRC medical events indicated statistically significant decreasing trends. Also shown in the summary table, there was one statistically significant increasing trend and that was in Agreement State Medical events.

However, based on the analysis of the event, enforcement, and performance metrics data for the current 10 year period, a specific reason was not identified for the statistical trends found in the report. It should be noted for the FY 2012 NMED Annual Report that the transfer of licensees from NRC to Agreement State authority could result in increasing numbers of

Agreement State events and decreasing numbers of NRC events.

For FY 2012, 45 of the 513 reportable events were considered to be of higher significance and are described in the FY 2012 NMED Annual Report. The breakdown of these significant events by category was as follows:

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

For the ten significant lost/abandoned/stolen material events, it should be noted that there were no nuclear material 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 1 sources. There were three Category 2 sources, and seven Category 3 sources that were lost, all of which were subsequently recovered with the exception of one Category 3 source. A summary of the significant events that took place in FY 2012 may be found in the Executive Summary of the enclosed NMED Annual Report (Pages xi – xii), and a detailed description of the significant events and events of interest may be found in the main body of the report for the specific event categories.

### AO Data

The staff determined that 22 events were identified as AOs involving nuclear materials during FY 2012. These AOs include 4 events at NRC licensed facilities and 18 events at Agreement State licensed facilities. One of the AOs at an NRC-licensed facility involved an electrical equipment fire at a commercial nuclear power plant that impacted safety-related equipment. One of the Agreement State identified AOs involved radiation exposure to an embryo fetus, and another involved an exposure to the extremities of a radiographer. The remaining 19 AOs were medical events as defined in 10 CFR Part 35, “Medical Use of Byproduct Material.” Given that these medical-related AOs are a small number of events in contrast to the significantly large number of medical procedures performed annually, the staff does not believe that these events represent a generic concern. Based on the results of last year’s special event study (SECY-12-0052, [Enclosure 2](#)), staff also determined that comparing the numbers of AO’s when they are reported versus when they actually occurred also affected the presence and/or appearance of statistically significant trends within the data. The results of that 10 year study indicated that there were no statistically significant trends or generic concerns in the data.

The staff’s analysis and evaluation found that human error was a main contributor to the root causes of these AO events. Reported causes for these 22 events include: poor maintenance practices; inability of the pregnancy test to provide positive determination so close to conception; corrosion of the drive cable and improper maintenance; failure to properly visualize, identify and/or verify the treatment site; failure to administer the correct dosage; failure to

properly review and/or verify the written directive; and failure to follow procedure.

In addition to these 22 AOs that were identified in the FY 2012 AO report, the staff has identified an additional 4 events (1 NRC, 3 Agreement State) that took place in FY 2007– FY 2012 that are potential AOs for which additional information is required. Reasons for not providing additional information include ongoing pre-decisional enforcement actions that must be resolved and the additional time needed for follow-up of certain events. The staff is working with the Agreement States and NRC licensees to obtain the necessary information; the events will be included in a future report.

#### Data Derived Through Escalated Enforcement Actions

For the 2012 calendar year (CY) period (January 1, 2012, through December 31, 2012), NRC issued 59 escalated enforcement actions involving NRC materials licensees (i.e., including fuel cycle licensees). Escalated enforcement actions in the Materials and Waste Programs includes civil penalties and Notices of Violation (NOV) for Severity Levels I, II, and III violations (some of these actions involved multiple violations that were grouped together and issued as one problem), as well as Orders and Demands for Information (DFI). The escalated enforcement actions issued in CY 2012 for the Materials and Waste Programs include one Severity Level II NOV, 49 Severity Level III NOVs, and 9 Orders. The nine Orders consisted of one Confirmatory Order that was issued to confirm a commitment, four Confirmatory Orders that were issued to confirm commitments associated with Alternative Dispute Resolution (ADR) agreements, and four individual action Orders. Also, for these 59 escalated enforcement actions, 12 of them involved issuance of a civil penalty.

For CY 2012, the number of escalated enforcement actions for the Materials and Waste Programs decreased by 7 actions from what was issued in CY 2011 (i.e. 66 escalated actions in CY 2011). The number of escalated enforcement actions issued in the last five years shows a decreasing trend (e.g., 118 actions to 59 actions). This is mainly due to a decrease in enforcement actions issued to gauge user licensees and appears to indicate that materials licensees have improved their compliance with the security and control requirements imposed in 2008. No significant performance trends were identified after review of the escalated enforcement action data.

#### Licensees Identified with Significant Performance Issues

SECY-11-0132 defines the criteria used to identify licensees with significant performance issues and licensees that warrant the highest level of NRC management attention. The criteria target the most critical issues involving: very serious events (those triggering NRC's strategic level measures); significant licensee issues; or licensee performance trends. For FY 2012, there are two nuclear materials licensees that met or will likely meet the criteria due to significant issues regarding information security. Due to the classified nature of the information related to these licensees, the details regarding these licensees will not be provided in this report. Additional information will be provided to the Commission in a separate and secure meeting.

#### NRC Final Safety Culture Policy Statement

On June 14, 2011, the NRC Final Safety Culture Policy Statement was published in the *Federal Register*. Since its publication, NRC staff has developed educational tools, such as case

studies, brochures, and posters to further communicate the Commission's expectations. In addition, the staff interacted directly with stakeholders, including domestic and foreign industry representatives and organizations, national trade groups, and international nuclear organizations to engage them on safety culture issues and implementation strategies.

OVERALL PERFORMANCE CONCLUSIONS:

Based on the review of event 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 staff review and subsequent revisions in 2008 and 2011 to the criteria for identifying nuclear materials licensees that warrant discussion at the AARM, staff has concluded that the current criteria is effective and valid, and appear to be working efficiently. The staff identified two nuclear materials licensees that met or will likely meet the criteria, as described in the enclosure of SECY-11-0132, for identifying nuclear materials licensees for discussion at the AARM.

COORDINATION:

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

***/RA/***

Mark A. Satorius, Director  
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and Environmental Management Programs

Enclosures:

1. Nuclear Material Events Database  
Annual Report FY 2012
2. Summary of Severity Level I and II  
Enforcement Actions for CY 2012



February 2013

# **Nuclear Material Events Database**

## **Annual Report**

*Fiscal Year 2012*

Prepared for the U.S. Nuclear Regulatory Commission  
by the Idaho National Laboratory (INL/LTD-13-28141)

ENCLOSURE 1

#### NOTICE

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# **Nuclear Material Events Database**

## **Annual Report**

### **Fiscal Year 2012**

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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. The reported events are classified into categories based on event reporting requirements defined in Title 10 of the Code of Federal Regulations. The categories in this report are (1) Lost/Abandoned/Stolen Material, (2) Medical, (3) Radiation Overexposure, (4) Release of Licensed Material or Contamination, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, (8) Fuel Cycle Process, and (9) Other.



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## ACRONYMS

AHTD	Arkansas Highway and Transportation Department
ALARA	as low as reasonably achievable
ALI	annual limit on intake
AO	abnormal occurrence
ARC	Alabama Office of Radiation Control
CDPHE	Colorado Department of Public Health and Environment
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
CT	computed tomography
DDE	deep dose equivalent
DE	dose equivalent
DOT	U.S. Department of Transportation
ECD	electron capture detector
EDE	effective dose equivalent
EH&S	environmental health and safety
EQP	Equipment
EXP	Radiation Overexposure
FCP	Fuel Cycle Process
FDA	U.S. Food and Drug Administration
FY	fiscal year
GTCC	greater than class C
HDR	high dose rate
HEPA	high-efficiency particulate air
HLW	high-level waste
IAEA	International Atomic Energy Agency
IAW	in accordance with
IEMA	Illinois Emergency Management Agency
INL	Idaho National Laboratory
IROFS	items relied on for safety
ISA	integrated safety analysis
LAS	Lost/Abandoned/Stolen Material
LKS	Leaking Sealed Source
LS	least squares

MED	Medical
MRI	magnetic resonance imaging
NA	not applicable
NJDEP	New Jersey Department of Environmental Protection
NMED	Nuclear Material Events Database
NMT	nuclear medicine technician
NR	not recovered
NRC	Nuclear Regulatory Commission
NRCB	NRC Bulletin
ODEQ	Oklahoma Department of Environmental Quality
OTH	Other
PDOH	Pennsylvania Department of Health
PET	positron emission tomography
RLM	Release of Licensed Material or Contamination
RSO	radiation safety officer
SDE	shallow dose equivalent
SNM	special nuclear material
SPECT	single-photon emission computed tomography
SSE	error sum of squares
SSR	regression sum of squares
SST	total sum of squares
TDRH	Tennessee Division of Radiological Health
TDSHS	Texas Department of State Health Services
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeter
TRS	Transportation
WDHS	Wisconsin Department of Health Services

## EXECUTIVE SUMMARY

The Nuclear Regulatory Commission's (NRC) 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 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 events of higher significance (referred to as significant events in this report).

The significant events that occurred in Fiscal Year 2012 are summarized below. Note that a single event may be listed in more than one event type category.

### **Lost/Abandoned/Stolen Radioactive Sources/Material Events**

Ten significant events occurred involving the loss of Category 1-3 sources as defined by the International Atomic Energy Agency's *Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. No Category 1 sources, three Category 2 sources, and seven Category 3 sources were lost, all of which were subsequently recovered, with the exception of one Category 3 source. The unrecovered Category 3 source was in a cardiac pacemaker that was buried with the deceased patient.

All three of the Category 2 events involved radiography exposure devices: one was lost during transportation from a job site, one was stolen from a parked truck, and the other was lost during shipment. Three of the seven Category 3 events involved the incorrect receipt of radioactive material at medical facilities; the sources were left uncontrolled for a period of time. Two of the Category 3 events involved items (a radiography exposure device and a well logging source) that were lost during transportation from jobsites. The other two Category 3 events involved cardiac pacemakers in deceased patients; one was retrieved by the funeral home before burial and the other was buried.

### **Medical Events**

Twelve significant events occurred, all of which were classified as potential Abnormal Occurrences. Seven of the events involved doses to the wrong site: five during high dose rate (HDR) brachytherapy, one during prostate brachytherapy, and one during Y-90 microsphere treatment. Four of the events involved treatments to the wrong patients: two during Y-90 microsphere treatment, one during prostate brachytherapy, and one during HDR treatment. The remaining event involved a patient that was administered too much I-131.

Two significant events classified as potential Abnormal Occurrences occurred prior to FY12 that were recently added to NMED. Both of these events involved doses to the wrong site during prostate brachytherapy. One of these events involved 13 patient implants performed from 2005 to 2012.

### **Radiation Overexposure Events**

Six significant events occurred, all of which were classified as International Nuclear Event Scale level 2 events. Four events involved the overexposure of radiographers who failed to retract the sources they were using before proceeding with their operations. One event involved the overexposure of three individuals who experienced difficulty loading a source into an irradiator. In the remaining event, a university student inhaled a uranium oxide compound that he was grinding in a glove box.

### **Release of Licensed Material or Contamination Events**

Two significant events occurred. In one event, a technician contaminated himself and his work area while removing a leaking source from a gauge that had been damaged in a fire. In the other event, a funeral home cremated the remains of an individual who had recently received an I-125 lung mesh.

One significant event occurred prior to FY12 that was recently added to NMED. In this event, I-131 was released from a glove box in a laboratory.

### **Leaking Sealed Source Events**

Two significant events occurred. In one event, a technician contaminated himself and his work area while removing a leaking source from a gauge that had been damaged in a fire. In the other event, a patient was implanted with at least one leaking I-125 brachytherapy seed.

### **Equipment Failure Events**

Eight significant events occurred. Three of the events involved radiography sources that could not be properly retracted. Three events involved damaged fixed gauges, one of which resulted in the overexposure of members of the public. One event involved a high dose rate remote afterloader treatment planning software malfunction. In the remaining event, a patient was implanted with at least one leaking I-125 brachytherapy seed.

One significant event occurred prior to FY12 that was recently added to NMED. In this event, I-131 was released from a glove box in a laboratory.

### **Transportation Events**

One significant event occurred. In this event, a truck carrying a radiography exposure device with a disconnected source was in a traffic accident. The source shifted, resulting in dose rates of 0.04 mSv/hour (40 mrem/hour) outside of the vehicle.

### **Fuel Cycle Process Events**

Two significant events occurred. In both events, uranium mass limits were exceeded in fuel production processes at a nuclear fuel manufacturer. No criticalities occurred.

### **Other Events**

Two significant events occurred. One event involved a dose to an embryo/fetus that resulted from an administration of I-131 to a pregnant patient. This event was also classified as a potential Abnormal Occurrence. In the second event, a truck carrying a radiography exposure device with a disconnected source was in a traffic accident. The source shifted, resulting in dose rates of 0.04 mSv/hour (40 mrem/hour) outside of the vehicle.

# Nuclear Material Events Database Annual Report: Fiscal Year 2012

## 1. INTRODUCTION

### 1.1 Overview and Objectives

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

A database for tracking nuclear material events was developed by the Nuclear Regulatory Commission (NRC) in 1981. In 1993, using existing material events databases, the NRC developed a new and more comprehensive database for tracking material events. This database, designated the Nuclear Material Events Database (NMED), contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by the Idaho National Laboratory (INL) and contains almost 22,000 records of material events submitted to the NRC from approximately January 1990 to present.

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

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

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 more than one NMED event category. 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).

The data presented in this report are limited to reportable events that occurred between October 1, 2002, and September 30, 2012. The data were downloaded from the NMED on January 16, 2013. 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).

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

For assistance on searches or other questions, contact Robert Sun ([nmednrc@nrc.gov](mailto:nmednrc@nrc.gov), 301-415-3421).

## 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 (FY03-12).

### 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 NRC-regulated events represent a statistically significant decreasing trend (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.

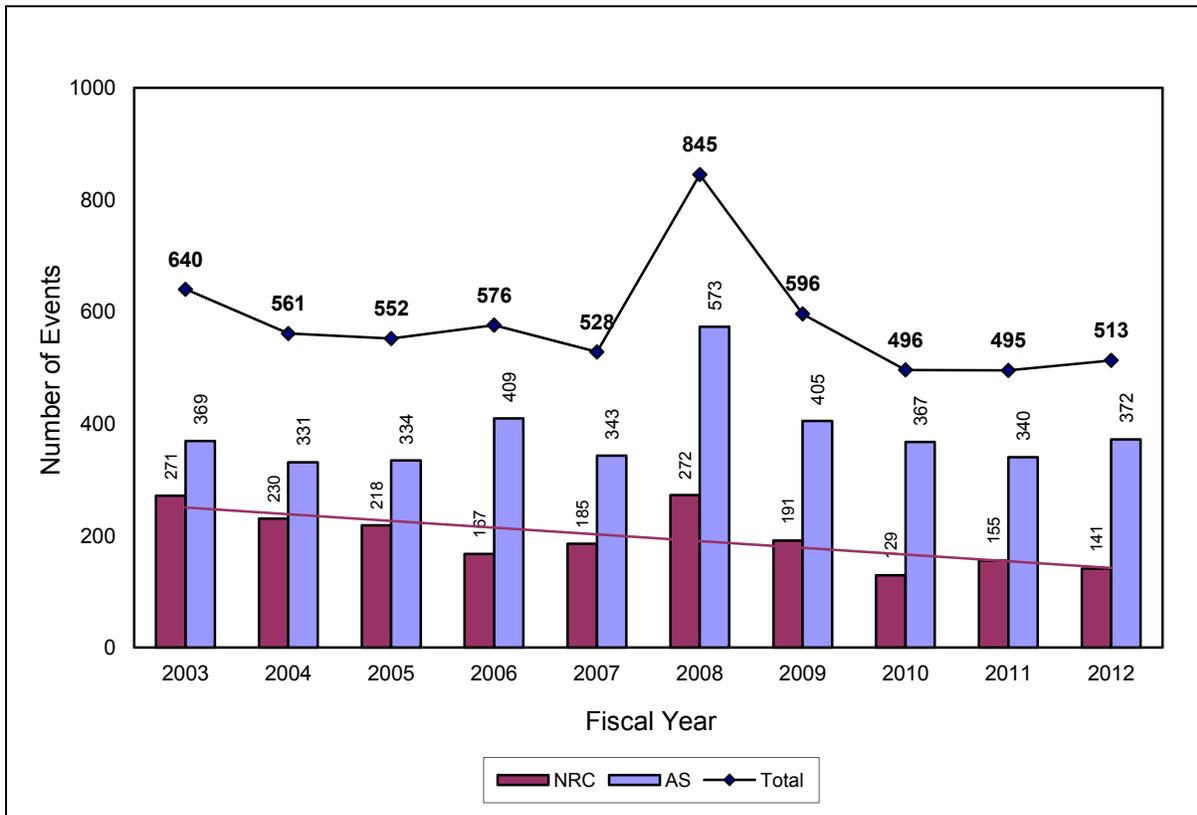


Figure 1. All NMED Events (5,802 total)

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

- In FY12, 436 occurrences accounted for 513 events; a single occurrence can be classified in different event categories.
- Starting with this FY12 report, TRS events involving fuel cycle process facilities are also coded as FCP events.
- The FY08 and FY09 data include 272 and 65 events respectively that resulted from Wal-Mart's one-time review of their tritium exit sign inventory.
- The most recent year's data are typically many records less than their final value when subsequent updates and late reports are received (see Appendix D, Figure D-1).

- The transition of states from NRC to Agreement State jurisdiction could result in increasing trends in Agreement State data and decreasing trends in NRC data.

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

Table 1. Summary of Trending Analysis

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

Notes:

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

## 2.2 Lost/Abandoned/Stolen Material

### 2.2.1 Ten-Year Data

Figure 2 displays the annual number and trend of LAS events that occurred during the 10-year period. The trend analysis determined that the NRC-regulated events represent a statistically significant decreasing trend (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.

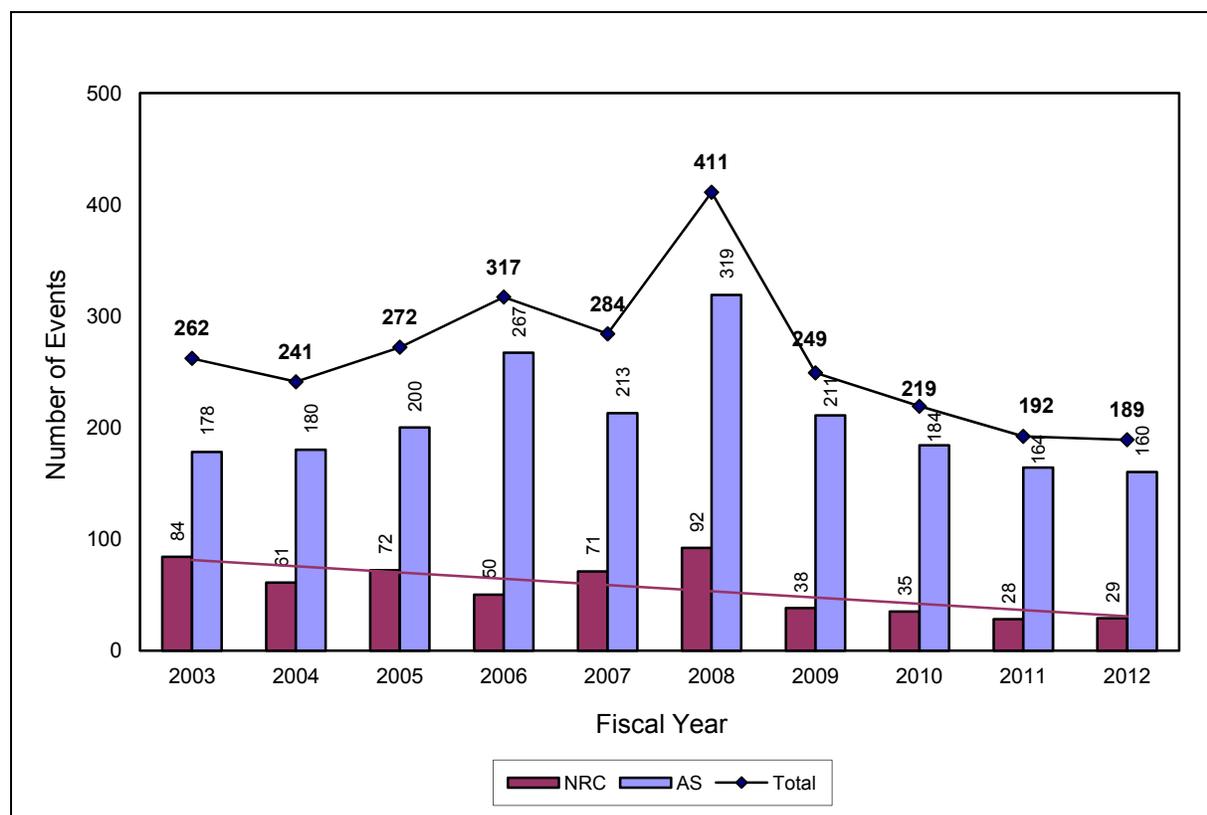


Figure 2. Lost/Abandoned/Stolen Material Events (2,636 total)

The FY08 and 09 data include 142 and 45 LAS events respectively that resulted from Wal-Mart's one-time review of their tritium exit sign inventory. Excluding these events results in a statistically significant trend in the total remaining events.

Appendix C contains a list of radionuclides derived from the International Atomic Energy Agency's (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, IAEA Category 1 through 3 source events (excluding irretrievable well-logging source events) are considered significant. Regardless of IAEA category, events involving irretrievable well-logging sources are not considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 2 displays the number of sources lost (approximately 4,477, excluding irretrievable well-logging sources) during the 10-year period and the number that have not been recovered (approximately 2379),

grouped by IAEA category where possible. These included zero Category 1 sources, 42 Category 2 sources, and 31 Category 3 sources. All of these sources were recovered, with the exception of two Category 2 and four Category 3 sources.

Table 2. Number of Sources Lost/Abandoned/Stolen (LAS) and Sources Not Recovered (NR) - Excluding Irretrievable Well Logging Sources

Category		Fiscal Year										Total
		2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	
1	LAS <sup>4</sup>	0	0	0	0	0	0	0	0	0	0	0
	NR <sup>5</sup>	0	0	0	0	0	0	0	0	0	0	0
2	LAS	5	5	8	4	2	11	2	0	2	3	42
	NR	0	0	1	0	0	0	0	0	1	0	2
3	LAS	0	1	6	4	1	3	1	4	4	7	31
	NR	0	0	2	0	0	0	0	1	0	1	4
4	LAS	89	76	109	95	57	71	50	74	37	40	698
	NR	30	29	35	48	19	35	25	28	19	16	284
5	LAS	137	106	151	109	70	129	77	87	69	74	1009
	NR	58	34	58	43	20	57	20	30	9	25	354
< 5	LAS	2	4	7	0	2	0	2	1	1	0	19
	NR	1	4	4	0	0	0	2	1	0	0	12
Activity Not Known <sup>1</sup>	LAS	1	8	3	7	3	9	5	10	13	4	63
	NR	0	3	0	1	0	0	0	1	0	0	5
Nuclide Not Known <sup>2</sup>	LAS	1	0	3	0	0	0	0	0	10	1	15
	NR	1	0	0	0	0	0	0	0	10	0	11
Other <sup>3</sup>	LAS	274	253	233	311	276	432	257	182	206	176	2600
	NR	170	172	146	185	146	354	154	127	137	116	1707
Total	LAS	509	453	520	530	411	655	394	358	342	305	4477
	NR	260	242	246	277	185	446	201	188	176	158	2379

Notes:

1. The “Activity Not Known” category includes sources containing radionuclides listed in Appendix C for which the activity was not reported. Therefore, the sources were not included in Categories 1 through 5.
2. The “Nuclide Not Known” category includes those sources for which the radionuclide was not reported. Thus, the sources were not included in Categories 1 through 5 or Other.
3. The “Other” category includes sources containing radionuclides not included in Appendix C.

4. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity). The Category 1 through 3 source counts were corrected for the “aggregate” source events.
5. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The Category 1 through 3 “not recovered” source counts were corrected for the “partially recovered” source events.

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

Table 3. Summary of IAEA Category 1-3 Sources Not Recovered (FY03-12)

Radionuclide	Half Life <sup>1</sup>	Number of Sources Not Recovered <sup>2,3</sup>	Total Activity (Ci)	Total Decayed Activity (Ci) <sup>4</sup>	Total Decayed Activity IAEA Category
Ir-192	73.83 days	5	100.70	0.20	4
Pu-238	87.7 years	1	2.50	2.48	3
<b>Total</b>		<b>6</b>	<b>103.20</b>	<b>2.68</b>	<b>3</b>

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity). The source counts were corrected for the “aggregate” source events.
3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the “partially recovered” source events.
4. The source activities were decayed from the event date to 1/16/2013 (data download date).

Table 4. Summary of IAEA Category 1-3 Sources Not Recovered (FY12)

Radionuclide	Half Life <sup>1</sup>	Number of Sources Not Recovered <sup>2,3</sup>	Total Activity (Ci)	Total Decayed Activity (Ci) <sup>4</sup>	Total Decayed Activity IAEA Category
Pu-238	87.7 years	1	2.50	2.48	3
<b>Total</b>		<b>1</b>	<b>2.50</b>	<b>2.48</b>	<b>3</b>

Notes:

1. Half-life values from the Chart of the Nuclides, 16<sup>th</sup> Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a

single source with a total combined activity). The source counts were corrected for the “aggregate” source events.

3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the “partially recovered” source events.
4. The source activities were decayed from the event date to 1/16/2013 (data download date).

### **2.2.2 FY12 Data**

One hundred eighty-nine LAS events occurred in FY12, 24 of which involved irretrievable well logging sources. Excluding the irretrievable well logging sources, approximately 305 sources were lost/abandoned/stolen, 158 of which have not been recovered. Of the 305 lost sources, none were Category 1, three were Category 2, and seven were Category 3 sources. All of the Category 1-3 sources were recovered, with the exception of one Category 3 source.

Ten of the FY12 LAS events were considered significant (involved Category 1-3 sources). Note that regardless of IAEA category, events involving irretrievable well logging sources are not considered significant.

#### Significant Events - Category 1 Source Events

None.

#### Significant Events - Category 2 Source Events

Item Number 120176 - A radiography services company reported the loss and recovery of a radiography exposure device that contained a 962 GBq (26 Ci) Ir-192 source. The radiographer had completed work on a pipeline near De Beque, Colorado, on 3/13/2012 and failed to secure the device in his pickup truck when he drove to the next location. Upon arriving at that location, the radiographer realized the device was missing and retraced his route. The radiographer did not find the device. A member of the public who was working at the jobsite found the device and placed it in the back of his truck. Approximately two hours later, he saw the radiographer and returned the device to him. It was determined that the source was intact and had not been tampered with. Corrective actions included terminating the employment of the involved radiographer, generating a new procedure, and providing additional training to the rest of the staff.

Item Number 120478 - On 8/15/2012, a radiography services company reported the theft and recovery of a radiography exposure device. The device had been in the dark room of a truck parked at their facility. The radiographer had left the device in the truck instead of transferring it to the storage vault. The device contained a 3 TBq (81 Ci) Ir-192 source. A thief broke into five radiography trucks, taking various items including the exposure device. It was determined that the thief had not taken a crank-out assembly or guide tube. Local law enforcement recovered the device on 8/15/2012. The truck used by the thief was identified on a surveillance camera. The exposure device was found in the back of that truck at the thief's residence. The Texas Department of State Health Services investigated the incident. A wipe test was conducted and the device was inspected. The device was returned to service. Employment of the radiographer that left the device in the truck was terminated. Corrective actions included providing additional training to personnel, increasing video surveillance, and installing improved lighting.

Item Number 120550 - A radiography services company reported the loss and recovery of a radiography exposure device that contained an Ir-192 source. The device was shipped by a transportation company, but had not been delivered to the radiography services company's facility. It had been shipped from a jobsite in Montoursville, Pennsylvania, on 9/11/2012 and was scheduled to arrive on 9/14/2012. A company investigation verified that the device was not at their facility as of 9/17/2012. The Arkansas Department of Health also performed an investigation into the location of the device. The device and source were found in the transportation company's Newark, New Jersey, facility on 9/17/2012 and subsequently delivered on 9/18/2012. The NRC Registry of Radioactive Sealed Sources and Devices

indicates that this exposure device contains an Ir-192 source with a maximum activity of 5.55 TBq (150 Ci).

#### Significant Events - Category 3 Source Events

Item Number 110632 - A hospital reported that a package containing a 419.95 GBq (11.35 Ci) Ir-192 source was improperly delivered on 11/25/2011. There were no radiation safety personnel present to receive the package, so the carrier left the package with the receptionist, who is not authorized to receive radioactive material. The package was stored in the shipping and receiving area over the weekend. On 11/28/2011, the radiation safety officer (RSO) became aware that the package had been unsecured all weekend. California Health and Human Services Agency conducted an investigation of the hospital's package receipt procedures. It was determined that personnel who work the holiday or weekend shifts were not familiar with the package receipt procedures. The hospital initiated a training program to ensure that radioactive material packages delivered after hours will be refused.

Item Number 120214 - A hospital reported that a patient with a pacemaker passed away on 1/31/2012. The body was buried without recovering the pacemaker. The NRC Registry of Radioactive Sealed Sources and Devices indicates that this device contains a Pu-238 source with a maximum activity of 92.5 GBq (2.5 Ci). There is no planned action to recover the pacemaker from the buried patient.

Item Number 120380 - A radiography services company reported the loss and recovery of a radiography exposure device that contained a 495.8 GBq (13.4 Ci) Ir-192 source. A radiography crew lost the device while returning to the office on 6/19/2012. The crew had traveled approximately 3.5 miles when a private individual motioned for them to pull over. The individual told them that the door to their dark room was open. When the radiographers looked into the dark room, they discovered that the device was missing. They traveled back to the worksite and searched for the device, but did not locate it. A private individual found the device on the road in Robstown, Texas, and contacted them on 6/19/2012. The radiography services company recovered the device from the private individual and returned it to their storage location. The transportation container was still locked and the device was not damaged. Radiation surveys of the device were normal. The cause of the event was determined to be failure to secure the radiography device in the darkroom of the truck. Corrective actions included providing additional training to personnel.

Item Number 120440 - A medical clinic reported that a package containing a 410.7 GBq (11.1 Ci) Ir-192 brachytherapy source was left in an unrestricted area for more than 43 hours. Radiation levels on the surface of the package were 30 mR/hour and the package had a transport index of 0.6 mR/hour. A Wisconsin Radiation Protection Section inspector visited the site on 5/17/2012. The clinic's RSO indicated that the package had been left near a surgical suite entrance and four elevators. The clinic conducted an investigation and determined that security staff failed to follow hospital policy for receiving radioactive material during non-working hours. Corrective actions included modifying procedures and providing additional training to personnel.

Item Number 120524 - An oilfield services company reported the loss and recovery of a 555 GBq (15 Ci) Am-Be well logging source. The source had been used early in the day on 9/11/2012 during well operations at a well site near Pecos, Texas. The well logging crew left the Pecos site and traveled about 130 miles to a well site near Odessa, Texas. The crew did not stop for any reason between well sites. When the crew arrived at the Odessa site, they discovered that the source was missing. The source transport container lock and plug were not in place. The lock was found in the storage compartment in the back of the truck and the plug was not in the container. The crew returned to the Pecos well site and searched for the source, but did not find it. The oilfield services company formed a search group to look for the source along the roadway between the two sites. That group did not find the source. They searched the Pecos well site two additional times and also used a scintillation survey instrument to aid in the search, but the source was not located. The company performed personnel interviews, but was not

able to determine how the source could have been lost. Local police were notified and responded to the site. The source was eventually recovered on 10/5/2012.

Item Number 120525 - A medical center reported that a patient implanted with a pacemaker died on 5/16/2012 and was scheduled to be buried on 5/26/2012. The pacemaker contained a 77.7 GBq (2.1 Ci) Pu-238 source, which had an original activity of 103.6 GBq (2.8 Ci) in 1976. Medical center staff became aware of the incident by reading the patient's obituary in the newspaper on 5/24/2012. The funeral home had extracted the pacemaker from the patient prior to cremation. The medical center's RSO contacted the funeral home and retrieved the pacemaker on 5/24/2012. Radiation measurements were less than 1 mR/hour near contact with the pacemaker. Leak tests revealed negative results. The medical center registered the pacemaker with the Department of Energy's Off-Site Recovery Project for final disposition. The center also stated that this had been their last nuclear pacemaker patient and that they would be terminating their special nuclear material (SNM) license.

Item Number 120642 - A hospital reported that an Ir-192 high dose rate (HDR) brachytherapy source was inappropriately delivered to their loading and receiving dock on 9/15/2012, where it was uncontrolled for approximately 47 hours. The shipment was unexpected, having arrived without the required prior notification from the supplier. Upon discovery of the delivery on 9/17/2012, the RSO moved the source to the hot laboratory, where it was surveyed and wipe tested. The radiation survey revealed 240 uSv/hr (24 mrem/hr) on the surface of the container and 8 uSv/hr (0.8 mrem/hr) at one meter. The wipe test results were indistinguishable from background. Two employees (non-radiation workers) worked in the vicinity of the source while it was uncontrolled. Dose estimates for these workers were 12 and 8 uSv (1.2 and 0.8 mrem). To prevent recurrence, the hospital contacted the supplier to re-emphasize proper delivery procedures. The hospital also trained all dock personnel regarding the rules and regulations for the shipment and receipt of radioactive material and implemented procedures for handling unexpected deliveries. The NRC Registry of Radioactive Sealed Sources and Devices indicates that this Ir-192 source contained a maximum activity of 555 GBq (15 Ci).

#### Events of Interest

Item Number 110568 - A scrap metal facility reported that a load of scrap aluminum leaving their facility set off their radiation monitor alarms on 10/24/2011. The load was inspected and the source of radiation was found to be on one end of an 18-inch stainless steel rod, which was 5/8 inch in diameter. There were no discernible markings or labels on the rod. The source had not been identified in an incoming load of aluminum scrap. Oklahoma Department of Environmental Quality (ODEQ) personnel visited the site on 11/1/2011. Using a Thermo Fisher Interceptor, the radionuclide was identified as Ra-226. Initial radiation surveys revealed levels of 600 mR/hour at a distance of approximately five inches. The possibility was raised that the source could be a Ra-Be source. ODEQ returned the following day to obtain additional measurements. Using a Victoreen 450P ion chamber, radiation levels were determined to be 44 mR/hour at a distance of 22 cm. Using a Ludlum 12-4, neutron dose rates were 0.8 mR/hour. The source activity was estimated to be 370 MBq (10 mCi). No removable activity was identified. The two workers who located the source were interviewed. One worker received an estimated exposure of 6 mSv (600 mrem) to the hands and a whole body exposure of less than 1 mSv (100 mrem) from handling the rod. The source was secured onsite until properly disposed of on 1/26/2012. The scrap metal facility also made procedure modifications to prevent recurrence.

Item Number 120045 - A hospital reported receiving a contaminated package containing Ge-168 sealed sources. On 1/5/2012, the package was swiped and results revealed H-3 contamination. Radiation safety staff investigated and discovered H-3 contamination uniformly distributed in their loading dock area and surrounding hallway. The highest concentration of H-3 was discovered on their trash compactor. Surveys revealed removable radiation readings of up to 14,000 dpm. The RSO restricted entry to the loading dock area. The loading dock was successfully decontaminated and the entry was re-opened on 1/12/2012. Bioassays of individuals working in the area revealed negligible uptakes. The outside of the trash compactor was decontaminated on 1/9/2012. The compactor was removed by a waste broker on

1/10/2012 for recycling and/or disposal in Pennsylvania. It was discovered that two contractors had disposed of eight radioluminescent exit signs in the trash compactor. The contractors had found those signs stored in a closet. Each sign contained a decay corrected activity of 318.2 GBq (8.6 Ci). It was determined that four of the signs were crushed/compromised. The hospital will remove all of their radioluminescent exit signs, search for improperly stored signs, and train employees in proper disposal. This event was classified as an EQP, LAS, and RLM event.

Item Number 120091 - A waste management company reported that a roll-off container of waste set off their radiation monitor alarms on 1/19/2012. The company's consulting health physicist investigated, along with representatives from the Pennsylvania Department of Health (PDOH). Four small cylinders were identified that contained Ra-226 with a total activity of approximately 37 GBq (1 Ci). The cylinders were contained within a lead-lined box. The box contained various other source holders, instruments, and applicators (some contained the name "Standard Chemical"). The Ra-226 sources are believed to be vintage (circa 1920) medical radiation therapy sources. Preliminary wipes revealed no source leakage. The consulting health physicist was given a U.S. Department of Transportation (DOT) Special Permit to take possession of the sources for safe and secure storage. Dose rates were as high as 2 R/hour on contact with the lead-lined box and approximately 110 R/hour on contact with the sources. It was determined that the unlocked roll-off container had been located in the parking lot of an adult living community in West Chester, Pennsylvania. The roll-off had been used during work on townhouses in the development. PDOH believes that the sources were intentionally abandoned in the dumpster.

Item Number 120269 - A load of scrap metal set off the radiation monitor alarms at steel mill on 4/11/2012. A DOT Exemption was issued and the load was returned to the scrap facility on 4/12/2012. An Alabama Office of Radiation Control (ARC) inspector responded to the site on 4/13/2012. Investigation revealed a damaged fixed gauge containing a Cs-137 source. Maximum radiation levels of 500 mR/hour were noted on contact with the gauge and 28 mR/hour at a distance of one foot. Field analysis determined that the source was not leaking. There were no markings on the device to indicate model number or source activity. However, ARC identified the manufacturer and series number. The scrap facility is negotiating possible avenues for disposal, including return to the manufacturer. This event was classified as an EQP and LAS event.

Item Number 120397 - A commercial nuclear power plant reported the loss of two nuclear instrumentation in-core detectors. Each detector contained 0.0041 grams of U-235, or 329.3 Bq (0.0089 uCi) of U-235. The detectors could not be accounted for on 6/21/2012 during a scheduled inventory when only 52 of 54 detectors were found in storage. According to site documentation, at least one of the detectors may have been shipped to a low-level radioactive waste disposal facility in 1986. However, detailed disposal records could not be located. The search for the detectors was suspended based on a determination that additional personnel dose was not justified by an equivalent offsetting safety benefit. It is unlikely that the detectors left the site other than in a radioactive waste shipment. The most likely location for the detectors is either in one of the onsite storage bunkers or at the low-level radioactive waste disposal facility. This event was caused by inadequate accounting practices related to small quantities of SNM from 1985 through 2012. Corrective actions included procedure modification related to the storage, transfer, and physical inventory of non-fuel SNM.

Item Number 120409 - A radiopharmacy reported that a courier left licensed material unsecured outside their facility on the evening of 5/20/2012. The courier attempted to deliver three packages, including a Mo-99/Tc-99m generator containing 518 GBq (14 Ci), three vials of Tl-201 containing a total activity of 1.11 GBq (30 mCi), and nine capsules of I-123 each containing 7.4 MBq (200 uCi). The courier forgot to bring his facility key and contacted the on-call pharmacist, who told the courier how to gain access to the facility. Due to a poor cell phone connection, the courier believed that he had been instructed to leave the packages at a certain location outside the facility. The courier covered the packages with a pallet to prevent them from being visible. Early the next morning, facility personnel were unable to find the packages inside the facility. The courier was contacted and identified where he had left the packages.

The packages, which had been unsecured for approximately 7.5 hours, were found in good condition and were moved into the facility. To prevent recurrence, the pharmacy changed their policy on couriers who forget their keys such that the on-call pharmacist is required to meet the courier at the facility.

Item Number 120431 - A commercial nuclear power plant reported the loss of a source range monitor that contained an estimated maximum activity of 6.92 kBq (0.187 uCi) of SNM. The incident was discovered during an annual inventory conducted on 7/25/2012. An investigation concluded that the monitor had been removed from storage during Refueling Outage 18 and discarded as radioactive waste. The event posed no threat to public health and safety because the monitor was not highly irradiated (it had failed testing in April 2012 and was removed from the reactor core prior to reactor startup) and was controlled as radioactive waste. Corrective actions included locking and adding signage to the storage area, and improved procedures for accountability and control of SNM.

Item Number 120452 - A construction services company reported that a portable density gauge fell out of the back of a pickup truck and was damaged by a bulldozer on 7/31/2012 at a temporary jobsite in Wake Forest, North Carolina. The gauge user had completed work for the day and left the jobsite when he noticed that his tailgate was down. When he stopped to close the tailgate, he determined that the gauge was missing. After retracing his route, the gauge user observed the gauge approximately 100 feet from where he had been working. Upon approaching the gauge, he saw that it had been crushed by a bulldozer. The source rod was in the safe position, but no trigger lock was present. The gauge was isolated and the RSO was notified and responded to the scene. Initial surveys of the gauge revealed 1 mR/hr on contact, with 0.4 mR/hr at one meter. The North Carolina Radiation Protection Section dispatched an inspector to the scene. Once it was determined that the gauge was safe to move, it was placed into the transport case. The tungsten sliding block was found to be damaged and loose. Surveys of the transport case revealed a maximum reading of 70 mR/hr on contact with the end of the case where the damaged source shield was located. The gauge was returned to the construction services company's office, where it was stored pending shipment to the manufacturer for evaluation. This event was classified as an EQP and LAS event.

Item Number 120492 - A hospital reported that a patient only received approximately 76% of the prescribed dose from an I-125 brachytherapy seed implant into the right lung. A piece of mesh containing 50 I-125 seeds was implanted into the patient through an invasive procedure on 5/31/2012. The mesh contained five strands of seeds, with 10 seeds per strand, and a total activity of 606.8 MBq (16.4 mCi). The patient was readmitted on 7/4/2012. On 7/7/2012, a chest x-ray found that only 38 of the 50 seeds were visible. Chest and abdomen x-rays were performed on 7/9/2012, which revealed 35 seeds in the chest and three in the abdomen. X-rays on 7/18/2012 revealed 13 seeds in the lung and 17 in the abdomen. On 8/4/2012, there were only six seeds remaining in the lung and eight in the abdomen. Final x-rays taken on 8/8/2012 revealed that no seeds remained in the patient. It is believed that the patient coughed up the loose seeds and swallowed them. A total of nine seeds were recovered during patient hospitalization and placed in the nuclear medicine hot laboratory. The failure of the device was reported to the manufacturer and Food and Drug Administration. This event was classified as an EQP, LAS, and MED event.

Item Number 120499 - A tractor trailer ran over a moisture/density gauge on 8/27/2012 on Interstate 40 near Hazen, Arkansas. The gauge was severely damaged and parts were identified on the side of the interstate. Highway police were notified and asked the Arkansas Highway and Transportation Department (AHTD) for assistance. The AHTD RSO responded to the scene. The base of the gauge was broken to the point that only the threaded cavity and surrounding lead remained. The 1.63 GBq (44 mCi) Am-Be source was still contained within its threaded cavity, while the 0.33 GBq (9 mCi) Cs-137 source remained attached to the source rod and inside its shielding. The shielding was sheared off just above the tungsten sliding block. The AHTD RSO secured the Am-Be source in a polyethylene box and the Cs-137 source was removed from the gauge and placed in a lead shield. Two health physicists from the Arkansas Department of Health (DOH) responded to the scene and performed smear tests; no loose radioactive

contamination was identified. The sources were transported to a DOH secure storage area. The gauge manufacturer identified the construction services company that owned the gauge on 8/28/2012. When the gauge user left the jobsite on the evening of 8/27/2012, he failed to secure the gauge in the back of his pickup truck. The gauge fell out of the truck and was struck by at least one vehicle. Upon arrival at his company's facility, the user determined that the gauge was missing and believed that he had left the gauge at the jobsite. On the morning of 8/28/2012, he returned to the jobsite and searched for the gauge, but did not find it. The construction services company's RSO was contacted and retrieved the two sources from DOH. This event was classified as an EQP and LAS event.

Item Number 120573 - A university medical center reported that a funeral home cremated the remains of an individual on 9/20/2012 who had recently received an I-125 lung mesh implant. The implant procedure was performed on 9/13/2012 and involved 40 seeds containing a total activity of 860 MBq (23.24 mCi) of I-125. The crematory closed and the Wisconsin Department of Health Services (WDHS) responded to the site on 9/21/2012. Using a Victoreen 451, radiation surveys inside the crematorium revealed 0.75 mR/hour. The cremated remains of the individual revealed readings of 3.8 mR/hour on contact with a plastic bag. The remains were placed in a concrete container and radiation levels were at background outside the container. No other areas of the facility were identified as radioactively contaminated. The crematory remained closed pending decontamination. WDHS accompanied university personnel to the crematory on 10/17/2012 to assess contamination levels. No seeds remained intact and some of the powder that was inside the seeds remained on the concrete. On 10/23/2012, university personnel performed decontamination efforts and were able to reduce radiation levels to twice background. It was estimated that a fraction of the original I-125 activity was vented to the atmosphere. The crematory was allowed to resume operations on 10/26/2012. This event was caused by inadequate communication between the patient's family and the crematory. No corrective actions were taken. This event was classified as an EQP, LAS, LKS, and RLM event.

Item Number 120660 - A steel mill reported the loss of a 3.7 GBq (100 mCi) Am-Be source that was missing from a fixed gauge. The source was located inside an insertion tube on a pellet hopper. The source was discovered to be missing on 10/11/2012 when the insertion tube was found to be broken off. Investigation concluded that the insertion tube fell through the pellet hopper, was transported to the furnace by conveyor, and was consumed in the blast furnace. The source was last seen during an inventory conducted on 6/27/2012. It was assumed that the source migrated into the slag. It was estimated that the activity of the slag was approximately 0.068 MBq (1.845 uCi) per cubic foot. The cause was believed to be a process change. Over time, the insertion tube wear protection plate dislodged and exposed the tube to damage and detachment. Radiation surveys of the hopper and conveyor areas identified no levels above background. Corrective actions included removing their remaining radioactive sources from service. This event was classified as an EQP and LAS event.

### **2.2.3 Events Recently Added to NMED That Occurred Prior to FY12**

Forty-five LAS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

#### Significant Events - Category 1 Source Events

None.

#### Significant Events - Category 2 Source Events

None.

#### Significant Events - Category 3 Source Events

None.

### Events of Interest

Item Number 120258 - A low and intermediate level radioactive waste company reported finding a 10.73 GBq (290 mCi) Ra-226 source while going through 18 30-gallon drums on 1/23/2009 that were identified as containing legacy lead. The company was segregating legacy lead for potential free release. When they reached the final 30-gallon drum, which was stored in a high radiation room, they found that it contained a 10-gallon drum. That 10-gallon drum was wrapped in a lead blanket and contained three lead pigs. One lead pig contained the Ra-226 source. The outer surface of that pig containing the source revealed a radiation reading of 2.5 R/hour. A shielded enclosure was constructed and the source was removed with proper handling tools. The exposure rate one inch from the source revealed initial results of 850 R/hour. The source was immediately placed back into the pig and returned to the 10-gallon drum. The drum was lined with lead blankets. Additional lead blankets were placed inside the drum and the drum was closed. Approximately 700 pounds of lead blankets were used to shield the source. The exposure rate on contact with the lead blankets revealed 61 mR/hour. It was determined that the source was approximately 50 years old. Subsequent radiation surveys revealed an exposure rate of 500 R/hour on contact with the source, with 75 mR/hour at four feet, 45 mR/hour at six feet, 28 mR/hour at eight feet, and 15 mR/hour at 12 feet. The source was subsequently disposed of.

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

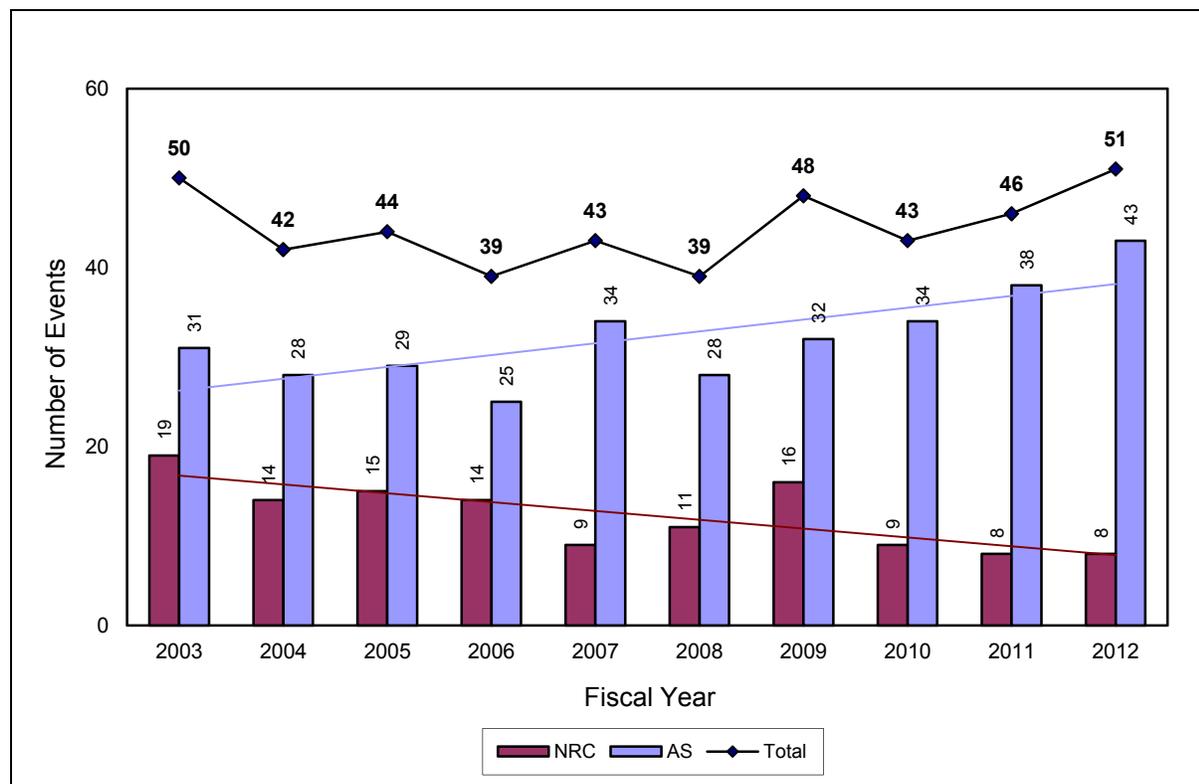


Figure 3. Medical Events (445 total)

Table 5 lists the number of MED events that were classified as Abnormal Occurrences (AOs) in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Table 5 also includes events involving doses to an embryo/fetus or a nursing child (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, they are included here for reference.

Table 5. Medical and Embryo/Fetus or Nursing Child AO Events

	Fiscal Year										Total <sup>1</sup>
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	
Medical	10	12	10	7	11	12	15	12	14	12	115
Embryo <sup>2</sup>	1	1	1	3	2	2	2	2	1	1	16
<b>Total</b>	<b>11</b>	<b>13</b>	<b>11</b>	<b>10</b>	<b>13</b>	<b>14</b>	<b>17</b>	<b>14</b>	<b>15</b>	<b>13</b>	<b>131</b>

Notes:

1. Events are marked as potential AOs until they complete the NRC's formal AO determination process and are reported in NUREG-0090. Potential AOs are included in this table.
2. Includes doses to an embryo/fetus or a nursing child reportable per 10 CFR 35.3047

For this report, events classified as AOs (or potential AOs) are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

### **2.3.2 FY12 Data**

Fifty-one MED events occurred in FY12, 12 of which were considered significant.

#### Significant Events - AOs or Potential AOs

Item Number 110625 - A brachytherapy treatment plan was performed on the wrong patient on 11/16/2011. The written directive for one patient's prostate seed implant procedure was inadvertently used for another patient. The hospital had back-to-back procedures on two patients on two consecutive days. The implant procedure used on the second patient was actually developed for the first patient. The mishap was noted by the radiation oncologist immediately following the procedure. Post implant computed tomography (CT) and magnetic resonance imaging (MRI) were performed. The written directive for both patients required the same number of seeds of the same radionuclide, the same activity, and both were prescribed the same dose. The patient was administered 79 I-125 seeds containing 15.02 MBq (0.406 mCi) each. The patient was informed of the error on 11/16/2011. The patient received a one-month post-implant CT and MRI on 12/16/2011 to evaluate the radiation dose distribution. Results revealed that the D90 dose delivered to the patient's prostate was only 73% of prescribed. The patient was prescribed a D90 dose of 14,500 cGy (rad) and only received 10,585 cGy (rad). The radiation oncologist elected to inject additional seeds into the patient's prostate to improve coverage. Corrective actions included developing a new procedure to assure the correct written directive is used when implanting brachytherapy seeds. All relevant radiation oncology personnel reviewed and signed the new procedure.

Item Number 120050 - A patient received a dose to an unintended site during treatment with an HDR afterloader containing a 148.37 GBq (4.01 Ci) Ir-192 source. The patient was prescribed to receive four fractions to the cervix of 400 cGy (rad) each. Subsequently, a physician noticed reddening of the skin to the upper thigh during examination on 1/6/2012. An Ohio Department of Health inspector went to the facility to investigate the incident on 1/12/2012. The hospital identified a constriction (corrosion) in the entry of the tandem used in the device, where the device narrows at the end. It is believed that during the fourth fraction, when the catheter was inserted into the tandem, it snagged on the constriction, causing the starting point of the source to be displaced by 9 cm. Preliminary calculations indicated a skin dose of 1,251 cGy (rad) to the right thigh and 1,273.9 cGy (rad) to the left, when no skin dose was intended. The dose to the intended site during the fourth fraction was 194.2 cGy (rad) instead of the prescribed 400 cGy (rad). The total dose to the intended site from all four fractions was 1,394.2 cGy (rad) instead of the prescribed 1,600 cGy (rad). The patient and referring physician were notified of the event. The hospital stated that the catheter they previously used successfully was no longer manufactured. As a result, the hospital substituted a replacement catheter that was slightly larger in diameter than the original. The original catheter did not get caught on the constriction in the tandem, but the replacement catheter did. Corrective actions taken by the university included marking the new catheters to provide a visual indication of full insertion into the tandem.

Item Number 120054 - A patient received about 10% of the prescribed dose during treatment for esophageal cancer on 1/5/2012. The patient also received dose to an unintended location. The patient was prescribed 700 cGy (rad) to the esophageal region using an HDR brachytherapy afterloader device and a 234.728 GBq (6.344 Ci) Ir-192 source. The location of the source was tracked by a

radiographically opaque marker near the source. In this case, the end of the catheter also appeared somewhat radiographically opaque and was mistaken for the source location. When the nasogastric tube and catheter were removed as a unit at the end of the procedure, it was discovered that the catheter was not advanced to the end of the nasogastric tube. An investigation determined that the source placement was 29 cm proximal to the treatment site. The 700 cGy (rad) dose was actually delivered to the majority of the nasal passages and nasopharyngeal area, and a 4-cm region in the same area received a maximum dose in excess of 1,000 cGy (rad). The physician and patient were notified of the event. The patient was scheduled for an anatomical examination to assess the presence of adverse effects. No adverse health effects were anticipated due to this event. Corrective actions included procedure modification such that catheter length measurements are performed prior to treatment and the catheter and nasogastric tube are introduced to the patient as a unit. Also, the entire length of the catheter will be visible in CT scans during all HDR procedures. NRC inspectors responded to the site on 1/18/2012. An NRC-contracted medical consultant agreed the hospital's analysis of this event.

Item Number 120067 - A patient received approximately 50% less dose to the breast than prescribed during two of 10 fractions of an HDR afterloader treatment using. The patient also received dose to an unintended site. The treatment involved a 234.28 GBq (6.332 Ci) Ir-192 source. The patient was prescribed 340 cGy (rad) during each fraction, for a total dose of 3,400 cGy (rad). After the first fraction on 1/16/2012, it was discovered that an incorrect treatment parameter length had been entered; the programmed length was 10 cm less than it should have been because the catheter had been measured incorrectly. Instead of being centered in the breast, the source position was caudal to the breast and resting within its guide tube on the skin covering the rib cage. The correct length was entered for the second fraction later that same day. However, the original incorrect treatment plan was inadvertently selected for the third fraction on 1/17/2012. Two additional fractions were added and the treatment plan was modified to achieve the total dose specified in the written directive. The radiation oncologist notified the attending physician and patient. The hospital performed computer simulation, calculations, and physical measurements simulating the treatment geometry to model the unintended dose. Estimates revealed an unintended dose to the skin covering the rib cage exceeding the skin erythema threshold of 200 cGy (rad). The hospital continued to monitor the patient and worked to refine the unintended skin dose estimates. The hospital's medical consultant determined that the patient received approximately 2,720 cGy (rad) of unintended skin dose. The hospital agreed with that determination. The NRC conducted a reactive inspection and contracted a medical consultant, who confirmed the unintended skin dose estimate. The consequences to the patient from the unintended skin dose progressed from an initial small area of erythema to a larger area of ulceration and the appearance of blackened skin tissue over a period of five months. The patient was referred for treatment with hyperbaric oxygen therapy. Corrective actions included procedure revision, personnel training, and organizational changes.

Item Number 120081 - Two patients received Y-90 microsphere doses that were different than prescribed on 1/19/2012. Both patients were scheduled to be treated on the same day. The worksheets were switched and each patient received the other patient's dose. The first patient reached stasis before receiving the full amount and received a dose 35% above the prescribed dose. The first patient was administered 513 MBq (13.86 mCi) instead of the prescribed 381.1 MBq (10.3 mCi). The second patient received 56% less than prescribed or 329.3 MBq (8.9 mCi) instead of the prescribed 751.1 MBq (20.3 mCi). The cause of the event was determined to be human error. To compensate, the second patient received a higher dose than planned during the next scheduled treatment. Written procedures were developed and implemented to both minimize the chance of errors occurring in the microsphere dose preparation process and to identify/correct any such errors prior to administration. The Pennsylvania Department of Environmental Protection conducted a reactive inspection.

Item Number 120083 - A patient prescribed to receive 2,100 cGy (rad) to the common bile duct during three HDR fractions received the first two fractions 4 cm proximal to the desired location. The event occurred after the dosimetrist made an error while correcting a change to the source dwell position due to

catheter migration. The dwell position was mistakenly adjusted out rather than in. Those two fractions were administered on 1/5 and 1/12/2012 and resulted in treating only 1 cm of the desired 5 cm length along the catheter. The treatment used an HDR that contained a 185.3 GBq (5.008 Ci) Ir-192 source. Approximately 1,400 cGy (rad) was delivered to 4 cm of the proximal portion of the bile duct and hepatic tissue (unintended site). The patient was informed of the event and received the correct third fraction as well as external beam therapy. Corrective actions included amending policy to require that any adjustment of dwell positions greater than 5 mm mandates replanning.

Item Number 120096 - A patient prescribed to receive 5.32 GBq (143.78 mCi) of Y-90 microspheres for a treatment dose of 12,000 cGy (rad) received another patient's dose. Two patients were at a medical facility on 2/2/2012 to receive microspheres. The first patient received the second patient's intended dose of 1.77 GBq (47.84 mCi). On 2/2/2012, both patients' doses were loaded into a shielded carrier. Patient specific markers (patient initials) were placed on each dose. At the time of the first patient's administration, the injecting technician was given the wrong microsphere vial. When preparing for the second patient's dose, the vial was surveyed and found to be much higher than anticipated. The error was identified prior to the second patient receiving treatment. Corrective actions included generating a requirement for two individuals to sign off on the dosage vial with the written directive present prior to administration. The facility also committed to follow protocol verification prior to treatment administration. The Utah Department of Environmental Quality, Division of Radiation Control, performed an onsite investigation.

Item Number 120103 - A patient received dose to unintended areas during a liver treatment on 2/2/2012 using 1.55 GBq (41.89 mCi) of Y-90 microspheres. The infusion procedure went according to plan. After accounting for normal loss within the delivery system, the final administered activity was 1.53 GBq (41.35 mCi). However, follow-up scans revealed that some of the microspheres were not in the liver. An investigation on 2/6/2012 determined that an estimated 10 to 15% of the microspheres were in the spleen, gastric fundus, and duodenum. The patient and the ordering physician were informed. Further investigation and single-photon emission computed tomography (SPECT) imaging revealed that the liver received 83.9% of the administered activity for a dose of 53 Gy (5,300 rad), the gastric fundus received 5.8% of the administered activity for a dose of 44 Gy (4,400 rad), the spleen received 9.3% of the administered activity for a dose of 35 Gy (3,500 rad), and the duodenum received 1% of the administered activity for a dose of 35 Gy (3,500 rad). These dose estimates have uncertainties of at least 20% and local concentrations and doses may be significantly higher. Maximum concentrations per pixel in the SPECT images were as much as 50% higher than the average concentration. The Minnesota Department of Health performed an onsite investigation on 2/6/2012. The hospital's investigation was unable to identify any procedural failures or human errors that may have produced the event. This event may result in unintended, permanent functional damage and some form of medical intervention is likely. The patient was administered the radio-protective pharmaceutical and will be monitored weekly to determine the extent of damage to the unintended organs.

Item Number 120341 - A patient did not receive the prescribed 14,500 cGy (rad) dose during a prostate brachytherapy seed implant. The patient was implanted with 65 brachytherapy seeds, each containing an activity of 12.58 MBq (0.34 mCi). Day zero computed tomography revealed that all seeds were located inferior to true base, resulting in placement in the penile bulb instead of the prostate gland. Ultrasound had been used to locate the prostate, but the penile bulb was mistaken as the prostate. There had been no instrument malfunctions, including the ultrasound. The urologist and patient were notified of the error. Risks to the urethra were discussed. The North Carolina Division of Radiation Protection investigated the incident on 6/12/2012. Corrective actions include using fluoroscopy to confirm needle placement.

Item Number 120480 - A patient treated with an HDR afterloader received treatment to the wrong site because the source position was offset from the intended site. Between 3/5/2012 and 3/9/2012, the patient received two single lumen treatments per day to the right breast using Ir-192. The total prescribed dose for the 10 fractions was 3,400 cGy (rad). During a follow-up appointment on 6/11/2012, it was noted that

the catheter insertion site had not healed. On 7/24/2012, a plastic surgeon performed excisional debridement of the entire skin and breast tissue area affected by the administration. The surgical pathology report received on 8/10/2012 showed a final diagnosis of fat necrosis with granulation tissue radiation effect. After reviewing the report, the prescribing physician requested a complete review of the treatment by a qualified consultant, which was completed on 8/15/2012. This review demonstrated an unintended dose to the right breast caused by the incorrect digitization of the treatment device. This led to a 42 mm offset of all dwell positions for all treatment fractions. This event was caused by a lack of familiarity and inadequate training with the treatment planning system. The treatment plan was calculated using a reference point of "catheter end." However, the patient was treated with a reference point of "tip end", resulting in a displacement of the dose distribution. Only 28.4% of the intended treatment volume received the prescribed dose. Breast and skin tissue outside of the intended treatment site received a maximum estimated dose of 20,400 cGy (rad). The patient and referring physician were notified of the event. The patient experienced toxicity of the skin in the region of the administration, with a central 1 cm area of ulceration that was draining serous fluid and a surrounding 4 cm deep region. The possibility of long term effects is low, although additional skin ulceration and breast tissue necrosis could occur. The NRC contracted a medical consultant to review this event. Corrective actions included an independent review of HDR treatment plans, an additional independent check to verify the physical orientation of the catheter, and personnel training.

Item Number 120481 - A patient received an HDR afterloader treatment using another patient's written directive on 8/1/2012. The incident involved a 271.95 GBq (7.35 Ci) Ir-192 source. The patient received 340 cGy (rad) to the breast tissue. It was determined that the two patients' treatment plans were essentially the same and the unintended patient received approximately 99.5% of her prescribed dose. The Florida Department of Health investigated the incident on 8/27/2012 and determined the cause to be operator error. The unintended patient received the same treatment that the prior patient received; the HDR had not been reprogrammed. Corrective actions included modifying procedures to require a time out to verify patient's name, plan, and treatment settings.

Item Number 120548 - A patient was administered 6.03 GBq (163 mCi) of I-131 on 9/10/2012, instead of the prescribed 3.7 GBq (100 mCi). The hospital's investigation revealed a misinterpretation of an admission order as a written directive by the nuclear medicine technologist, due to inclusion of the authorized user's name and 5.55 GBq (150 mCi) of activity on the admission order. The written directive was never received by the Nuclear Medicine Department. The root cause stemmed from a new communication process by which written directives are conveyed from the authorized user to Central Scheduling, and then to the Nuclear Medicine Department. The referring physician and patient were notified on 9/10/2012. The new procedures for communicating written directives had only been in place for two months and only one I-131 administration was performed during that time. The hospital has since reverted back to their old procedures where written directives are communicated directly from the authorized user to the nuclear medicine department.

#### Events of Interest

Item Number 120178 - A hospital reported an aborted fractional dose treatment involving an HDR brachytherapy unit containing a 269.36 GBq (7.28 Ci) Ir-192 source. The patient was prescribed to receive 600 cGy (rad) during the first fractional dose treatment, with a total of five fractions. The treatment included 14 dwell positions in two different catheters, with six dwell positions in the ring to be treated on HDR channel 1 and eight dwell positions in the tandem to be treated on channel 3. At the completion of the channel 1 treatment, the HDR unit gave an error stating that there was a "possible incomplete source retraction in channel 2". Radiation indicators did not detect the presence of radiation and channel 2 was not being used. Immediate emergency procedures were implemented. The emergency stop was activated and the room was entered with a survey meter to verify that there were no elevated radiation levels. All indications were that the source was retracted properly. The error could not be cleared using the reset button. The HDR unit's manufacturer was contacted and attempted to walk

hospital personnel through steps to clear the error, but were unsuccessful. The remaining portion of the patient's treatment was aborted. The manufacturer scheduled a service engineer visit to repair the HDR unit. The patient only received 120 cGy (rad) of the prescribed 600 cGy (rad). The authorized user notified the patient of the problem. Corrective actions included always covering the HDR unit with the manufacturer supplied dust cover except for when the unit is in use. In addition, the hospital will ensure the environment surrounding the unit is appropriate. This event was classified as an EQP and MED event.

Item Number 120303 - A hospital reported a potential radiation overexposure to a patient who was treated in November 2011. The patient was treated using an HDR unit with a 296 GBq (8 Ci) Ir-192 source. On 5/10/2012, the patient responded to the hospital and had a 1 cm by 3 cm oval necrotic area of tissue on the inner thigh consistent with radiation exposure. Hospital personnel investigated the incident and estimated a maximum skin dose of 600 cGy (rad). Three scenarios could have caused the incident; the compression fitting was not tight enough to hold the catheter, the catheter may have slipped while being handled by the therapist, or the catheter slipped while the patient's legs were being manipulated up and down. Corrective actions included procedure modifications.

Item Number 120393 - A patient was implanted with at least one leaking I-125 brachytherapy seed on 5/2/2012. The patient was implanted with 90 seeds, each containing an activity of 22.94 MBq (0.62 mCi). The incident was discovered on 6/28/2012, when hospital personnel were surveying the packing material used to ship I-125 seeds for the brachytherapy procedure. They found elevated readings between 2,500 and 350,000 cpm and 0.2 mrem/hour. No abnormal radiation readings were identified on equipment or in the operating room during and following the patient's medical procedure. They stated that the implant procedure went fine and that nothing unusual occurred. The patient was evaluated for uptake on 7/2/2012. Urine bioassays and thyroid counts revealed an uptake of I-125. Estimates identified an uptake of 3.7 MBq (0.1 mCi), a thyroid dose of 330 cGy (rad), and a whole body dose of 12 cSv (rem). The hospital concluded that the cause of the contamination was due to a manufacturing error. The seed manufacturer concluded that the seeds had been damaged in transit or that hospital personnel damaged the seeds either during initial surveys or during the implantation. The California Health and Human Services Agency concluded that the most logical explanation for the leaking seeds was a manufacturing error, but that cannot be conclusively proven. The hospital switched to another brachytherapy seed manufacturer. In addition, they initiated a procedure to require wipe testing seed needles upon removing them for their shipping container. This event was classified as an EQP, LKS, and MED event.

Item Number 120316 - A skin cancer patient scheduled for a lymphoscintigraphy procedure was incorrectly injected with 925 MBq (25 mCi) of Tc-99m MDP instead of the prescribed 111 MBq (3 mCi) of Tc-99m Sulfur Colloid on 5/17/2012. The Tc-99m MDP was equally divided among three injection sites approximately 2.5 cm apart. The cause of the event was human error in that the nuclear medicine technologist inadvertently obtained a syringe intended for another patient and failed to check the labels. The mistake was discovered 20 minutes later by another technologist. The patient and physician were notified. Initial dose estimates indicated about 40 cSv (rem) to each injection site. However, the NRC determined that a 2 cc area of skin and tissue at each injection site received 209 cSv (rem). No long-term medical effects to the patient were anticipated because the injection sites were excised (standard lymphoscintigraphy procedure) on 5/22/2012. To prevent recurrence, the nuclear medicine staff added this event to staff training to ensure that staff double check the label, dosage, and drug prior to administration.

Item Number 120489 - A patient received 600 cGy (rad) instead of the prescribed 340 cGy (rad) during the first fraction of radiation therapy treatment using an HDR remote afterloader on 8/20/2012. The hospital stated that the afterloader's treatment planning software malfunctioned, resulting in the 76.5% overdose. Hospital staff also failed to complete a required worksheet, which may have alerted the authorized user to the dose difference prior to treatment. The patient was notified on 8/20/2012 and the referring physician was notified on 8/21/2012. Investigation revealed that the treatment system

erroneously recalculated the dwell times after the indexer lengths were corrected. The system printed the incorrect dose to verification point. In addition, the errors were not covered in the system manufacturer's customer information bulletin. Corrective actions included implementing a requirement for repeating the independent second check of all aspects of a treatment plan any time it is unapproved, modified, or re-exported. In addition, procedures were modified and personnel were counseled. The manufacturer was notified and will perform an upgrade. Physicists will also perform full acceptance testing of the new version. This event was classified as an EQP and MED event.

Item Number 120492 - A patient only received approximately 76% of the prescribed dose from an I-125 brachytherapy seed implant into the right lung. A piece of mesh containing 50 I-125 seeds was implanted into the patient through an invasive procedure on 5/31/2012. The mesh contained five strands of seeds, with 10 seeds per strand, and a total activity of 606.8 MBq (16.4 mCi). The patient was readmitted on 7/4/2012. On 7/7/2012, a chest x-ray found that only 38 of the 50 seeds were visible. Chest and abdomen x-rays were performed on 7/9/2012, which revealed 35 seeds in the chest and three in the abdomen. X-rays on 7/18/2012 revealed 13 seeds in the lung and 17 in the abdomen. On 8/4/2012, there were only six seeds remaining in the lung and eight in the abdomen. Final x-rays taken on 8/8/2012 revealed that no seeds remained in the patient. It is believed that the patient coughed up the loose seeds and swallowed them. A total of nine seeds were recovered during patient hospitalization and placed in the nuclear medicine hot laboratory. The failure of the device was reported to the manufacturer and Food and Drug Administration. This event was classified as an EQP, LAS, and MED event.

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

Doses to an embryo/fetus or nursing child are reportable per 10 CFR 35.3047. By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as "Other" events. However, it is appropriate to also discuss these events in this section. One such event occurred in FY12 and was classified as a potential AO.

Item Number 110566 - A pregnant patient received 2.73 GBq (73.7 mCi) of I-131 for thyroid therapy on 10/6/2011. The patient had taken a pregnancy test on 10/5/2011 and the results were negative. The patient subsequently discovered that she was pregnant and contacted the hospital on 10/26/2011. It was determined that the embryo/fetus was 10 days old at the time of treatment. The estimated dose to the embryo/fetus was 17.4 cSv (rem). The State of Pennsylvania performed a reactive inspection to review hospital procedures and investigate the event. No corrective actions were required beyond current practices.

### **2.3.3 Events Recently Added to NMED That Occurred Prior to FY12**

Ten MED events and no embryo/fetal dose events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Two of the MED events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

#### Significant Events - AOs or Potential AOs

Item Number 120159 - A patient received less than 80% of the prescribed dose during a prostate seed implant procedure performed on 2/25/2011. In addition, a small volume of tissue outside and adjacent to the prostate gland received a dose greater than 1,000 cGy (rad) and more than 50% of prescribed. The short term effect on the patient was minimal, as the desired response was achieved. The long term effect will be under constant follow-up. The entire implant process will be reviewed with special attention to real time seed placement and subsequent 30-day image evaluation. The attending physician did not feel that notifying the patient would be beneficial.

Item Number 120432 - A hospital reported that 13 patients received prostate implant treatments that differed from prescribed. The incidents were discovered on 7/18/2012 during a Wisconsin Department of Health Services inspection. All prostate procedures performed since 2001 were evaluated. One patient

received an overdose to the prostate, seven patients received underdoses to the prostate (two of whom also received overdoses to the rectum), and five patients received overdoses to the rectum. The medical events occurred between 7/15/2005 and 5/20/2012. It was determined that the hospital had not reviewed prostate brachytherapy cases against medical event criteria. These events were caused by human error. Corrective actions included generating new policies and procedures.

#### Events of Interest

Item Number 110646 - A manufacturer of clinical agents used in medical imaging procedures reported increased radiation exposure in patients who underwent cardiac positron emission tomography (PET) scans with Rb-82 chloride injections. This event was discovered after two patients triggered radiation detectors when travelling to/from the United States. One of these individuals had been treated on 3/8/2011; subsequent whole body counting revealed a dose of 4.9 cSv (rem). Isotopic analysis indicated the presence of Sr-85 and Sr-82. As a result of further investigations by the U.S. Food and Drug Administration (FDA), the manufacturer voluntarily recalled all of the rubidium generators from the market on 7/25/2011. At that time, there were over 100 users of the generator. FDA, NRC, the Center for Disease Control, the State of Nevada, the State of Florida, and the manufacturer began collecting and analyzing data to determine the extent of condition. A Nevada medical facility reported that three of 204 patients treated between 2/11/2011 and 4/7/2011 were confirmed to have received whole body exposures of 5.54, 5.66, and 5.83 cSv (rem). The FDA determined that the generator manufacturing procedures were not sufficient to reliably prevent strontium breakthrough. In February 2012, the manufacturer returned the generators to the market with FDA-approved revised package labeling, which included enhanced testing information to help minimize the risk for exposure to unintended levels of strontium radiation. In addition, technologists were retrained by the manufacturer and shall adopt updated policies concerning breakthrough testing. An online worksheet was constructed to simplify and monitor the breakthrough recording process. This event was classified as an EQP and MED event.

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

None.

## 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 data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within the annual values represent random fluctuation around the average of the data.

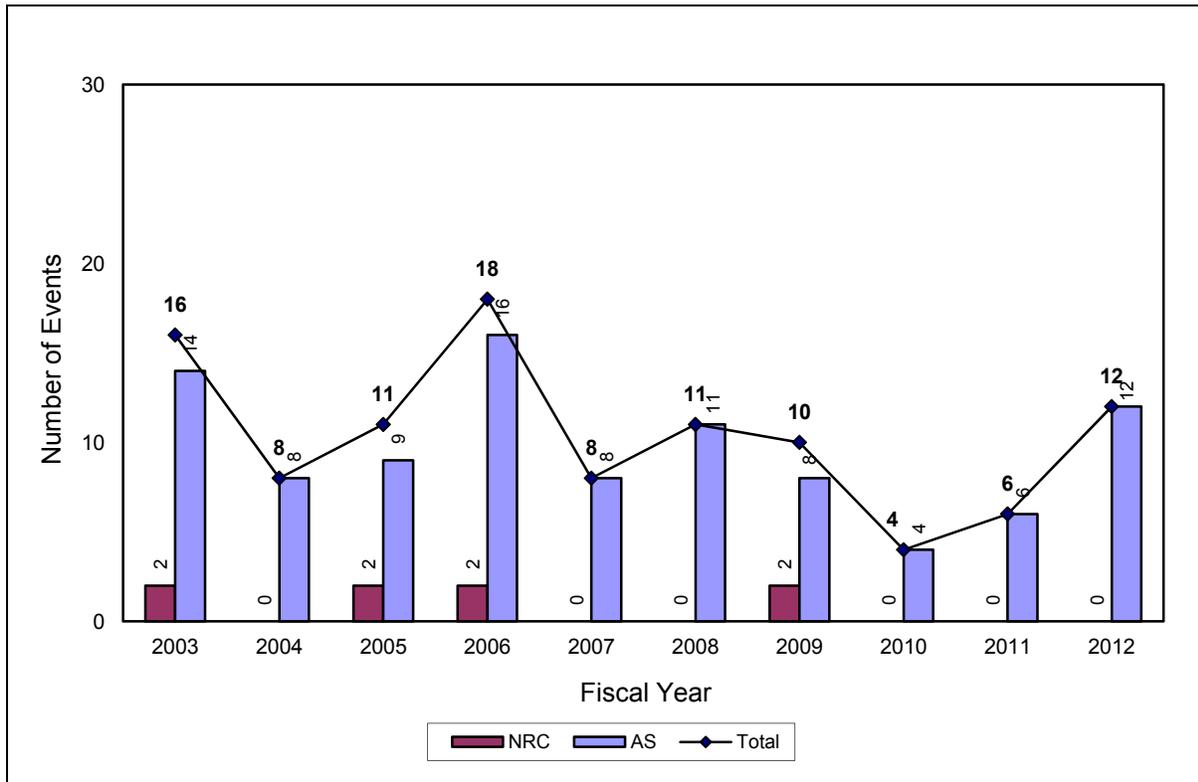


Figure 4. Radiation Overexposure Events (104 total)

The significance of individual EXP events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, events requiring immediate or 24-hour reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

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

	Fiscal Year										Total
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	
<b>Immediate</b>	2	1	0	1	1	0	0	0	1	1	<b>7</b>
<b>24-Hour</b>	1	1	1	3	1	3	1	1	0	5	<b>17</b>
<b>30-Day</b>	13	6	10	14	6	8	9	3	5	6	<b>80</b>
<b>Total</b>	<b>16</b>	<b>8</b>	<b>11</b>	<b>18</b>	<b>8</b>	<b>11</b>	<b>10</b>	<b>4</b>	<b>6</b>	<b>12</b>	<b>104</b>

### 2.4.2 FY12 Data

Twelve EXP events occurred in FY12, six of which were considered significant.

#### Significant Events - Immediate Reports

None.

#### Significant Events - Within 24-Hour Reports

Item Number 110533 - Three radiation workers were overexposed while performing maintenance on an irradiator. The workers were contracted to load a 44.77 TBq (1,210 Ci) Co-60 source assembly into an irradiator in a facility in Raritan, New Jersey, on 10/8/2011. During the procedure, the eight-inch tall source assembly was dislodged from its shielded position and approximately four inches of the assembly was exposed in an unshielded configuration. In addition, the insertion tool prevented the workers from quickly reinserting the source assembly. The workers were able to shield the assembly using tungsten. They then had to force the assembly into place and break off the insertion tool, following which the Co-60 was confirmed to be in a shielded configuration and safely secured. The total time the source was unshielded was estimated at between 25 and 30 seconds. The two individuals loading the source received whole body exposures of 17.5 and 17.2 cSv (rem) and extremity exposures of 61.6 and 101.3 cGy (rad), respectively. The third individual (RSO) received a whole body dose of 11.4 cSv (rem). Four additional workers were in attendance during the source exchange. Their estimated whole body exposures ranged between 1.5 cSv (rem) and 3.5 cSv (rem). The root causes of the event were lack of control and communication of the RSO over the operation, no functioning radiation survey meter, lack of operational and emergency procedures, and misalignment of the tungsten shield over the transfer shield which prevented the source from being reinserted into the transfer shield without manual manipulation of the tungsten shield. Corrective actions included rewriting operational and emergency procedures and adding a pressure gauge to the vacuum tool. As of 7/17/2012, this incident was classified as an International Nuclear Event Scale level 2 event.

Item Number 110569 - A personnel overexposure occurred following the incomplete retraction of a 2.33 TBq (63 Ci) Ir-192 radiography source. Two radiographers were performing operations on a pipeline project in Wyalusing, Pennsylvania, on 10/28/2011. The radiography crew approached the pipe after cranking in the source to set up for their next shot. While placing the film on a weld, a radiographer noticed that the locking mechanism on the exposure device had not popped up. Both radiographers confirmed that their survey meters read zero. However, one radiographer's rate alarm was chirping, but not very loudly. The other radiographer's rate alarm was silent. Problems had been identified with both radiographers' rate alarms prior to beginning work, but operations were still conducted. The radiographers went back to the crank assembly and were able to make approximately one turn to fully retract the source. Both radiographers' electronic dosimeters were off-scale. Their personnel dosimeters were sent for emergency processing and revealed whole body exposures of 5.133 and 1.447 cSv (rem). The cause of the event is believed to be faulty equipment. In addition, the radiographers made decisions that were not in accordance with protocols. Corrective actions included providing additional training to

involved personnel. As of 11/3/2011, this incident was classified as an International Nuclear Event Scale level 2 event. This event was classified as an EQP and EXP event.

Item Number 120129 - A personnel overexposure occurred during radiography at a materials inspection facility on 2/17/2012. A radiographer was working in a shooting bay using an exposure device that contained a 1.37 TBq (37 Ci) Ir-192 source. The radiographer entered the shooting bay to setup for the next operation. The radiographer carried a dose rate meter, but did not pay attention to the reading. The radiographer was talking on his cell phone during this process. The radiographer completed the setup, left the shooting bay, and attempted to crank the source out, but discovered that the source was already cranked into the collimator. The radiographer retracted the source and contacted the RSO. The RSO initially determined that the radiographer may have received as much as 20 cSv (rem) TEDE. However, following two reenactments of the event, the RSO determined that the radiographer received a TEDE of 8.1 cSv (rem). The RSO did not believe an extremity overexposure occurred because the radiographer did not have to relocate the collimator. The radiographer provided three blood samples for evaluation, the results of which were normal. Prior to the event, the electrical breaker that supplied power to the shooting bay had been opened, which rendered the bay's alarm inoperable. The individual that opened the breaker believed that it only supplied power to a ventilation fan. The radiographer was removed from all work involving potential radiation exposure and dosimetry was sent for processing. The facility assigned a TEDE exposure of 8.1 cSv (rem) to the radiographer's dose of record, which brought the radiographer's yearly TEDE up to 8.2 cSv (rem). The Texas Department of State Health Services conducted an onsite investigation during the week of 3/5/2012. Corrective actions included implementing a new policy of banning cell phone use during radiography operations, procedure modifications, and additional training to personnel. The facility also painted, labeled, and locked the breaker box supplying power to the shooting bay alarms. As of 6/7/2012, this incident was classified as an International Nuclear Event Scale level 2 event.

Item Number 120198 - A personnel overexposure occurred after a radiography source disconnected from its drive cable at a temporary jobsite in Pasadena, Texas, on 3/24/2012. A radiography exposure device containing a 2.41 TBq (65 Ci) Ir-192 source was being used. The source drive cable broke and the source completely disconnected inside the guide tube. Thinking the source had been properly retracted, the radiographer disconnected the guide tube from the exposure device, placed it around his neck, and climbed down the ladder of a scaffold. When the trainer reached the platform, he removed the guide tube from around his neck. He then noted that the radiographer trainee was having problems disconnecting the crank assembly from the exposure device and that the exposure device locking mechanism was still unlocked. Radiation surveys revealed that the source was within the guide tube. Both the radiographer's and trainee's alarming rate meters sounded at some point in the process. The radiographer picked up the guide tube with long tongs and the source fell out onto the platform. Radiation surveys were performed and the 2 mR/hour boundary was adjusted. An authorized individual responded to the site and performed source retrieval. Preliminary dose estimates for the radiographer revealed a whole body exposure of 56 cSv (rem) and an extremity exposure exceeding 100 cSv (rem). The radiographer's film badge was processed on 3/28/2012, which revealed a DDE whole body dose of 0.82 mSv (812 mrem). The radiography services company and the Texas Department of State Health Services (TDSHS) conducted an investigation into the event. During a reenactment, it was determined that the radiographer had the guide tube around his neck for approximately 35 seconds. The radiographer had worn his film badge on his right chest pocket. Dose assessment calculations estimated that the radiographer received a DDE of 29.32 cSv (rem). Most of that exposure was to the radiographer's left upper thigh. Blood tests revealed negative results and no symptoms of local radiation injury were identified. The equipment was returned to the manufacturer. Investigation revealed that the drive cable had been severed directly behind the connector, which was heavily worn. The cable was corroded, rusted, and stiff at the broken location. The cable was also dry of any lubricant and had not been properly inspected and maintained. The control assembly components revealed significant signs of rusting and the housing had been taped together to allow continued use. According to the manufacturer, the cable failed due to a combination of wear,

corrosion, and lack of lubrication. There were no indications of improper manufacture or defect in the drive cable. The radiographer stated that he had not checked the condition of the cable prior to performing radiography. The survey meter and alarming rate meters were also sent to their manufacturers for evaluation. All were within calibration date and operated properly. The radiography services company modified their procedures to require performance of routine inspections and maintenance by the manufacturer. DSHS concluded that the cause of the event was failure to properly inspect and maintain radiography equipment, failure to perform proper radiation surveys, failure to perform daily equipment inspections, and failure to ensure an exposure device is in the locked position prior to disconnections. As of 10/17/2012, this incident was classified as an International Nuclear Event Scale level 2 event. This event was classified as EQP and EXP event, as well as a potential AO.

Item Number 120263 - A personnel overexposure occurred during radiography at a materials inspection facility. An assistant radiographer notified the RSO on 4/16/2012 that his 0-200 mR pocket dosimeter went off scale on 4/6/2012. The radiographers were using an exposure device that contained a 2.41 GBq (65 Ci) Ir-192 source. While the radiographer was developing film, the assistant set up for the next shot. The assistant then noticed that his dosimeter was off-scale. His film badge was immediately sent for processing. Results revealed a 24.378 cSv (rem) whole body exposure, which brought his annual exposure to 24.801 cSv (rem). The Florida Department of Health (DOH) investigated the incident. Based on records review, reenactment, and personnel interviews, DOH concluded that the radiographer received the overexposure. The direct cause of the incident was the failure to follow radiation safety procedures. As of 8/24/2012, this incident was classified as an International Nuclear Event Scale level 2 event.

Item Number 120515 - A university reported that a graduate student inhaled a mixture of U-233 and U-238. The incident occurred while the student was grinding a compound of uranium oxide in a glove box. University procedures require that task be performed in a hood with a high efficiency particulate (HEPA) filter. The incident occurred twice between 10/1/2011 and 4/1/2012. Bioassays based on an inhalation date of 10/1/2011 revealed a TEDE of 17.72 cSv (rem). Those results based on an inhalation date of 4/1/2012 revealed a TEDE of 5.52 cSv (rem). The student was restricted from all laboratory work. A lung, kidney, and hand count were performed on 9/5/2012. The lung count revealed less than detectable activity for Th-234, U-233, U-234, and U-235. No activity was detected with the kidney and hand counts. Bioassays results received on 9/12/2012 revealed 0.66 dpm/sample of U-238, 1.25 dpm/sample of U-233/234, and less than detectable for U-235. All personnel that had access to the laboratory where the incident occurred submitted bioassay samples. That included 46 individuals, including the RSO and assistant RSO. From that group, it appears that one additional graduate student received an uptake. That student was restricted from work involving radioactive material. That individual's dose results are being investigated. There are 13 bioassays that remain to be analyzed and three of those remain to be collected. The RSO had elevated uptake results, but attributed them to previous work. As of 9/5/2012, this incident was classified as an International Nuclear Event Scale level 2 event.

#### Events of Interest

Item Number 110557 - A radiographer received a whole body and extremity overexposure on 10/12/2011. The radiographer was using an exposure device that contained a 1.824 TBq (49.3 Ci) Ir-192 source. The radiographer had climbed a ladder to remove the source guide tube from the exposure device. While the radiographer was disconnecting the guide tube, another employee observed that the radiographer's survey meter indicated that the source was not in the shielded position. The radiographer climbed down the ladder and cranked the source back into the camera. The radiographer's badge was sent for processing. Results revealed a whole body effective dose equivalent of 4.192 cSv (rem), bringing his total exposure for the year to 5.225 cSv (rem). The radiographer was unable to ascertain where the source had been in the guide tube during the incident. The company conducted reenactments of the event and calculated the dose to the radiographer's hands to be 58.15 cSv (rem). The radiographer was removed from duties and

provided additional training. As of 7/30/2012, this incident was classified as an International Nuclear Event Scale level 2 event.

Item Number 110607 - An iron pipe manufacturer reported that the shutter on a locked out gauge had fallen and resulted in the overexposure of members of the public. The gauge contained a 296 GBq (8 Ci) Cs-137 source. Two gauges had been locked out for maintenance on refractory equipment during the weekend of 10/22/2011. On the morning of 10/24/2011, it was discovered that the shutter on one gauge had fallen, leaving the source unshielded. Inspectors from the New Jersey Department of Environmental Protection (NJDEP) visited the site on 11/15/2011. NJDEP believes that four workers received in excess of 1 cSv (rem). NJDEP calculations demonstrate that those workers may have received over 1.7 cSv (rem). A total of 10 workers were exposed to radiation, but not all of them received over 1 mSv (100 mrem). The gauge was removed, the shield was welded back in place, and the gauge was sent back to the gauge manufacturer for failure analysis. That analysis determined that the shutter was badly corroded and rusted, which was unexpected because it was only five years old. A contributing factor to the failure was chipping that occurred while the gauge was still attached to the cupola. The pipe manufacturer had used pneumatic chipping hammers to remove a refractory brick layer from inside the cupola. It is believed that the vibrations caused the badly rusted and corroded shield to fall off. The gauge manufacturer will house the gauge in stainless steel in the future rather than carbon steel. This event was classified as an EQP and EXP event.

Item Number 120086 - A materials inspection company reported that an assistant radiographer's dosimetry badge received a radiation exposure of 2.925 cSv (rem) during October 2011. That badge result increased the individual's whole body exposure for 2011 to 6.056 cSv (rem). The company stated that the individual's October badge had not been turned in for processing until several days after the October reporting period ended. The individual stated that he had placed the badge in his coat pocket and hung the coat in a work area where it was exposed to radiation. The individual also lost his November badge and then found it on the floor while moving cabinets in December. The State of Oklahoma performed a reactive inspection on 12/21/2011. During an interview with the individual, it was determined that his pocket ion chamber had gone off-scale during the October dosimetry period and he had not reported the incident to the RSO or company management. The State Agency concluded that the individual received the exposure of 6.056 cSv (rem) during 2011. Corrective actions included re-training workers on badge procedures and having the RSO or assistants oversee badge exchanges.

Item Number 120651 - A personnel overexposure resulted from a 4.033 TBq (109 Ci) Ir-192 radiography source that was not fully retracted. Pipe-weld inspections were being performed at a site near Avella, Pennsylvania, on 8/23/2012. After the 30th exposure, the assistant radiographer did not fully retract the source to the secured position. The retraction mechanism (pistol grip) then fell to the ground from the pipe and allowed the source to travel to an unshielded position. The condition was not discovered when the retraction mechanism was picked up and returned to the pipe. The radiographer failed to observe the assistant radiographer retract the source and also failed to ensure the required radiation surveys were performed to confirm that the source was retracted. The survey meter was in hand, on the correct scale, and in a pegged condition. However, the assistant radiographer was not observing the meter. The radiographer and assistant were suspended from work for dose investigation and completion of remedial training. The radiographer will be audited on occasion in the future to ensure adherence to operating requirements. The assistant received a whole body exposure of 39.2 mSv (3.92 rem) during the incident, with a cumulative seven-month whole body exposure of 50.85 mSv (5.085 rem). The radiographer received a whole body exposure of 14.38 mSv (1.438 rem) during the incident. This event was classified as an EQP and EXP event.

#### **2.4.3 Events Recently Added to NMED That Occurred Prior to FY12**

One EXP event was recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. This event was not considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and

subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate or 24-Hour Reporting

None.

Events of Interest

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 data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within the annual values represent random fluctuation around the average of the data.

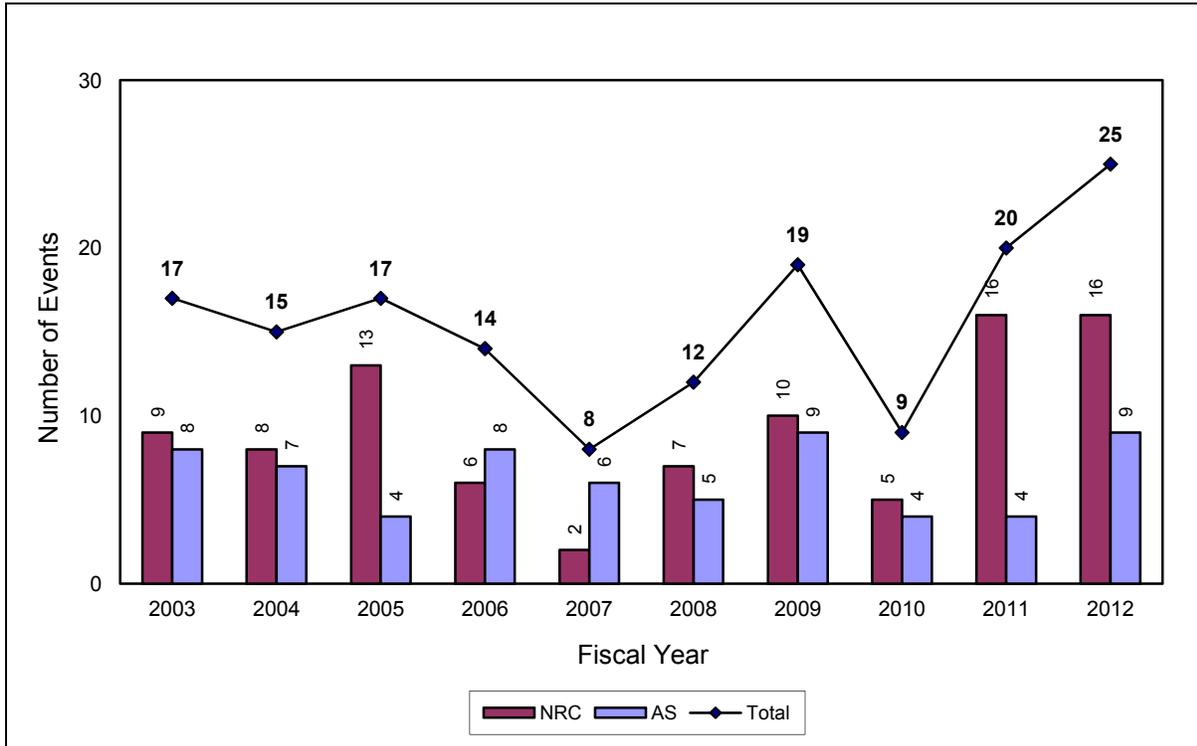


Figure 5. Release of Licensed Material or Contamination Events (156 total)

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, events requiring immediate reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

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

	Fiscal Year										Total
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	
<b>Immediate</b>	0	2	0	0	0	2	1	2	0	2	<b>9</b>
<b>24-Hour</b>	16	13	17	12	8	8	13	4	19	21	<b>131</b>
<b>30-Day</b>	1	0	0	2	0	2	5	3	1	2	<b>16</b>
<b>Total</b>	<b>17</b>	<b>15</b>	<b>17</b>	<b>14</b>	<b>8</b>	<b>12</b>	<b>19</b>	<b>9</b>	<b>20</b>	<b>25</b>	<b>156</b>

### 2.5.2 FY12 Data

Twenty-five RLM events occurred in FY12, two of which were considered significant.

#### Significant Events - Immediate Reporting

Item Number 120383 - While attempting to repair a fixed nuclear gauge that had been severely damaged in a fire (see NMED Item 110660), a technician contaminated himself, a bench-top work area, and the floor in front of the bench-top. The incident occurred on 6/19/2012 while the technician was removing the 11.1 GBq (300 mCi) Cs-137 source. During removal of the gauge lid, the bench-top detector alarmed. The technician pulled the source holder containing the source capsule from the gauge housing and placed it in a lead cave on his bench-top. Containment and decontamination procedures were commenced immediately. A small amount of Cs-137 contamination was removed from the technician's hands and the area was cordoned off to prevent the spread of contamination. The gauge housing was enclosed in plastic and placed inside a drum. Tools used in the area were also placed in the waste drum. The bench-top work area was decontaminated. Following initial decontamination, a swipe of the entire bench-top was obtained and analyzed. Results revealed over 500 MBq (13.51 mCi). Decontamination continued until contamination swipes revealed background results. The small area of contamination identified on the floor in front of the bench-top was also decontaminated to background levels. The transportation container was surveyed for removable contamination and none was identified. The gauge and leaking source were properly disposed of. The company implemented additional procedures for handling sources that have been involved in an event that may have damaged the source. This event was classified as an EQP, LKS, and RLM event.

Item Number 120573 - A university medical center reported that a funeral home cremated the remains of an individual on 9/20/2012 who had recently received an I-125 lung mesh implant. The implant procedure was performed on 9/13/2012 and involved 40 seeds containing a total activity of 860 MBq (23.24 mCi) of I-125. The crematory closed and the Wisconsin Department of Health Services (WDHS) responded to the site on 9/21/2012. Using a Victoreen 451, radiation surveys inside the crematorium revealed 0.75 mR/hour. The cremated remains of the individual revealed readings of 3.8 mR/hour on contact with a plastic bag. The remains were placed in a concrete container and radiation levels were at background outside the container. No other areas of the facility were identified as radioactively contaminated. The crematory remained closed pending decontamination. WDHS accompanied university personnel to the crematory on 10/17/2012 to assess contamination levels. No seeds remained intact and some of the powder that was inside the seeds remained on the concrete. On 10/23/2012, university personnel performed decontamination efforts and were able to reduce radiation levels to twice background. It was estimated that a fraction of the original I-125 activity was vented to the atmosphere. The crematory was allowed to resume operations on 10/26/2012. This event was caused by inadequate communication between the patient's family and the crematory. No corrective actions were taken. This event was classified as an EQP, LAS, LKS, and RLM event.

### Events of Interest

Item Number 120045 - A hospital reported receiving a contaminated package containing Ge-168 sealed sources. On 1/5/2012, the package was swiped and results revealed H-3 contamination. Radiation safety staff investigated and discovered H-3 contamination uniformly distributed in their loading dock area and surrounding hallway. The highest concentration of H-3 was discovered on their trash compactor. Surveys revealed removable radiation readings of up to 14,000 dpm. The RSO restricted entry to the loading dock area. The loading dock was successfully decontaminated and the entry was re-opened on 1/12/2012. Bioassays of individuals working in the area revealed negligible uptakes. The outside of the trash compactor was decontaminated on 1/9/2012. The compactor was removed by a waste broker on 1/10/2012 for recycling and/or disposal in Pennsylvania. It was discovered that two contractors had disposed of eight radioluminescent exit signs in the trash compactor. The contractors had found those signs stored in a closet. Each sign contained a decay corrected activity of 318.2 GBq (8.6 Ci). It was determined that four of the signs were crushed/compromised. The hospital will remove all of their radioluminescent exit signs, search for improperly stored signs, and train employees in proper disposal. This event was classified as an EQP, LAS, and RLM event.

Item Number 120136 - A radioactive source manufacturer reported the discovery of approximately 18.5 Bq (0.5 nCi) of Ir-192 contamination outside of a restricted area during routine contamination surveys conducted on 1/31/2012. In addition, radiation surveys discovered an 18,500 Bq (0.5 uCi) Ir-192 particle on the heel of an employee's work boot. Those discoveries prompted the manufacturer to perform additional surveys to determine the cause of the contamination. Survey wipes revealed 10,000 to 30,000 dpm over other areas (approximately two feet by two feet) at different locations. The manufacturer discovered that the exhaust fan on the Ir-192 source production hot cell had been turned off. The fan was immediately turned back on. Ir-192 from a supplier had been transferred into the hot cell approximately one week earlier. That transfer required the exhaust fan to be turned off temporarily. The fan had not been turned back on due to human error. Radiation workers who performed hot cell production operations during the time the exhaust fan was off were subjected to whole body counts. Those whole body counts indicated that workers ingested between 444 and 740 Bq (12 and 20 nCi) of Ir-192. The RSO calculated the CEDE to personnel to be less than 20 uSv (2 mrem). The employee with the Ir-192 particle on his heel received an estimated dose of 7 uSv (0.7 mrem) to his heel. The manufacturer performed decontamination of the first and a second floor of the facility, implemented daily monitoring of those two floors, and requires personnel performing production operations to wear full personal protective equipment. Corrective actions also include enhanced contamination surveillance and implementing a more robust system for monitoring individuals leaving the Ir-192 manufacturing facility (implemented on 3/1/2012). In addition, the ventilation system for the Ir-192 manufacturing facility was scheduled to be upgraded by 5/30/2012.

Item Number 120369 - A radiopharmacy reported that a vial containing approximately 70.3 GBq (1.9 Ci) of Tc-99m Sestamibi burst and likely volatilized following placement on a heating block during compounding activities for preparation of cardiac imaging radiopharmaceuticals. The incident occurred on 6/15/2012 and resulted in contamination of the pharmacist (also the RSO), compounding area, and areas within the main pharmacy. The pharmacist was the only person in the facility at the time of the event. Other staff arrived after the incident and provided some assistance, but did not enter the laboratory area. Radiation survey instruments in the laboratory became contaminated so the pharmacy borrowed instrumentation from a local hospital. Following the incident, the pharmacist initiated limited decontamination activities on himself and the area. He then continued with the preparation of other radiopharmaceuticals. The pharmacist then left the facility and traveled to his residence to shower and change clothing. The Colorado Department of Public Health and Environment (CDPHE) requested that the pharmacist provide a urine sample, submit personnel dosimeter badges for processing, and arrange for a backup pharmacist. A CDPHE inspector was dispatched to the facility and arrived on 6/16/2012. A whole body scan of the pharmacist revealed no radioactivity. The radioactive contamination is believed

to be contained within the laboratory, with exception of minor contamination discovered near the back door to the pharmacy.

### **2.5.3 Events Recently Added to NMED That Occurred Prior to FY12**

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

#### Significant Events - Immediate Reporting

Item Number 120151 - A hospital reported that the exhaust fan connected to an I-131 glovebox was discovered to be inoperable on 8/10/2009. Maintenance was contacted and determined that the fan belt was broken, which was repaired that same day. The hospital stated that up to 35% of the air exhaust containing I-131 vapor was not available for dilution. On 8/28/2009, the hospital noted that the effluent concentration of I-131 was 0.0077 Bq/liter (0.21 pCi/liter), which exceeded the regulatory limit. An investigation revealed that I-131 had been released through the ventilation system. There were minor releases within the laboratory, but the continuous air concentration in the pharmacist's breathing zone remained below regulatory limits. The I-131 glovebox was decontaminated. Radiation surveys of the laboratory revealed three locations of fixed contamination. Those locations were covered with cardboard and allowed to decay to background. All staff bioassays were below detectable limits. This event was classified as an EQP and RLM event.

#### Events of Interest

Item Number 120279 - A calibration facility reported that while attempting to calibrate an intravascular brachytherapy device on 1/18/2011, the Sr-90 source train became stuck in the catheter. The source train was 4 cm long and contained 16 seeds with a total activity of 2.07 GBq (56 mCi). The facility believed that they could cut the catheter and isolate the source train. While cutting the catheter, they misjudged the location of the source train and severed it. Approximately 10 ml of water spilled onto the table along with the train. Paper towels were used to wipe up the water. A radiation survey was performed to locate the Sr-90 seeds. Calculated leaking activity was less than 0.13 GBq (3.5 mCi). Two members of the Tennessee Division of Radiological Health (TDRH) responded to the site to investigate. TDRH determined that the facility was not licensed to cut the catheter to retrieve the source train. Corrective actions included discontinuing unlicensed activities, terminating employment of involved personnel, and properly disposing of the damaged intravascular brachytherapy system. This event was classified as an EQP, LKS, and RLM event.

Item Number 120298 - A university veterinary resident became contaminated with Tc-99m on 3/22/2011. The incident occurred when the resident was preparing to inject an animal with 44.4 MBq (1.2 mCi) of Tc-99m Mebrofenin. When the resident attempted to remove the cap from the syringe, she squirted approximately two drops of Tc-99m into her eye. She then dropped the syringe onto the table and the remaining syringe contents were ejected onto the table and floor. The resident immediately proceeded to flush her eye. The RSO was contacted and responded to the eye wash station. After the resident flushed her eye, the RSO performed radiation surveys and identified that 1.1 mR/hour still existed in the area of the eye and forehead. The resident was instructed to shower using soap. The RSO again surveyed the resident and identified 0.8 mR/hour in the area of the eye. The resident was taken to the university's medical center. After two additional eye flushes, radiation levels were still 0.2 mR/hour. Radiation surveys of the resident's forehead revealed 1.8 mR/hour. The resident was sent home to allow the Tc-99m to decay. The resident's eye reached background levels on the morning of 3/24/2011 and her forehead reached background levels on 3/25/2011. Corrective actions included modifying safety procedures and requiring the use of proper protective equipment.

## 2.6 Leaking Sealed Sources

### 2.6.1 Ten-Year Data

Figure 6 displays the annual number and trend of LKS events that occurred during the 10-year period. An event reporting anomaly associated with a single electron capture detector (ECD) manufacturer occurred from Fiscal Year 2000 through early 2005, which notably increased the number of LKS events. The anomalous events were not significant and involved leaking ECD sources (Ni-63 foil sources) that had been returned to the manufacturer for refurbishment. The manufacturer discontinued refurbishing ECDs and now disposes of the returned sources without leak testing. To show this affect, Figure 6 displays the anomalous events as yellow shaded bars.

The trend analysis determined that the Total events and NRC-regulated events (excluding the anomalous data) represent statistically significant decreasing trends (indicated by the trend lines). The Agreement State-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line). Therefore, variations within the Agreement State-regulated values represent random fluctuation around the average of the data.

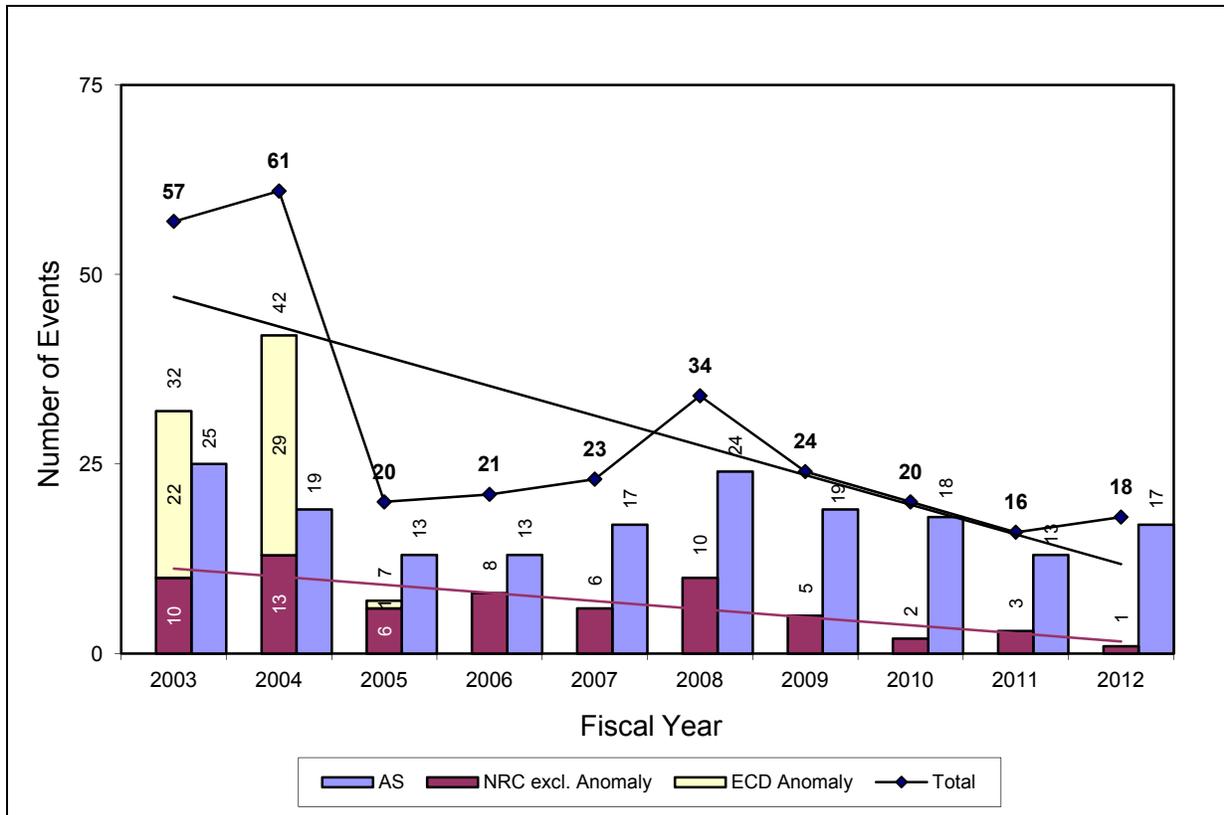


Figure 6. Leaking Sealed Source Events (294 total)

It is not possible to discern the significance of LKS events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9). 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. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

## 2.6.2 FY12 Data

Eighteen LKS events occurred in FY12, two of which were considered significant.

### Significant Events

Item Number 120383 - While attempting to repair a fixed nuclear gauge that had been severely damaged in a fire (see NMED Item 110660), a technician contaminated himself, a bench-top work area, and the floor in front of the bench-top. The incident occurred on 6/19/2012 while the technician was removing the 11.1 GBq (300 mCi) Cs-137 source. During removal of the gauge lid, the bench-top detector alarmed. The technician pulled the source holder containing the source capsule from the gauge housing and placed it in a lead cave on his bench-top. Containment and decontamination procedures were commenced immediately. A small amount of Cs-137 contamination was removed from the technician's hands and the area was cordoned off to prevent the spread of contamination. The gauge housing was enclosed in plastic and placed inside a drum. Tools used in the area were also placed in the waste drum. The bench-top work area was decontaminated. Following initial decontamination, a swipe of the entire bench-top was obtained and analyzed. Results revealed over 500 MBq (13.51 mCi). Decontamination continued until contamination swipes revealed background results. The small area of contamination identified on the floor in front of the bench-top was also decontaminated to background levels. The transportation container was surveyed for removable contamination and none was identified. The gauge and leaking source were properly disposed of. The company implemented additional procedures for handling sources that have been involved in an event that may have damaged the source. This event was classified as an EQP, LKS, and RLM event.

Item Number 120393 - A patient was implanted with at least one leaking I-125 brachytherapy seed on 5/2/2012. The patient was implanted with 90 seeds, each containing an activity of 22.94 MBq (0.62 mCi). The incident was discovered on 6/28/2012, when hospital personnel were surveying the packing material used to ship I-125 seeds for the brachytherapy procedure. They found elevated readings between 2,500 and 350,000 cpm and 0.2 mrem/hour. No abnormal radiation readings were identified on equipment or in the operating room during and following the patient's medical procedure. They stated that the implant procedure went fine and that nothing unusual occurred. The patient was evaluated for uptake on 7/2/2012. Urine bioassays and thyroid counts revealed an uptake of I-125. Estimates identified an uptake of 3.7 MBq (0.1 mCi), a thyroid dose of 330 cGy (rad), and a whole body dose of 12 cSv (rem). The hospital concluded that the cause of the contamination was due to a manufacturing error. The seed manufacturer concluded that the seeds had been damaged in transit or that hospital personnel damaged the seeds either during initial surveys or during the implantation. The California Health and Human Services Agency concluded that the most logical explanation for the leaking seeds was a manufacturing error, but that cannot be conclusively proven. The hospital switched to another brachytherapy seed manufacturer. In addition, they initiated a procedure to require wipe testing seed needles upon removing them for their shipping container. This event was classified as an EQP, LKS, and MED event.

### Events of Interest

Item Number 110660 - A petroleum refinery reported that a fire occurred in a coker unit on 12/10/2011. The fire involved four fixed nuclear gauges, each containing an 11.1 GBq (300 mCi) Cs-137 source. Two gauges were directly in the fire and were damaged. The other two gauges were shielded from the fire by the drums they were mounted on. The area was barricaded to prevent entry and initial radiation surveys conducted below the drums identified no levels above background. The refinery made arrangements with a gauge repair company to remove the gauges from their facility. As of 6/13/2012, all four gauges were leak tested with acceptable results and sent to the repair company. The refinery found that one of the gauges was void of lead shielding and that one of the sources was determined to be leaking; see NMED Item 120383 for additional details. This event was classified as an EQP and LKS event.

Item Number 120375 - A research and development facility reported the discovery of six leaking sources on 5/23/2012. They included a Ni-63 source (actually two sources in one case) with a total activity of 296 MBq (8 mCi - assay date of 1990) from an electron capture detector that had 481 Bq (0.013 uCi) of

removable activity, a Ni-63 disc source that had an activity of 185 MBq (5 mCi - assay date of 4/23/1969) and 1,480 Bq (0.04 uCi) of removable activity, a Ba-133 ring source that had an activity of 0.37 MBq (10 uCi - assay date of 10/1963) and 296 Bq (0.008 uCi) of removable activity, a Cs-137 ring source that had an activity of 1.3 MBq (35 uCi - assay date of 2/1962) and 1,184 Bq (0.032 uCi) of removable activity, and a Bi-207 source that had an activity of 0.42 MBq (11.26 uCi - assay date of 7/8/2011) and 370 Bq (0.01 uCi) of removable activity. In addition, an H-3 foil source that contained an activity of 18.13 GBq (0.49 Ci - with an original activity of 185 GBq or 5 Ci - on assay date 7/8/1971), which was exempt from leak testing, was also identified as leaking. Radioactive contamination was identified around the bell jar container that contained that H-3 foil source. All six sources were removed from service and secured to prevent the spread of contamination. It was determined that the sources had been leaking in previous leak tests, but always below limits. The facility changed leak test vendors and the new vendor's wipe test process and more sensitive instrumentation identified that the sources were leaking above limits. A complete survey and evaluation was completed by a consultant. A decontamination plan was prepared and all areas were decontaminated on 7/20/2012. The sources will be properly disposed of through a licensed waste broker. This event was classified as an EQP and LKS event.

Item Number 120573 - A university medical center reported that a funeral home cremated the remains of an individual on 9/20/2012 who had recently received an I-125 lung mesh implant. The implant procedure was performed on 9/13/2012 and involved 40 seeds containing a total activity of 860 MBq (23.24 mCi) of I-125. The crematory closed and the Wisconsin Department of Health Services (WDHS) responded to the site on 9/21/2012. Using a Victoreen 451, radiation surveys inside the crematorium revealed 0.75 mR/hour. The cremated remains of the individual revealed readings of 3.8 mR/hour on contact with a plastic bag. The remains were placed in a concrete container and radiation levels were at background outside the container. No other areas of the facility were identified as radioactively contaminated. The crematory remained closed pending decontamination. WDHS accompanied university personnel to the crematory on 10/17/2012 to assess contamination levels. No seeds remained intact and some of the powder that was inside the seeds remained on the concrete. On 10/23/2012, university personnel performed decontamination efforts and were able to reduce radiation levels to twice background. It was estimated that a fraction of the original I-125 activity was vented to the atmosphere. The crematory was allowed to resume operations on 10/26/2012. This event was caused by inadequate communication between the patient's family and the crematory. No corrective actions were taken. This event was classified as an EQP, LAS, LKS, and RLM event.

### **2.6.3 Events Recently Added to NMED That Occurred Prior to FY12**

Three LKS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

#### Significant Events

None.

#### Events of Interest

Item Number 120279 - A calibration facility reported that while attempting to calibrate an intravascular brachytherapy device on 1/18/2011, the Sr-90 source train became stuck in the catheter. The source train was 4 cm long and contained 16 seeds with a total activity of 2.07 GBq (56 mCi). The facility believed that they could cut the catheter and isolate the source train. While cutting the catheter, they misjudged the location of the source train and severed it. Approximately 10 ml of water spilled onto the table along with the train. Paper towels were used to wipe up the water. A radiation survey was performed to locate the Sr-90 seeds. Calculated leaking activity was less than 0.13 GBq (3.5 mCi). Two members of the Tennessee Division of Radiological Health (TDRH) responded to the site to investigate. TDRH determined that the facility was not licensed to cut the catheter to retrieve the source train. Corrective

actions included discontinuing unlicensed activities, terminating employment of involved personnel, and properly disposing of the damaged intravascular brachytherapy system. This event was classified as an EQP, LKS, and RLM event.

Item Number 120368 - A gauge manufacturer reported that a consultant discovered evidence of radioactive contamination in a source storage room. The contamination resulted from leaking sources that were no longer at the facility. The facility manufactures beta gauges that measure material thickness and weight, which contain Sr-90 or Am-241 sources. The leaks apparently resulted from improperly applying tape to the source windows upon packaging. The manufacturer stated that practice is no longer used and that the contamination was likely caused prior to November 2009. One or more sources could have been involved. The manufacturer stated that the sources were sent to a company in Germany in 2009. However, there is no record of the transfer of the sources to Germany. Wipe tests were performed on all available sources on 1/19/2012. None of those sources were identified as leaking. The Massachusetts Radiation Control Program performed an investigation. Corrective actions taken by the manufacturer included revising their Radiation Protection Program manual and instituting a Radiation Safety Program Compliance Calendar for the periodic activities as part of the manual. They had previously revised their packaging procedure to exclude application of tape to the source holders. This event was classified as an EQP and LKS event.

## 2.7 Equipment

### 2.7.1 Ten-Year Data

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

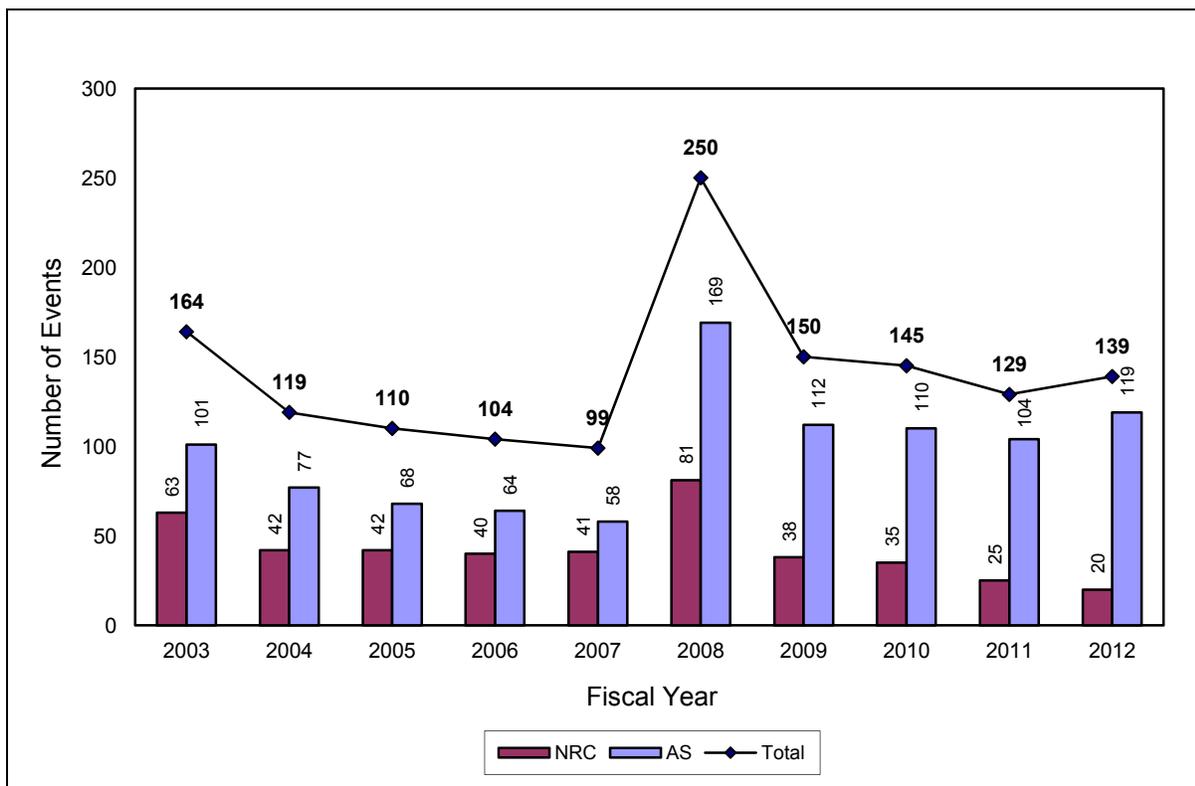


Figure 7. Equipment Events (1,409 total)

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

It is not possible to discern the significance of EQP events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9) because essentially all of the CFRs associated with EQP events require reporting within 24-hours. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

### 2.7.2 FY12 Data

One hundred thirty-nine EQP events occurred in FY12, eight of which were considered significant.

#### Significant Events

Item Number 110569 - A personnel overexposure occurred following the incomplete retraction of a 2.33 TBq (63 Ci) Ir-192 radiography source. Two radiographers were performing operations on a pipeline project in Wyalusing, Pennsylvania, on 10/28/2011. The radiography crew approached the pipe after cranking in the source to set up for their next shot. While placing the film on a weld, a radiographer

noticed that the locking mechanism on the exposure device had not popped up. Both radiographers confirmed that their survey meters read zero. However, one radiographer's rate alarm was chirping, but not very loudly. The other radiographer's rate alarm was silent. Problems had been identified with both radiographers' rate alarms prior to beginning work, but operations were still conducted. The radiographers went back to the crank assembly and were able to make approximately one turn to fully retract the source. Both radiographers' electronic dosimeters read off-scale. Their personnel dosimeters were sent for emergency processing and revealed whole body exposures of 5.133 and 1.447 cSv (rem). The cause of the event is believed to be faulty equipment. In addition, the radiographers made decisions that were not in accordance with protocols. Corrective actions included providing additional training to involved personnel. As of 11/3/2011, this incident was classified as an International Nuclear Event Scale level 2 event. This event was classified as an EQP and EXP event.

Item Number 110607 - An iron pipe manufacturer reported that the shutter on a locked out gauge had fallen and resulted in the overexposure of members of the public. The gauge contained a 296 GBq (8 Ci) Cs-137 source. Two gauges had been locked out for maintenance on refractory equipment during the weekend of 10/22/2011. On the morning of 10/24/2011, it was discovered that the shutter on one gauge had fallen, leaving the source unshielded. Inspectors from the New Jersey Department of Environmental Protection (NJDEP) visited the site on 11/15/2011. NJDEP believes that four workers received in excess of 1 cSv (rem). NJDEP calculations demonstrate that those workers may have received over 1.7 cSv (rem). A total of 10 workers were exposed to radiation, but not all of them received over 1 mSv (100 mrem). The gauge was removed, the shield was welded back in place, and the gauge was sent back to the gauge manufacturer for failure analysis. That analysis determined that the shutter was badly corroded and rusted, which was unexpected because it was only five years old. A contributing factor to the failure was chipping that occurred while the gauge was still attached to the cupola. The pipe manufacturer had used pneumatic chipping hammers to remove a refractory brick layer from inside the cupola. It is believed that the vibrations caused the badly rusted and corroded shield to fall off. The gauge manufacturer will house the gauge in stainless steel in the future rather than carbon steel. This event was classified as an EQP and EXP event.

Item Number 120009 - A radiography services company reported that a 1.184 TBq (32 Ci) Ir-192 radiography source became disconnected from the exposure device drive cable. The incident occurred on 12/22/2011 at facility in Humble, Texas. The radiographer stated that the source separated from the drive cable and that he used a pair of pliers to insert the source back into the exposure device. The radiographer could not disconnect the crank assembly from the exposure device and had to insert the source backwards into the device's guide tube port to shield it. The guide tube port had to then be covered with duct tape to prevent the source from coming out. The device was placed into the truck darkroom between a wall and the device's transport container. The truck was involved in a traffic accident while driving back to the storage location. The accident caused the source to move in the device S-tube towards the drive cable connection. Radiation levels around the exposure device increased. Levels of 0.04 mSv/hour (40 mrem/hour) were measured outside the truck following the accident by the Harris County fire marshal. The radiographer used the crank assembly to push the source closer to the center of the S-tube. Lead sheets were also used to help decrease radiation levels. At that time, dose rates were between 0.02 and 0.04 mSv/hour (2 and 4 mrem/hour) at one meter. All equipment was returned to the company's storage location. The source was removed from the exposure device and placed into a source changer. The radiographer received 1.8 mSv (180 mrem) during the event, as recorded on his pocket dosimeter. His thermoluminescent dosimeter (TLD) revealed a DDE of 0.75 mSv (75 mrem) for the month of December. The radiographer trainee's pocket dosimeter received 0.55 mSv (55 mrem) and his TLD revealed 2.2 mSv (220 mrem) for the month of December. The company returned the source and exposure device to the manufacturer for inspection. The manufacturer could not recreate the problem but suspected the drive cable failed at a weak point. Corrective actions also included providing additional training to involved personnel. The Texas Department of State Health Services estimated that the radiographer received 2.74

cSv (rem) to the hand when he inserted the source into the exposure device with a wrench. This event was classified as an EQP, OTH, and TRS event.

Item Number 120198 - A personnel overexposure occurred after a radiography source disconnected from its drive cable at a temporary jobsite in Pasadena, Texas, on 3/24/2012. A radiography exposure device containing a 2.41 TBq (65 Ci) Ir-192 source was being used. The source drive cable broke and the source completely disconnected inside the guide tube. Thinking the source had been properly retracted, the radiographer disconnected the guide tube from the exposure device, placed it around his neck, and climbed down the ladder of a scaffold. When the trainer reached the platform, he removed the guide tube from around his neck. He then noted that the radiographer trainee was having problems disconnecting the crank assembly from the exposure device and that the exposure device locking mechanism was still unlocked. Radiation surveys revealed that the source was within the guide tube. Both the radiographer's and trainee's alarming rate meters sounded at some point in the process. The radiographer picked up the guide tube with long tongs and the source fell out onto the platform. Radiation surveys were performed and the 2 mR/hour boundary was adjusted. An authorized individual responded to the site and performed source retrieval. Preliminary dose estimates for the radiographer revealed a whole body exposure of 56 cSv (rem) and an extremity exposure exceeding 100 cSv (rem). The radiographer's film badge was processed on 3/28/2012, which revealed a DDE whole body dose of 0.82 mSv (812 mrem). The radiography services company and the Texas Department of State Health Services (TDSHS) conducted an investigation into the event. During a reenactment, it was determined that the radiographer had the guide tube around his neck for approximately 35 seconds. The radiographer had worn his film badge on his right chest pocket. Dose assessment calculations estimated that the radiographer received a DDE of 29.32 cSv (rem). Most of that exposure was to the radiographer's left upper thigh. Blood tests revealed negative results and no symptoms of local radiation injury were identified. The equipment was returned to the manufacturer. Investigation revealed that the drive cable had been severed directly behind the connector, which was heavily worn. The cable was corroded, rusted, and stiff at the broken location. The cable was also dry of any lubricant and had not been properly inspected and maintained. The control assembly components revealed significant signs of rusting and the housing had been taped together to allow continued use. According to the manufacturer, the cable failed due to a combination of wear, corrosion, and lack of lubrication. There were no indications of improper manufacture or defect in the drive cable. The radiographer stated that he had not checked the condition of the cable prior to performing radiography. The survey meter and alarming rate meters were also sent to their manufacturers for evaluation. All were within calibration date and operated properly. The radiography services company modified their procedures to require performance of routine inspections and maintenance by the manufacturer. DSHS concluded that the cause of the event was failure to properly inspect and maintain radiography equipment, failure to perform proper radiation surveys, failure to perform daily equipment inspections, and failure to ensure an exposure device is in the locked position prior to disconnections. As of 10/17/2012, this incident was classified as an International Nuclear Event Scale level 2 event. This event was classified as EQP and EXP event, as well as a potential AO.

Item Number 120269 - A load of scrap metal set off the radiation monitor alarms at steel mill on 4/11/2012. A DOT Exemption was issued and the load was returned to the scrap facility on 4/12/2012. An Alabama Office of Radiation Control (ARC) inspector responded to the site on 4/13/2012. Investigation revealed a damaged fixed gauge containing a Cs-137 source. Maximum radiation levels of 500 mR/hour were noted on contact with the gauge and 28 mR/hour at a distance of one foot. Field analysis determined that the source was not leaking. There were no markings on the device to indicate model number or source activity. However, ARC identified the manufacturer and series number. The scrap facility is negotiating possible avenues for disposal, including return to the manufacturer. This event was classified as an EQP and LAS event.

Item Number 120383 - While attempting to repair a fixed nuclear gauge that had been severely damaged in a fire (see NMED Item 110660), a technician contaminated himself, a bench-top work area, and the

floor in front of the bench-top. The incident occurred on 6/19/2012 while the technician was removing the 11.1 GBq (300 mCi) Cs-137 source. During removal of the gauge lid, the bench-top detector alarmed. The technician pulled the source holder containing the source capsule from the gauge housing and placed it in a lead cave on his bench-top. Containment and decontamination procedures were commenced immediately. A small amount of Cs-137 contamination was removed from the technician's hands and the area was cordoned off to prevent the spread of contamination. The gauge housing was enclosed in plastic and placed inside a drum. Tools used in the area were also placed in the waste drum. The bench-top work area was decontaminated. Following initial decontamination, a swipe of the entire bench-top was obtained and analyzed. Results revealed over 500 MBq (13.51 mCi). Decontamination continued until contamination swipes revealed background results. The small area of contamination identified on the floor in front of the bench-top was also decontaminated to background levels. The transportation container was surveyed for removable contamination and none was identified. The gauge and leaking source were properly disposed of. The company implemented additional procedures for handling sources that have been involved in an event that may have damaged the source. This event was classified as an EQP, LKS, and RLM event.

Item Number 120393 - A patient was implanted with at least one leaking I-125 brachytherapy seed on 5/2/2012. The patient was implanted with 90 seeds, each containing an activity of 22.94 MBq (0.62 mCi). The incident was discovered on 6/28/2012, when hospital personnel were surveying the packing material used to ship I-125 seeds for the brachytherapy procedure. They found elevated readings between 2,500 and 350,000 cpm and 0.2 mrem/hour. No abnormal radiation readings were identified on equipment or in the operating room during and following the patient's medical procedure. They stated that the implant procedure went fine and that nothing unusual occurred. The patient was evaluated for uptake on 7/2/2012. Urine bioassays and thyroid counts revealed an uptake of I-125. Estimates identified an uptake of 3.7 MBq (0.1 mCi), a thyroid dose of 330 cGy (rad), and a whole body dose of 12 cSv (rem). The hospital concluded that the cause of the contamination was due to a manufacturing error. The seed manufacturer concluded that the seeds had been damaged in transit or that hospital personnel damaged the seeds either during initial surveys or during the implantation. The California Health and Human Services Agency concluded that the most logical explanation for the leaking seeds was a manufacturing error, but that cannot be conclusively proven. The hospital switched to another brachytherapy seed manufacturer. In addition, they initiated a procedure to require wipe testing seed needles upon removing them for their shipping container. This event was classified as an EQP, LKS, and MED event.

Item Number 120489 - A patient received 600 cGy (rad) instead of the prescribed 340 cGy (rad) during the first fraction of radiation therapy treatment using an HDR remote afterloader on 8/20/2012. The hospital stated that the afterloader's treatment planning software malfunctioned, resulting in the 76.5% overdose. Hospital staff also failed to complete a required worksheet, which may have alerted the authorized user to the dose difference prior to treatment. The patient was notified on 8/20/2012 and the referring physician was notified on 8/21/2012. Investigation revealed that the treatment system erroneously recalculated the dwell times after the indexer lengths were corrected. The system printed the incorrect dose to verification point. In addition, the errors were not covered in the system manufacturer's customer information bulletin. Corrective actions included implementing a requirement for repeating the independent second check of all aspects of a treatment plan any time it is unapproved, modified, or re-exported. In addition, procedures were modified and personnel were counseled. The manufacturer was notified and will perform an upgrade. Physicists will also perform full acceptance testing of the new version. This event was classified as an EQP and MED event.

#### Events of Interest

Item Number 110550 - A gaseous diffusion plant reported discovering two cracks in a uranium hexafluoride (UF<sub>6</sub>) side accumulator vessel on 10/26/2011. The one-of-a-kind vessel provides storage for up to 20,000 pounds of liquid UF<sub>6</sub> during the product withdrawal process. The cracks in the vessel allowed a small release of material, which caused the process gas leak detection system to alarm on

10/21/2011. Investigation revealed that the base metal contained stress defects that allowed multiple cracks to form, with some of the cracks penetrating through the outer wall. The cracks were a result of fabrication deficiencies. The vessel was repaired by cutting out the defective area and replacing it. This event was classified as an EQP and FCP event.

Item Number 110626 - A hospital reported that a patient received less than 50% of the prescribed dose fraction during gamma knife therapy on 11/14/2011 due to mechanical failure. Halfway through the procedure, the treatment was automatically terminated when the latch that fastens the immobilizing frame of the head to the couch failed. An inspection by the New York City Office of Radiological Health was conducted on 11/17/2011. Corrective actions included replacement of the latch mechanism. This event was classified as an EQP and MED event.

Item Number 110660 - A petroleum refinery reported that a fire occurred in a coker unit on 12/10/2011. The fire involved four fixed nuclear gauges, each containing an 11.1 GBq (300 mCi) Cs-137 source. Two gauges were directly in the fire and were damaged. The other two gauges were shielded from the fire by the drums they were mounted on. The area was barricaded to prevent entry and initial radiation surveys conducted below the drums identified no levels above background. The refinery made arrangements with a gauge repair company to remove the gauges from their facility. As of 6/13/2012, all four gauges were leak tested with acceptable results and sent to the repair company. The refinery found that one of the gauges was void of lead shielding and that one of the sources was determined to be leaking; see NMED Item 120383 for additional details. This event was classified as an EQP and LKS event.

Item Number 120022 - A recycling company reported finding two fixed nuclear gauges at their scrap yard on 12/28/2011. Each gauge contained a 740 MBq (20 mCi) Cs-137 source (assay dates of December and October 1986, respectively). The gauges were being stored in a steel drum away from public access. Wipe tests revealed negative results. Both gauges were found without shutter locks; one gauge with its shutter partially opened. That shutter was completely closed and the recycling company provided padlocks to lock both shutters closed. The highest radiation reading on the gauge with the shutter partially open was approximately 700 uSv/hour (70 mrem/hour) on contact. The two gauges with their shutters closed revealed readings of 25 uSv/hour (2.5 mrem/hour) on contact. Radiation readings around the storage drum were 15 uSv/hour (1.5 mrem/hour) on contact, with 3 uSv/hour (0.3 mrem/hour) at one foot, and 0.8 uSv/hour (0.08 mrem/hour) at one meter. It was determined that the two gauges came from a company located in Johnstown, Colorado, which had been dissolved in the late 1990s. The Colorado Department of Health (DOH) contacted the dissolved company's legal successor to ensure proper disposal of the two gauges. This event was classified as an EQP and LAS event.

Item Number 120045 - A hospital reported receiving a contaminated package containing Ge-168 sealed sources. On 1/5/2012, the package was swiped and results revealed H-3 contamination. Radiation safety staff investigated and discovered H-3 contamination uniformly distributed in their loading dock area and surrounding hallway. The highest concentration of H-3 was discovered on their trash compactor. Surveys revealed removable radiation readings of up to 14,000 dpm. The RSO restricted entry to the loading dock area. The loading dock was successfully decontaminated and the entry was re-opened on 1/12/2012. Bioassays of individuals working in the area revealed negligible uptakes. The outside of the trash compactor was decontaminated on 1/9/2012. The compactor was removed by a waste broker on 1/10/2012 for recycling and/or disposal in Pennsylvania. It was discovered that two contractors had disposed of eight radioluminescent exit signs in the trash compactor. The contractors had found those signs stored in a closet. Each sign contained a decay corrected activity of 318.2 GBq (8.6 Ci). It was determined that four of the signs were crushed/compromised. The hospital will remove all of their radioluminescent exit signs, search for improperly stored signs, and train employees in proper disposal. This event was classified as an EQP, LAS, and RLM event.

Item Number 120052 - A medical equipment sterilization company reported that their dry storage irradiator could be operated without closing both shielded collar doors that allow access to the sample

chamber. The problem was identified during routine weekly safety checks on 1/4/2012. The irradiator contains 349.13 TBq (9,436 Ci) of Co-60. Further investigation revealed that a proximity sensor associated with one of the doors failed in the “on” configuration, which gave a false indication that the unit was ready for operation and allowing the irradiation sequence to be initiated. No samples were being irradiated in the unit at the time of the safety check. The irradiator was subsequently locked out of service pending repairs. The company contacted the manufacturer and an authorized service vendor to discuss the problem. On 1/5/2012, replacement parts were obtained and repairs were performed by trained technical staff according to the manufacturer’s instructions.

Item Number 120178 - A hospital reported an aborted fractional dose treatment involving an HDR brachytherapy unit containing a 269.36 GBq (7.28 Ci) Ir-192 source. The patient was prescribed to receive 600 cGy (rad) during the first fractional dose treatment, with a total of five fractions. The treatment included 14 dwell positions in two different catheters, with six dwell positions in the ring to be treated on HDR channel 1 and eight dwell positions in the tandem to be treated on channel 3. At the completion of the channel 1 treatment, the HDR unit gave an error stating that there was a “possible incomplete source retraction in channel 2”. Radiation indicators did not detect the presence of radiation and channel 2 was not being used. Immediate emergency procedures were implemented. The emergency stop was activated and the room was entered with a survey meter to verify that there were no elevated radiation levels. All indications were that the source was retracted properly. The error could not be cleared using the reset button. The HDR unit’s manufacturer was contacted and attempted to walk hospital personnel through steps to clear the error, but were unsuccessful. The remaining portion of the patient’s treatment was aborted. The manufacturer scheduled a service engineer visit to repair the HDR unit. The patient only received 120 cGy (rad) of the prescribed 600 cGy (rad). The authorized user notified the patient of the problem. Corrective actions included always covering the HDR unit with the manufacturer supplied dust cover except for when the unit is in use. In addition, the hospital will ensure the environment surrounding the unit is appropriate. This event was classified as an EQP and MED event.

Item Number 120184 - A pipe manufacturer reported that a fire at one of their facilities resulted in damage to a radiography exposure device that contained a 1.22 TBq (33 Ci) Ir-192 source. The fire, which occurred on 3/15/2012, charred the outer casing of the exposure device and made it brittle. The source remained intact and in the shielded position. All radiation levels were normal for a shielded source. The device manufacturer was contacted to take possession of the device.

Item Number 120196 - A medical imaging company reported an equipment malfunction that occurred on 3/22/2012 during a patient treatment. A fire occurred while performing a lung perfusion study on the patient during the administration of 2.22 GBq (60 mCi) of Tc-99m DTPA. The RSO stated that the lung perfusion kit burst into flames. The nuclear medicine technician (NMT) removed the patient’s face mask and the patient’s hair caught on fire. The NMT put the fire out with his hands. The patient was immediately taken to the emergency room and the first degree burns on their face and neck were treated. The area was secured and radiation surveys were performed. The company did not conduct any nuclear medicine procedures until the Wisconsin Radiation Protection Section performed an investigation. The perfusion kit’s manufacturer hired a medical devices testing company to perform an analysis of the incident. They concluded that benzyl alcohol was present in the residual DTPA administered to the patient. Benzene and alcohol group compounds were identified in the area of the oxygen supply port, which is immediately adjacent to the nebulizer during treatment.

Item Number 120276 - A nuclear material recycling and disposal company reported that some shipping casks were taken out of service due to a regulatory compliance issue. The casks will remain out of service until a complete determination can be made by the company and the NRC. As part of the relicensing of new casks, the company identified a hypothetical accident scenario that was not previously analyzed as part of the original or ongoing licensing activities. That analysis confirmed that the current cask design does not comply with the requirement for the specific accident scenario. The casks were

taken out of service as of 4/27/2012. The company will submit a design change request to NRC for approval. Owners/users of the packages have been informed of the defect. Once NRC has approved the design change, owners/users will be notified and modifications to the casks will be made.

Item Number 120381 - A construction services company reported that a moisture/density gauge was struck by an asphalt truck on 6/26/2012 in Interstate 90 in Chicago, Illinois. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (9 mCi) Cs-137 source. The truck crossed the barriers and ran over the gauge while it was in use in an inactive traffic lane. The source rod was thrown from the gauge housing. Illinois Emergency Management Agency (IEMA) inspectors were dispatched to the scene. State police were also dispatched for traffic control. Using their survey meter, the company located the source rod two lanes over near the center median. They were able to scoop up the rod in an asphalt shovel and place it in a five-gallon bucket and shielded with sand. IEMA inspectors arrived approximately one hour later and were able to secure the source rod back into the damaged gauge. A leak test revealed no removable radioactive contamination. The gauge shield and shutter were intact and radiation levels were 0.5 mR/hour at one meter. The gauge was transported back to the company's storage area for further investigation. IEMA determined that the gauge operator was about five feet from the gauge when the truck crossed the barrier and they do not feel a surveillance violation occurred. The gauge was returned to the manufacturer for disposal.

Item Number 120492 - A hospital reported that a patient only received approximately 76% of the prescribed dose from an I-125 brachytherapy seed implant into the right lung. A piece of mesh containing 50 I-125 seeds was implanted into the patient through an invasive procedure on 5/31/2012. The mesh contained five strands of seeds, with 10 seeds per strand, and a total activity of 606.8 MBq (16.4 mCi). The patient was readmitted on 7/4/2012. On 7/7/2012, a chest x-ray found that only 38 of the 50 seeds were visible. Chest and abdomen x-rays were performed on 7/9/2012, which revealed 35 seeds in the chest and three in the abdomen. X-rays on 7/18/2012 revealed 13 seeds in the lung and 17 in the abdomen. On 8/4/2012, there were only six seeds remaining in the lung and eight in the abdomen. Final x-rays taken on 8/8/2012 revealed that no seeds remained in the patient. It is believed that the patient coughed up the loose seeds and swallowed them. A total of nine seeds were recovered during patient hospitalization and placed in the nuclear medicine hot laboratory. The failure of the device was reported to the manufacturer and Food and Drug Administration. This event was classified as an EQP, LAS, and MED event.

Item Number 120499 - A tractor trailer ran over a moisture/density gauge on 8/27/2012 on Interstate 40 near Hazen, Arkansas. The gauge was severely damaged and parts were identified on the side of the interstate. Highway police were notified and asked the Arkansas Highway and Transportation Department (AHTD) for assistance. The AHTD RSO responded to the scene. The base of the gauge was broken to the point that only the threaded cavity and surrounding lead remained. The 1.63 GBq (44 mCi) Am-Be source was still contained within its threaded cavity, while the 0.33 GBq (9 mCi) Cs-137 source remained attached to the source rod and inside its shielding. The shielding was sheared off just above the tungsten sliding block. The AHTD RSO secured the Am-Be source in a polyethylene box and the Cs-137 source was removed from the gauge and placed in a lead shield. Two health physicists from the Arkansas Department of Health (DOH) responded to the scene and performed smear tests; no loose radioactive contamination was identified. The sources were transported to a DOH secure storage area. The gauge manufacturer identified the construction services company that owned the gauge on 8/28/2012. When the gauge user left the jobsite on the evening of 8/27/2012, he failed to secure the gauge in the back of his pickup truck. The gauge fell out of the truck and was struck by at least one vehicle. Upon arrival at his company's facility, the user determined that the gauge was missing and believed that he had left the gauge at the jobsite. On the morning of 8/28/2012, he returned to the jobsite and searched for the gauge, but did not find it. The construction services company's RSO was contacted and retrieved the two sources from DOH. This event was classified as an EQP and LAS event.

Item Number 120573 - A university medical center reported that a funeral home cremated the remains of an individual on 9/20/2012 who had recently received an I-125 lung mesh implant. The implant procedure was performed on 9/13/2012 and involved 40 seeds containing a total activity of 860 MBq (23.24 mCi) of I-125. The crematory closed and the Wisconsin Department of Health Services (WDHS) responded to the site on 9/21/2012. Using a Victoreen 451, radiation surveys inside the crematorium revealed 0.75 mR/hour. The cremated remains of the individual revealed readings of 3.8 mR/hour on contact with a plastic bag. The remains were placed in a concrete container and radiation levels were at background outside the container. No other areas of the facility were identified as radioactively contaminated. The crematory remained closed pending decontamination. WDHS accompanied university personnel to the crematory on 10/17/2012 to assess contamination levels. No seeds remained intact and some of the powder that was inside the seeds remained on the concrete. On 10/23/2012, university personnel performed decontamination efforts and were able to reduce radiation levels to twice background. It was estimated that a fraction of the original I-125 activity was vented to the atmosphere. The crematory was allowed to resume operations on 10/26/2012. This event was caused by inadequate communication between the patient's family and the crematory. No corrective actions were taken. This event was classified as an EQP, LAS, LKS, and RLM event.

Item Number 120591 - A hospital reported that Pd-103 seed cartridges failed to function as designed during a prostate seed implant procedure. The hospital ordered 145 seeds. Pre-implant testing was appropriately performed. While attempting to link the seeds and spacers, the hospital immediately identified jams. They initially believed the link-making device was at fault and obtained a spare, but encountered the same problem. They then discovered that the seed cartridge was defective; the hole on the entrance side of the cartridge was not completely open, thus the link wire could not enter the cartridge to push the seed through. A second cartridge was also identified with the same problem. On a third cartridge, the hospital was able to make a linked needle, but the operation was not smooth. The authorized user decided to change from the seed implanting tool to an applicator. All seeds were transferred to sterilized applicator cartridges and the implant procedure was successfully performed. On 10/3/2012, a meeting was held with the seed manufacturer. Another manufacturer had sent them 500 cartridges, nearly all of which were subsequently found to be missing the hole that allows the seeds to be ejected. Although a quality control check of 10% of the cartridges was documented to have occurred, it was later found that an employee falsified the document. That employee was terminated. It is believed that a pin to make the hole in the cartridge broke off during the manufacturing process. The seed manufacturer notified their customers of the defect.

Item Number 120651 - A personnel overexposure resulted from a 4.033 TBq (109 Ci) Ir-192 radiography source that was not fully retracted. Pipe-weld inspections were being performed at a site near Avella, Pennsylvania, on 8/23/2012. After the 30th exposure, the assistant radiographer did not fully retract the source to the secured position. The retraction mechanism (pistol grip) then fell to the ground from the pipe and allowed the source to travel to an unshielded position. The condition was not discovered when the retraction mechanism was picked up and returned to the pipe. The radiographer failed to observe the assistant radiographer retract the source and also failed to ensure the required radiation surveys were performed to confirm that the source was retracted. The survey meter was in hand, on the correct scale, and in a pegged condition. However, the assistant radiographer was not observing the meter. The radiographer and assistant were suspended from work for dose investigation and completion of remedial training. The radiographer will be audited on occasion in the future to ensure adherence to operating requirements. The assistant received a whole body exposure of 39.2 mSv (3.92 rem) during the incident, with a cumulative seven-month whole body exposure of 50.85 mSv (5.085 rem). The radiographer received a whole body exposure of 14.38 mSv (1.438 rem) during the incident. This event was classified as an EQP and EXP event.

Item Number 120660 - A steel mill reported the loss of a 3.7 GBq (100 mCi) Am-Be source that was missing from a fixed gauge. The source was located inside an insertion tube on a pellet hopper. The

source was discovered to be missing on 10/11/2012 when the insertion tube was found to be broken off. Investigation concluded that the insertion tube fell through the pellet hopper, was transported to the furnace by conveyor, and was consumed in the blast furnace. The source was last seen during an inventory conducted on 6/27/2012. It was assumed that the source migrated into the slag. It was estimated that the activity of the slag was approximately 0.068 MBq (1.845 uCi) per cubic foot. The cause was believed to be a process change. Over time, the insertion tube wear protection plate dislodged and exposed the tube to damage and detachment. Radiation surveys of the hopper and conveyor areas identified no levels above background. Corrective actions included removing their remaining radioactive sources from service. This event was classified as an EQP and LAS event.

### **2.7.3 Events Recently Added to NMED That Occurred Prior to FY12**

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

#### Significant Events

Item Number 120151 - A hospital reported that the exhaust fan connected to an I-131 glovebox was discovered to be inoperable on 8/10/2009. Maintenance was contacted and determined that the fan belt was broken, which was repaired that same day. The hospital stated that up to 35% of the air exhaust containing I-131 vapor was not available for dilution. On 8/28/2009, the hospital noted that the effluent concentration of I-131 was 0.0077 Bq/liter (0.21 pCi/liter), which exceeded the regulatory limit. An investigation revealed that I-131 had been released through the ventilation system. There were minor releases within the laboratory, but the continuous air concentration in the pharmacist's breathing zone remained below regulatory limits. The I-131 glovebox was decontaminated. Radiation surveys of the laboratory revealed three locations of fixed contamination. Those locations were covered with cardboard and allowed to decay to background. All staff bioassays were below detectable limits. This event was classified as an EQP and RLM event.

#### Events of Interest

Item Number 110646 - A manufacturer of clinical agents used in medical imaging procedures reported increased radiation exposure in patients who underwent cardiac positron emission tomography (PET) scans with Rb-82 chloride injections. This event was discovered after two patients triggered radiation detectors when travelling to/from the United States. One of these individuals had been treated on 3/8/2011; subsequent whole body counting revealed a dose of 4.9 cSv (rem). Isotopic analysis indicated the presence of Sr-85 and Sr-82. As a result of further investigations by the U.S. Food and Drug Administration (FDA), the manufacturer voluntarily recalled all of the rubidium generators from the market on 7/25/2011. At that time, there were over 100 users of the generator. FDA, NRC, the Center for Disease Control, the State of Nevada, the State of Florida, and the manufacturer began collecting and analyzing data to determine the extent of condition. A Nevada medical facility reported that three of 204 patients treated between 2/11/2011 and 4/7/2011 were confirmed to have received whole body exposures of 5.54, 5.66, and 5.83 cSv (rem). The FDA determined that the generator manufacturing procedures were not sufficient to reliably prevent strontium breakthrough. In February 2012, the manufacturer returned the generators to the market with FDA-approved revised package labeling, which included enhanced testing information to help minimize the risk for exposure to unintended levels of strontium radiation. In addition, technologists were retrained by the manufacturer and shall adopt updated policies concerning breakthrough testing. An online worksheet was constructed to simplify and monitor the breakthrough recording process. This event was classified as an EQP and MED event.

Item Number 120279 - A calibration facility reported that while attempting to calibrate an intravascular brachytherapy device on 1/18/2011, the Sr-90 source train became stuck in the catheter. The source train was 4 cm long and contained 16 seeds with a total activity of 2.07 GBq (56 mCi). The facility believed

that they could cut the catheter and isolate the source train. While cutting the catheter, they misjudged the location of the source train and severed it. Approximately 10 ml of water spilled onto the table along with the train. Paper towels were used to wipe up the water. A radiation survey was performed to locate the Sr-90 seeds. Calculated leaking activity was less than 0.13 GBq (3.5 mCi). Two members of the Tennessee Division of Radiological Health (TDRH) responded to the site to investigate. TDRH determined that the facility was not licensed to cut the catheter to retrieve the source train. Corrective actions included discontinuing unlicensed activities, terminating employment of involved personnel, and properly disposing of the damaged intravascular brachytherapy system. This event was classified as an EQP, LKS, and RLM event.

Item Number 120582 - A hospital reported that a patient only received 217 cGy (rad) during one HDR unit brachytherapy treatment fraction on 5/13/2011, instead of the intended 340 cGy (rad). The incident resulted in a 36% underdose during the sixth of ten fractions. The HDR unit contained a 312.021 GBq (8.433 Ci) Ir-192 source. The hospital initially believed that the patient only received 130 cGy (rad) during the fraction, which would have been a 62% underdose. During the treatment fraction, the HDR unit experienced a power supply error. Sensing the power variation, the unit automatically withdrew the source and did not complete the treatment for channel 3. Additional attempts were made to clear the error and continue the treatment, but none of the remaining four channels could be completed. The hospital experienced a similar problem during the week of 5/7/2012, which resulted in a service call on 5/10/2012. During that call, the manufacturer adjusted the power supply to within specifications. Following the 5/13/2012 incident, the power supply and main controller were replaced by the manufacturer on 5/19/2012. The patient's remaining fractions were administered.

## 2.8 Transportation

### 2.8.1 Ten-Year Data

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

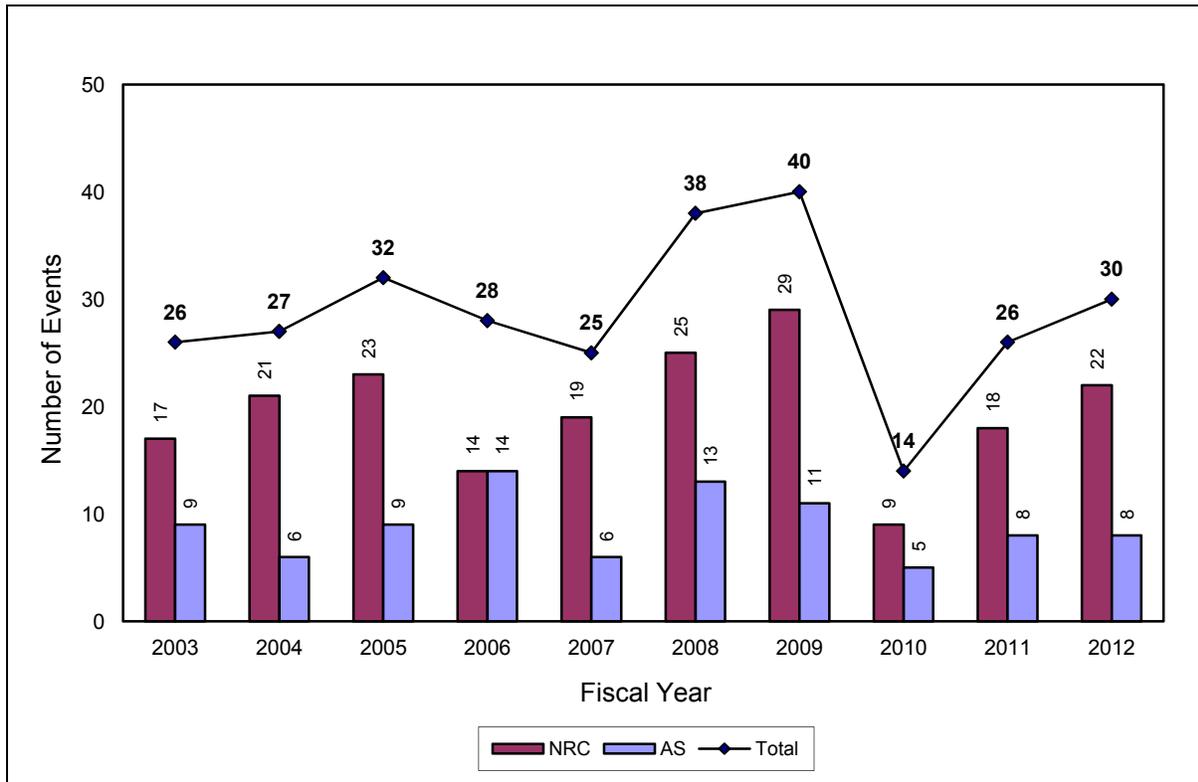


Figure 8. Transportation Events (286 total)

It is not possible to discern the significance of TRS events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

### 2.8.2 FY12 Data

Thirty TRS events occurred in FY12, one of which was considered significant.

#### Significant Events

Item Number 120009 - A radiography services company reported that a 1.184 TBq (32 Ci) Ir-192 radiography source became disconnected from the exposure device drive cable. The incident occurred on 12/22/2011 at facility in Humble, Texas. The radiographer stated that the source separated from the drive cable and that he used a pair of pliers to insert the source back into the exposure device. The radiographer could not disconnect the crank assembly from the exposure device and had to insert the source backwards into the device's guide tube port to shield it. The guide tube port had to then be covered with duct tape to prevent the source from coming out. The device was placed into the truck darkroom between a wall and the device's transport container. The truck was involved in a traffic accident while driving back to the storage location. The accident caused the source to move in the device S-tube towards the drive cable

connection. Radiation levels around the exposure device increased. Levels of 0.04 mSv/hour (40 mrem/hour) were measured outside the truck following the accident by the Harris County fire marshal. The radiographer used the crank assembly to push the source closer to the center of the S-tube. Lead sheets were also used to help decrease radiation levels. At that time, dose rates were between 0.02 and 0.04 mSv/hour (2 and 4 mrem/hour) at one meter. All equipment was returned to the company's storage location. The source was removed from the exposure device and placed into a source changer. The radiographer received 1.8 mSv (180 mrem) during the event, as recorded on his pocket dosimeter. His thermoluminescent dosimeter (TLD) revealed a DDE of 0.75 mSv (75 mrem) for the month of December. The radiographer trainee's pocket dosimeter received 0.55 mSv (55 mrem) and his TLD revealed 2.2 mSv (220 mrem) for the month of December. The company returned the source and exposure device to the manufacturer for inspection. The manufacturer could not recreate the problem but suspected the drive cable failed at a weak point. Corrective actions also included providing additional training to involved personnel. The Texas Department of State Health Services estimated that the radiographer received 2.74 cSv (rem) to the hand when he inserted the source into the exposure device with a wrench. This event was classified as an EQP, OTH, and TRS event.

#### Events of Interest

Item Number 110595 - A medical imaging center received a package from a manufacturer of diagnostic imaging agents that contained a Mo-99/Tc-99m generator with a contact radiation reading of greater than 200 mR/hour. The transport index on the labeling was stated to be 4.2, while the actual transport index upon receipt was 8. Contamination wipes were completed on the outside of the package and results were negative. Contamination wipes on the inside of the package also revealed negative results. The generator was manufactured on 11/8/2011 and delivered to imaging center on 11/9/2011. It was determined that the secondary lead shielding that surrounds the generator was absent. The generator was removed from the packaging and eluted. There was no damage to the generator and the eluted material passed all quality control testing. The cause was determined to be inattention to detail and corrective actions included improving radioactive material labeling and handling.

Item Number 120153 - A nuclear fuel testing facility received a shipment containing 21 Am-Be sources that caused radiation levels in the occupied portion of the transportation vehicle to exceed allowable levels. On 3/1/2012, receipt surveys identified a dose rate of 34 uSv/hr (3.4 mrem/hr) in the vehicle's sleeper compartment, which exceeds the 20 uSv/hr (2 mrem/hr) limit. The private carrier personnel did not have dosimetry. Digital photographs were taken, confirmatory radiation surveys were obtained, and notifications were made. The receipt survey and shipping papers were forwarded to the NRC and the Agreement State Agency for additional review with the shipper and carrier. This event was classified as an FCP, OTH, and TRS event.

Item Number 120324 - A manufacturer of hand-held x-ray fluorescence analyzers reported that the shutter on an analyzer containing a 218.3 MBq (5.9 mCi) Co-57 source was stuck in the open position. An environmental health and safety (EH&S) services company had sent this analyzer to the manufacturer for repair on 5/22/2012. The analyzer shutter remained in the open position even after disengaging the trigger mechanism to close the shutter. The EH&S company had packaged the analyzer for shipment, knowing the shutter was open, with nothing shielding the source. When the manufacturer received the package, radiation readings revealed exposure rates in excess of limits on the outside of the package. Using a Bicon Surveyor 50, radiation levels were 0.3 mR/hour at approximately three feet. Readings at approximately six inches pegged the dose rate meter on the 0 to 0.5 mR/hour scale. The manufacturer placed the analyzer in the source exchange pit and removed the source from the analyzer. They examined the analyzer, determined that the source block was defective, and replaced the source block. Additionally, they generated training to teach their customers the proper response to mechanical failures.

### **2.8.3 Events Recently Added to NMED That Occurred Prior to FY12**

Eleven TRS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note

that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events

None.

Events of Interest

None.

## 2.9 Fuel Cycle Process

### 2.9.1 Ten-Year Data

Figure 9 displays the annual number and trend of FCP events that occurred during the 10-year period. This figure differs from those in previous sections of this report because FCP events are only associated with NRC-regulated facilities (not Agreement State-regulated). Additionally, unlike the other event types, NMED incorporates a dual use of the FCP event type; one use (Unique FCP) is for events unique to the fuel cycle process (such as a degradation of criticality controls), while the other use (Other FCP) is for any event occurring at a fuel cycle process facility (such as a lost calibration source).

The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data.

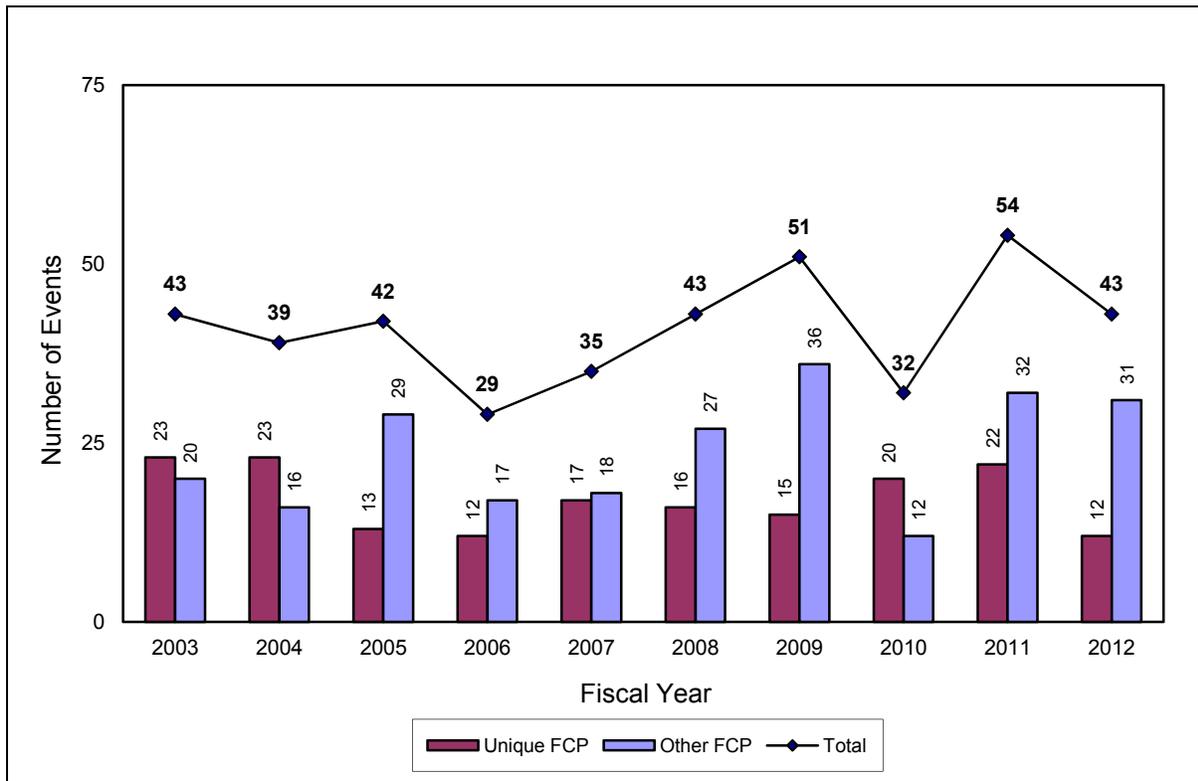


Figure 9. Fuel Cycle Process Events (411 total)

Starting with this FY12 report, the dual use methodology was expanded such that TRS events involving fuel cycle process facilities are now also coded as FCP events. Thus, a comparison of Figure 9 with previous fiscal year reports will show an increase in the number of FCP events.

The remainder of this section will limit discussion to only those Unique FCP events (173 events).

The significance of individual FCP events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 24-hour reporting requirement. For this report, those events requiring immediate reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

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

Table 8. Unique FCP Events Classified by CFR Reporting Requirement

	Fiscal Year										Total
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	
<b>Immediate</b>	1	5	3	3	5	3	3	1	1	2	<b>27</b>
<b>24-Hour</b>	22	18	10	9	12	13	12	19	21	10	<b>146</b>
<b>Total</b>	<b>23</b>	<b>23</b>	<b>13</b>	<b>12</b>	<b>17</b>	<b>16</b>	<b>15</b>	<b>20</b>	<b>22</b>	<b>12</b>	<b>173</b>

## 2.9.2 FY12 Data

Twelve Unique FCP events occurred in FY12, two of which were considered significant.

### Significant Events - Immediate Reports

Item Number 120217 - During an NRC inspection beginning on 3/5/2012 at a nuclear fuel manufacturing facility, an event involving the loss of double contingency for the gadolinia press rotary valve was identified. While reassembling the rotary valve after a routine cleanout on 2/13/2012, the valve did not seat properly, which went unnoticed. This error resulted in an open pathway for powder from the feed hood to enter the feed tube. The operator loaded three cans of material (approximately 43 kg) to the feed hopper to ensure proper valve installation. A high-high level sensor activated because the material in the feed tube exceeded the criticality mass limit of 36 kg, indicating a loss of mass control. Due to the short duration of this event, it had low safety significance. This event was caused by inadequate worker oversight practices and procedures. Corrective actions included personnel training, procedure modification, and fabricating a gauge to ensure proper valve assembly.

Item Number 120471 - A nuclear fuel manufacturer reported that only one Item Relied On For Safety (IROFS) remained in place to prevent a potential criticality event in the ceramics area of the facility on 8/17/2012. The IROFS Fuel Business System Control of Mass of Uranium Transportable Container failed due to an overweight pellet boat detected at the grinder feed area. The pellet boat weighed 15.83 kg net, exceeding the mass limit of 15 kg. The pellets were removed from the overweight boat and placed into an approved container, restoring the IROFS. Other pellet boats in the area were checked and found to be acceptable. A root cause investigation determined that this event was caused either by a scale measurement error or by the addition of pellets after weight verification. A stand down was held with all affected fuel production employees to re-enforce the proper weighing of containers. Additional corrective actions included procedure and process modification.

### Events of Interest

Item Number 110550 - A gaseous diffusion plant reported discovering two cracks in a uranium hexafluoride (UF<sub>6</sub>) side accumulator vessel on 10/26/2011. The one-of-a-kind vessel provides storage for up to 20,000 pounds of liquid UF<sub>6</sub> during the product withdrawal process. The cracks in the vessel allowed a small release of material, which caused the process gas leak detection system to alarm on 10/21/2011. Investigation revealed that the base metal contained stress defects that allowed multiple cracks to form, with some of the cracks penetrating through the outer wall. The cracks were a result of fabrication deficiencies. The vessel was repaired by cutting out the defective area and replacing it. This event was classified as an EQP and FCP event.

Item Number 110629 - A gaseous diffusion plant reported a localized loss of criticality control on 11/28/2011. During an annual inspection of floor drains and sumps, an eye wash drain was identified as no longer properly sealed from preventing solutions from entering the drain. The concrete base

surrounding the drain was discovered broken loose from the floor and could no longer provide a seal to prevent spilled uranium solution from getting into the drain system (an unfavorable geometry). Two independent controls remained, so double contingency was maintained. Fissile solution operations in the vicinity of the eye wash drain were stopped. The plant restored the seal and resumed fissile solution operations.

Item Number 120585 - A nuclear fuel manufacturer reported that certain loss of containment accident sequences resulting in ocular exposure to uranyl nitrate solution had been wrongly determined to be low consequence events. Further review determined that the accident sequences had the potential for creating ocular exposures that could lead to intermediate consequences. Two other types of chemical exposures (dermal contact and inhalation of liquid aerosols) originally documented as low consequence events also required re-evaluation. This issue was identified on 9/28/2012 while completing integrated safety analysis (ISA) meetings on a new process. Actions in progress include verifying that appropriate spray shields/deflectors are in place, verifying that existing safety protocols are adequate, and modifying the safety analysis and implementing documents to declare appropriate personal protective equipment and safety protocols as IROFS. This is an industry-wide issue stemming from a lack of clear regulatory guidance. The manufacturer will continue to work with the Nuclear Energy Institute and other fuel cycle facilities in an effort to establish quantitative standards for dermal and ocular exposures to hazardous chemicals.

### **2.9.3 Events Recently Added to NMED That Occurred Prior to FY12**

In this section, it is not practical to list all of the additional events that resulted from adding the FCP classification to TRS events involving fuel cycle facilities. Disregarding those events, no Unique FCP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Note that this data may differ from the associated Appendix D graph, which displays the number of events (all FCP events, not just Unique FCP events) added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

#### Significant Events

None.

#### Events of Interest

None.

## 2.10 Other

### 2.10.1 Ten-Year Data

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

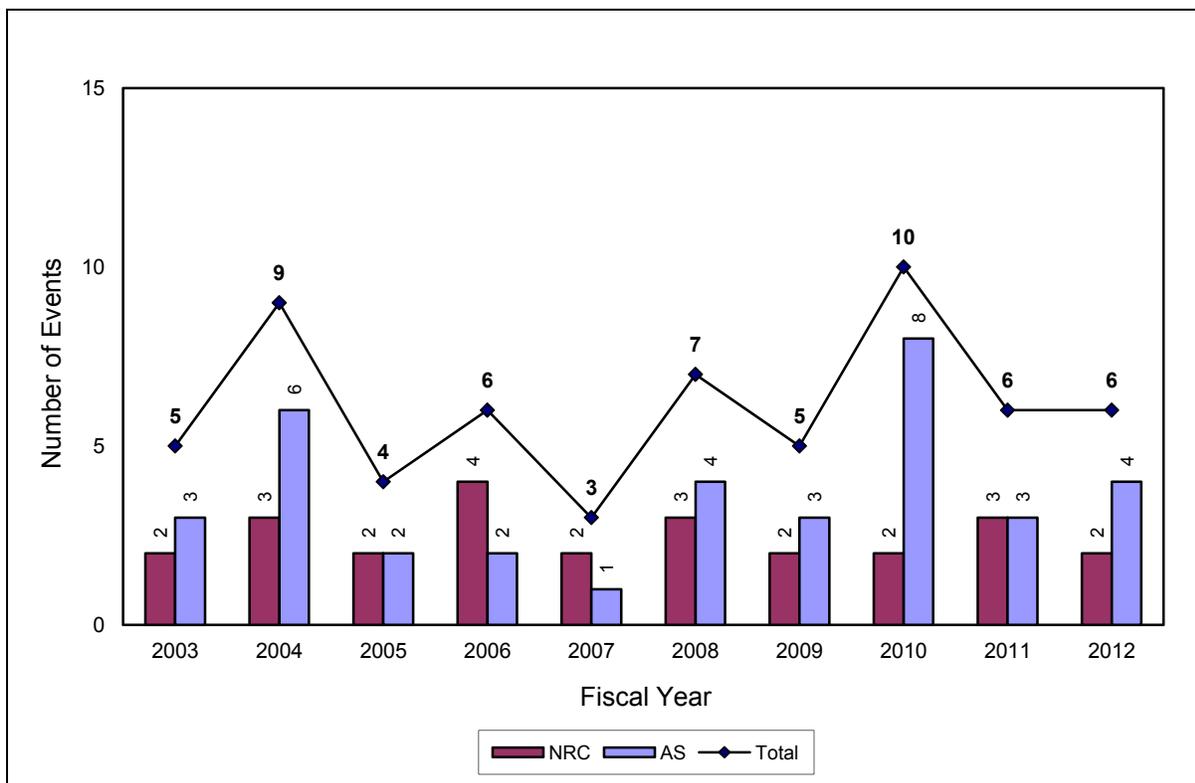


Figure 10. Other Events (61 total)

It is not possible to discern the significance of OTH events strictly from the CFR reporting requirements (as in Sections 2.4, 2.5, and 2.9). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

### 2.10.2 FY12 Data

Six OTH events occurred in FY12, two of which were considered significant.

#### Significant Events

Item Number 110566 - A pregnant patient received 2.73 GBq (73.7 mCi) of I-131 for thyroid therapy treatment on 10/6/2011. The patient had taken a pregnancy test on 10/5/2011 and results were negative. The patient discovered she was pregnant and contacted the hospital on 10/26/2011. It was determined that the embryo/fetus was 10 days old at the time of treatment. The estimated dose to the embryo/fetus is 17.4 cSv (rem). The State of Pennsylvania performed a reactive inspection to review hospital procedures and investigate the event. No corrective actions were required beyond current practices. This event was classified as a potential AO.

Item Number 120009 - A radiography services company reported that a 1.184 TBq (32 Ci) Ir-192 radiography source became disconnected from the exposure device drive cable. The incident occurred on

12/22/2011 at facility in Humble, Texas. The radiographer stated that the source separated from the drive cable and that he used a pair of pliers to insert the source back into the exposure device. The radiographer could not disconnect the crank assembly from the exposure device and had to insert the source backwards into the device's guide tube port to shield it. The guide tube port had to then be covered with duct tape to prevent the source from coming out. The device was placed into the truck darkroom between a wall and the device's transport container. The truck was involved in a traffic accident while driving back to the storage location. The accident caused the source to move in the device S-tube towards the drive cable connection. Radiation levels around the exposure device increased. Levels of 0.04 mSv/hour (40 mrem/hour) were measured outside the truck following the accident by the Harris County fire marshal. The radiographer used the crank assembly to push the source closer to the center of the S-tube. Lead sheets were also used to help decrease radiation levels. At that time, dose rates were between 0.02 and 0.04 mSv/hour (2 and 4 mrem/hour) at one meter. All equipment was returned to the company's storage location. The source was removed from the exposure device and placed into a source changer. The radiographer received 1.8 mSv (180 mrem) during the event, as recorded on his pocket dosimeter. His thermoluminescent dosimeter (TLD) revealed a DDE of 0.75 mSv (75 mrem) for the month of December. The radiographer trainee's pocket dosimeter received 0.55 mSv (55 mrem) and his TLD revealed 2.2 mSv (220 mrem) for the month of December. The company returned the source and exposure device to the manufacturer for inspection. The manufacturer could not recreate the problem but suspected the drive cable failed at a weak point. Corrective actions also included providing additional training to involved personnel. The Texas Department of State Health Services estimated that the radiographer received 2.74 cSv (rem) to the hand when he inserted the source into the exposure device with a wrench. This event was classified as an EQP, OTH, and TRS event.

#### Events of Interest

Item Number 120153 - A nuclear fuel testing facility received a shipment containing 21 Am-Be sources that caused radiation levels in the occupied portion of the transportation vehicle to exceed allowable levels. On 3/1/2012, receipt surveys identified a dose rate of 34 uSv/hr (3.4 mrem/hr) in the vehicle's sleeper compartment, which exceeded the 20 uSv/hr (2 mrem/hr) limit. The private carrier personnel did not have dosimetry. Digital photographs were taken, confirmatory radiation surveys were obtained, and notifications were made. The receipt survey and shipping papers were forwarded to the NRC and the Agreement State Agency for additional review with the shipper and carrier. This event was classified as an FCP, OTH, and TRS event.

Item Number 120315 - A commercial electrical power plant (non-nuclear) reported a potential radiation overexposure to two contract workers who removed six fixed nuclear gauges from their mounted locations on 3/23/2012. During boiler repairs, the contract workers removed the gauges from an ash hopper without authorization. The gauges were discovered the following day by plant personnel and it was noted that the shutters were in the open position. Each gauge contained a 3.7 GBq (100 mCi) Cs-137 source. Exposure rates were approximately 3.4 mSv/hour (340 mrem/hour) at one foot. The RSO secured the gauges and began an investigation. Based on dose reconstruction, the two contract workers received approximately 0.02 and 0.06 mSv (2 and 6 mrem). The root cause of the incident was determined to be failure of the contractor's supervisor approved work plan. Corrective actions included more visible signage, additional procedures, and additional training for contractors.

Item Number 120374 - During an NRC inspection of an in situ recovery uranium mine conducted between 4/16/2012 and 4/18/2012, unrestricted areas were identified where dose rates were 0.03 mSv/hr (3 mrem/hr), exceeding the 0.02 mSv/hr (2 mrem/hr) limit. The company had not been surveying these areas due to misunderstanding the regulations. A fence was installed and the areas were posted as restricted areas. The NRC inspection also identified areas that should have been posted as radiation areas. The dose rate in these areas was as high as 0.08 mSv/hr (8 mrem/hr) at 30 cm from the applicable surface. The company determined that radiation levels in these areas fluctuate due to changes in the concentration

of radon daughters. The survey frequency was increased from monthly to weekly and these areas were posted as radiation areas.

### **2.10.3 Events Recently Added to NMED That Occurred Prior to FY12**

No OTH events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

#### Significant Events

None.

#### Events of Interest

None.



# **Appendix A**

## **Event Type Descriptions and Criteria**



## Appendix A Event Type Descriptions and Criteria

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

### Lost/Abandoned/Stolen Material (LAS)

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

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

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

Table A-1. Primary LAS Reporting Requirements

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

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

Table A-2. Secondary LAS Reporting Requirements

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

## Medical (MED)

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

Table A-3. MED Reporting Requirements

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

Events are not considered MED events if they involve:

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

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

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

## Radiation Overexposure (EXP)

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

Table A-4. EXP Reporting Requirements

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

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

EXP limits do not apply to patients receiving medical procedures.

## Release of Licensed Material or Contamination (RLM)

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

Table A-5. RLM Reporting Requirements

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

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

## Leaking Sealed Source (LKS)

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

Table A-6. LKS Reporting Requirements

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

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

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

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

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

## Equipment (EQP)

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

Table A-7. EQP Reporting Requirements

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

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

### Transportation (TRS)

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

Table A-8. TRS Reporting Requirements

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

### Fuel Cycle Process

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

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

Table A-9. FCP Reporting Requirements

FCP Reporting Requirements	Reporting Requirement Summary
70.52(a)	Inadvertent nuclear criticality.
70.App A(a)(1)	Inadvertent nuclear criticality.
70.App A(a)(2)	Acute intake by an individual of 30 mg or greater of uranium in a soluble form.
70.App A(a)(3)	Acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in 70.61(b)(4).
70.App A(a)(4)(i)	Event or condition such that no IROFSs remain available and reliable to perform the safety function IAW 70.61(b) and 70.61(c).
70.App A(a)(4)(ii)	Event or condition such that no IROFSs remain available and reliable to prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).
70.App A(a)(5)	Loss of controls such that only one IROFS has been available and reliable (for longer than the past eight hours) to prevent a nuclear criticality accident.
70.App A(b)(1)	Event or condition that results in the facility being in a state not analyzed, improperly analyzed, or different from that analyzed, and results in failure to meet the performance requirements of 70.61.
70.App A(b)(2)	Loss or degradation of IROFSs that results in failure to meet the performance requirement of 70.61.
70.App A(b)(3)	Acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of 70.61(c)(4).
70.App A(b)(4)	Natural phenomenon or external event, including fires internal and external to the facility, that affected or may have affected the safety function, availability, or reliability of one or more IROFSs.
70.App A(b)(5)(i)	Occurrence of an event or process deviation that was considered in the ISA and was dismissed due to its likelihood.
70.App A(b)(5)(ii)	Occurrence of an event or process deviation that was considered in the ISA, categorized as unlikely, and whose associated unmitigated consequences would have exceeded those in 70.61(b) had the IROFSs not performed their safety function(s).
72.74(a)	Accidental criticality or any loss of special nuclear material.
76.120(a)(1)	Criticality event.
76.120(a)(4)	Emergency condition that has been declared an alert or site area emergency.

<p>NRCB 91-01</p> <p>Immediate reports: NRCB 91-01 – A</p> <p>24 hour reports: NRCB 91-01 – B</p>	<p>The loss of criticality safety controls where (1) moderation is used as the primary criticality control, or (2) more than a safe mass of fissionable material is involved (regardless of the type of controls used to satisfy the double contingency principle), and that meet one or more of the following immediate reporting criteria:</p> <ol style="list-style-type: none"> <li>1. Any event that results in the violation of the double contingency principle, as defined in ANSI 8.1, and where the double contingency principle cannot be re-established within 4 hours after the initial observation of the event.</li> <li>2. The occurrence of any unanticipated or unanalyzed event for which the safety significance of the event or corrective actions to re-establish the double contingency principle are not readily identifiable.</li> <li>3. Any case where it is determined that a criticality safety analysis was deficient and where the necessary controlled parameters were not established or maintained.</li> <li>4. Any event involving a controlled parameter previously identified by the NRC or the licensee as requiring immediate reporting to the NRC and where the double contingency principle cannot be re-established within 4 hours after the initial observation of the event.</li> </ol> <p>All other criticality safety events that do not meet the aforementioned criteria, but still result in a violation of the double contingency principle, such as events where the double contingency principle is violated but control is immediately re-established, should be reported to the NRC within 24 hours in accordance with the commitments in the responses to the bulletin.</p>
<p>S.E.A</p>	<p>Safety equipment actuation.</p>

### Other (OTH)

The OTH event category includes the following types of events:

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

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

Table A-10. OTH Reporting Requirements

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



# **Appendix B**

## **Statistical Trending Methodology**



## Appendix B Statistical Trending Methodology

### General

The following is a general discussion of statistical trending techniques.

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

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

### Fitting a Straight Line to Data

Consider a linear function

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

where  $\alpha$  and  $\beta$  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,  $\sigma^2$ . 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,  $\sigma^2$ .

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  $\alpha$  and  $\beta$  is the method of least squares (LS). In this method,  $\alpha$  and  $\beta$  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  $\sigma$  is

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

### Testing for Trend

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

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

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

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

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

One can show by algebra that

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

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

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

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

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

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

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

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

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

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

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

can be shown to have an  $F$  distribution with degrees of freedom 1 and  $n - 2$ , where  $n$  is the number of data points. When the data satisfy the assumptions except that there is a significant trend,  $r^2$  will be closer to 1 and the computed  $F$  statistic will be much larger. Specifically, if the computed  $F$  exceeds the upper fifth percentile of the  $F$  distribution with 1 and  $n - 2$  degrees of freedom, we infer that the data contain evidence that  $\beta$  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 95<sup>th</sup> percentile of the  $F(1, 11)$  distribution is 4.84. Since 163.3 far exceeds the upper 95<sup>th</sup>  $F$  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 95<sup>th</sup> percentile, the trend line was shown on the graph and identified as being statistically significant.

In future reports, methods slightly different than that explained above could be employed because the NMED data in many cases does not follow the assumptions listed above. In particular, three considerations apply.

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

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

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

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

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

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

# **Appendix C**

## **IAEA Radionuclide Categorization**



## Appendix C

### IAEA Radionuclide Categorization

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

- Category 1: Extremely dangerous.** These sources could cause permanent injury within a few minutes if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from a few minutes to an hour.
  
- Category 2: Very dangerous.** These sources could cause permanent injury within minutes to hours if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from hours to days.
  
- Category 3: Dangerous.** These sources could cause permanent injury within hours if handled. Doses could possibly (but unlikely) be fatal to someone in close proximity to an unshielded source for periods ranging from days to weeks.
  
- Category 4: Unlikely to be dangerous.** These sources would not cause permanent injury, although delayed health effects are possible. Doses could possibly (but unlikely) cause temporary injury to someone in close proximity to an unshielded source for a period of many weeks.
  
- Category 5: Most unlikely to be dangerous.** These sources would not cause permanent injury.

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

Radionuclide	Category 1		Category 2		Category 3		Category 4		Category 5	
	TBq	Ci <sup>1</sup>								
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. This activity can result in additions or subtractions to data that was published in previous issues of this report. 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 type
- Changes between fiscal years due to event date changes on individual events
- Record additions or subtractions due to changes in event reportability
- 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-10 below display the changes in the data published in the previous quarterly report. A positive value indicates that records were added and a negative value indicates that records were removed. Note that Figures D-1 and D-9 do not include all of the additional FCP events that resulted from adding the FCP classification to TRS events involving fuel cycle facilities.

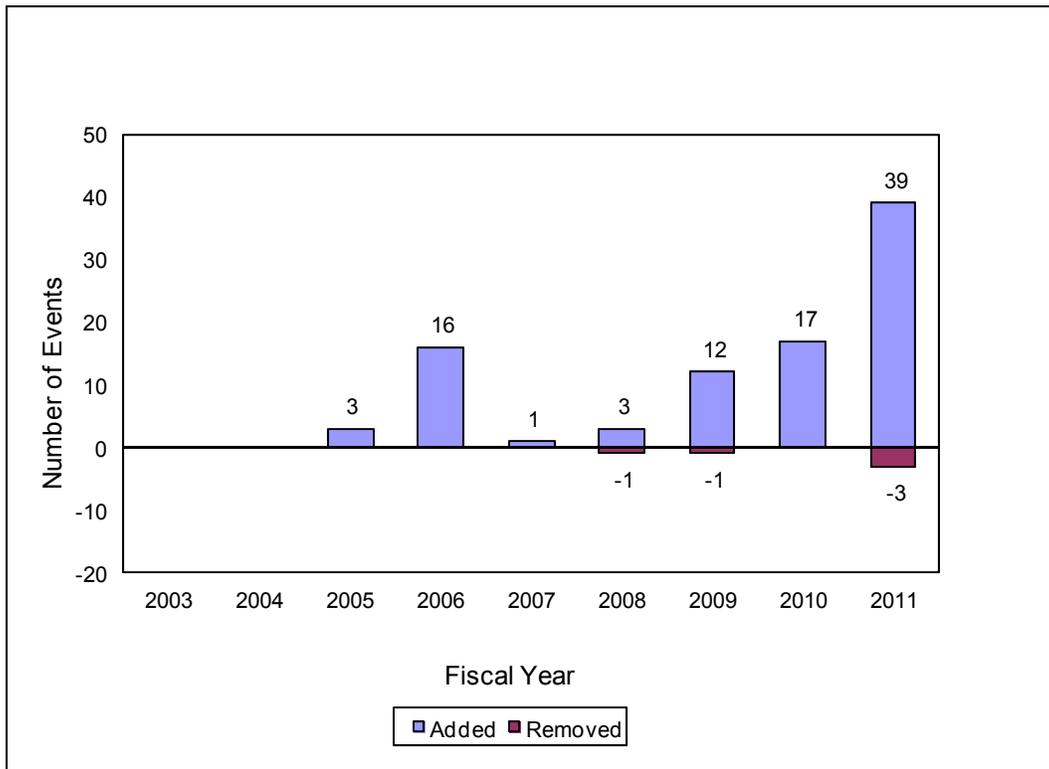


Figure D-1. Changes to All NMED Event Data

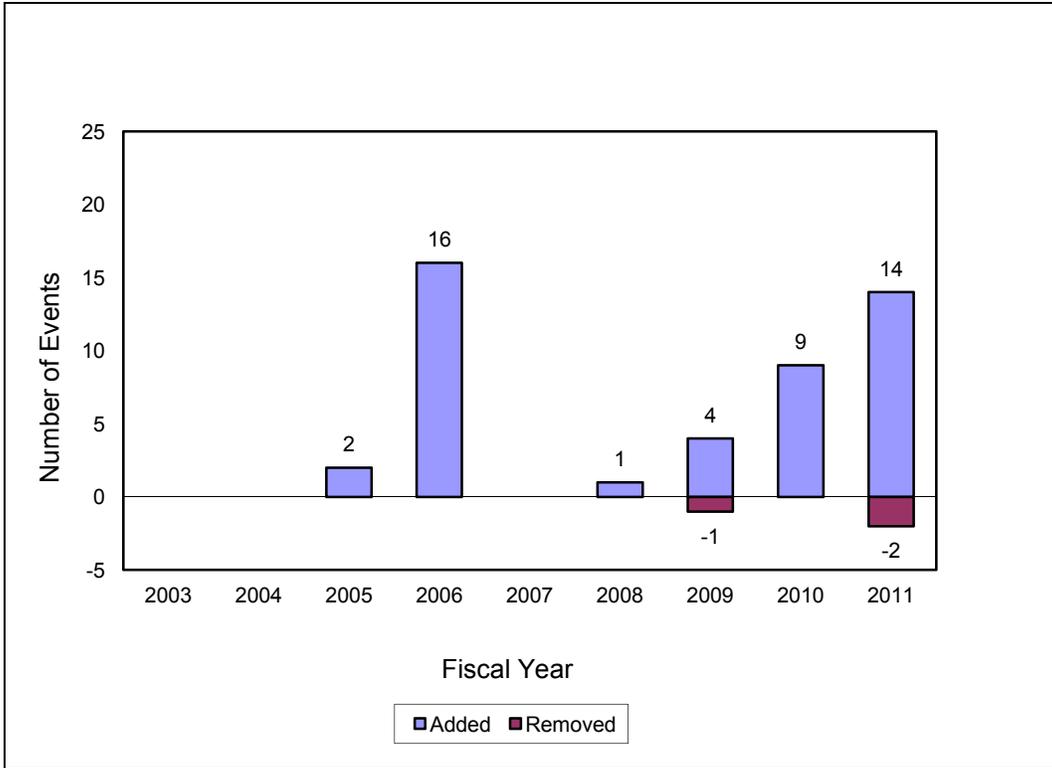


Figure D-2. Changes to LAS Data

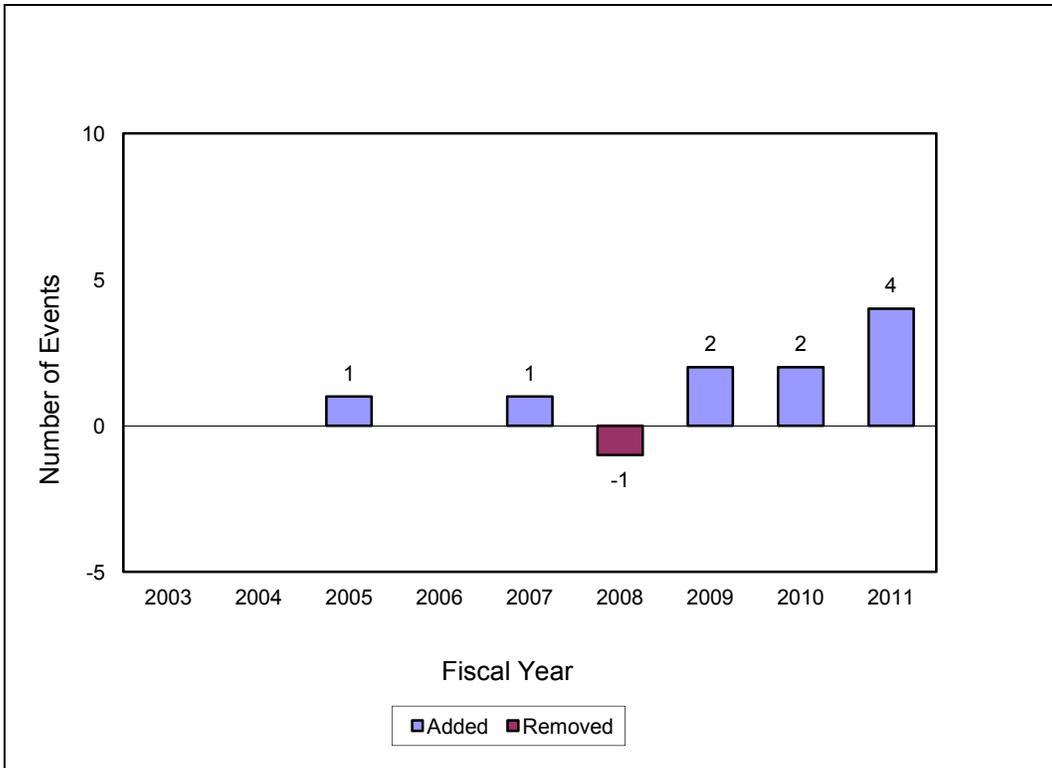


Figure D-3. Changes to MED Data

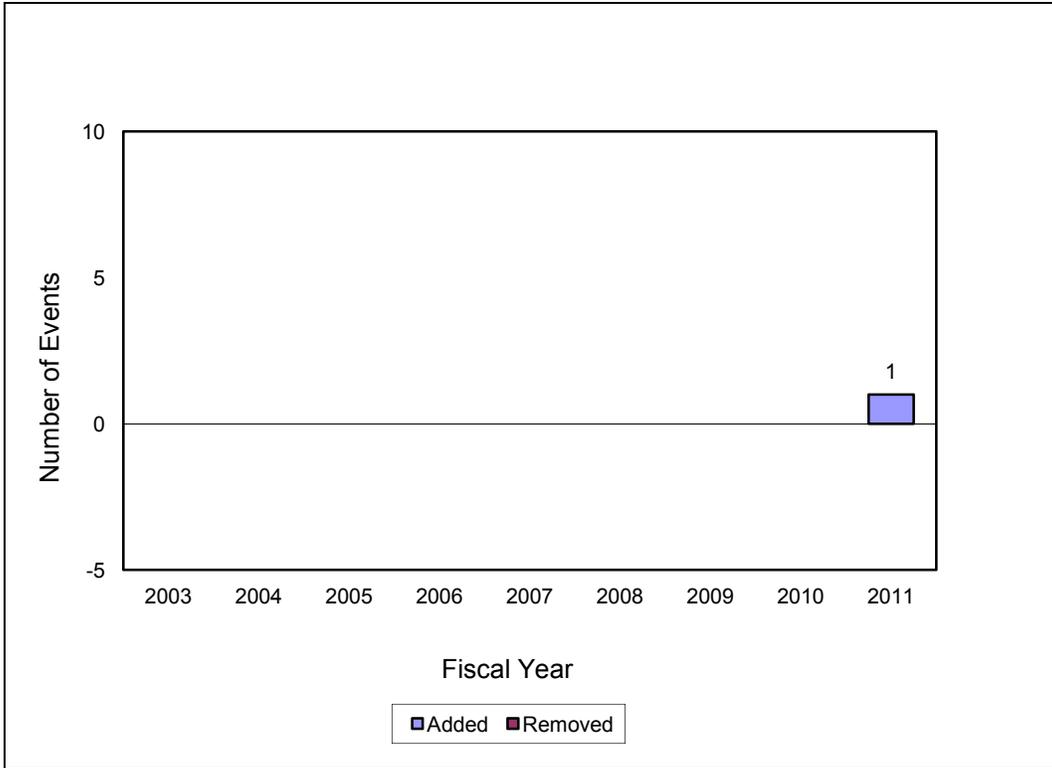


Figure D-4. Changes to EXP Data

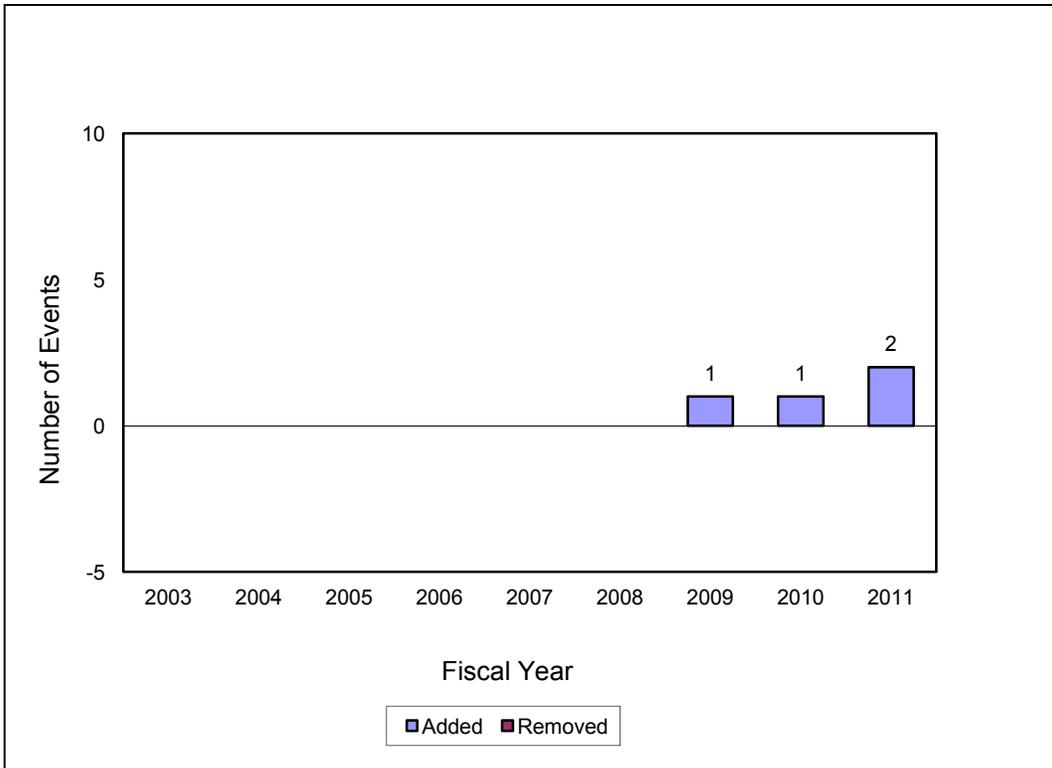


Figure D-5. Changes to RLM Data

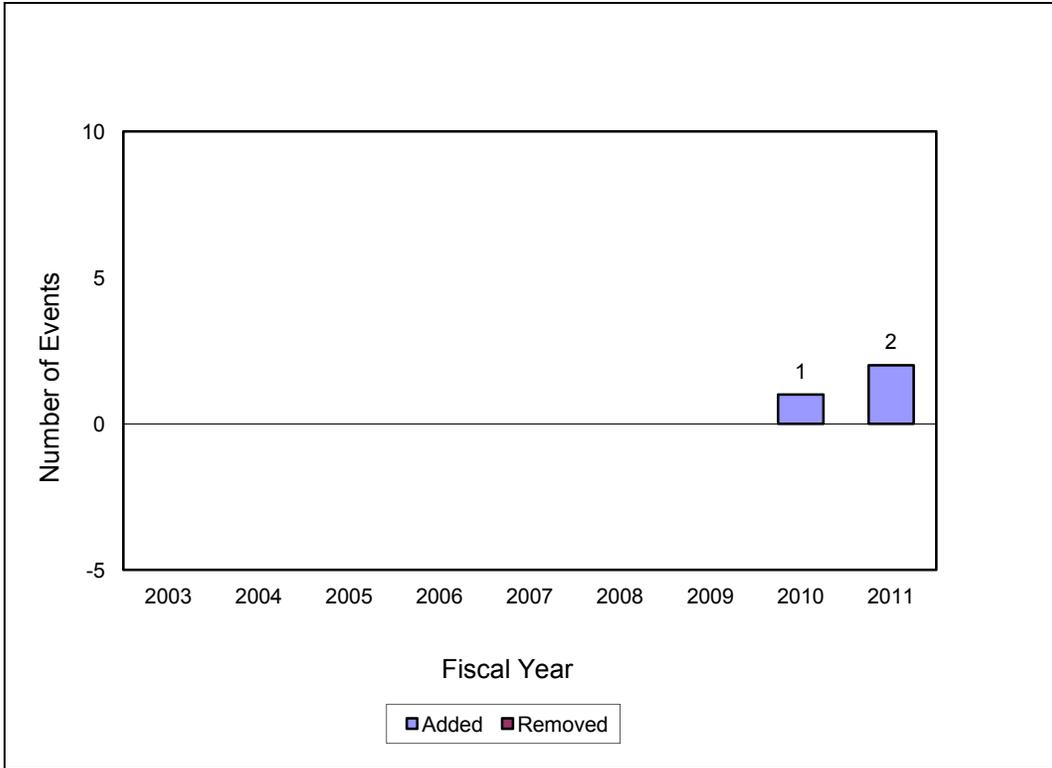


Figure D-6. Changes to LKS Data

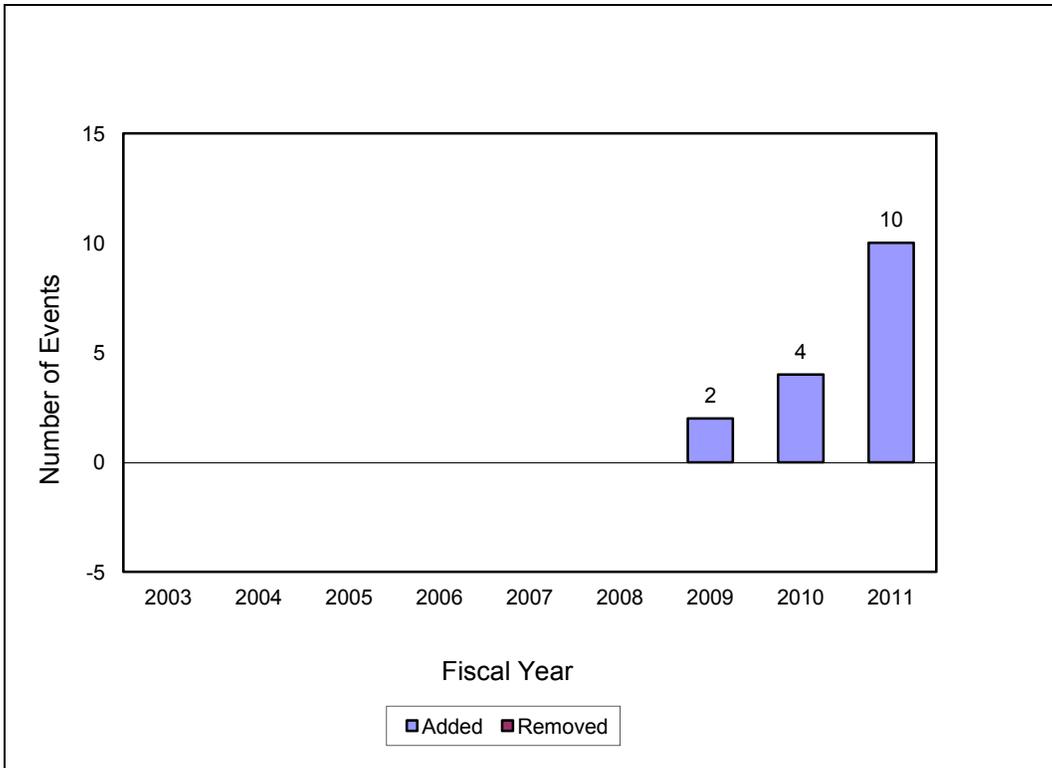


Figure D-7. Changes to EQP Data

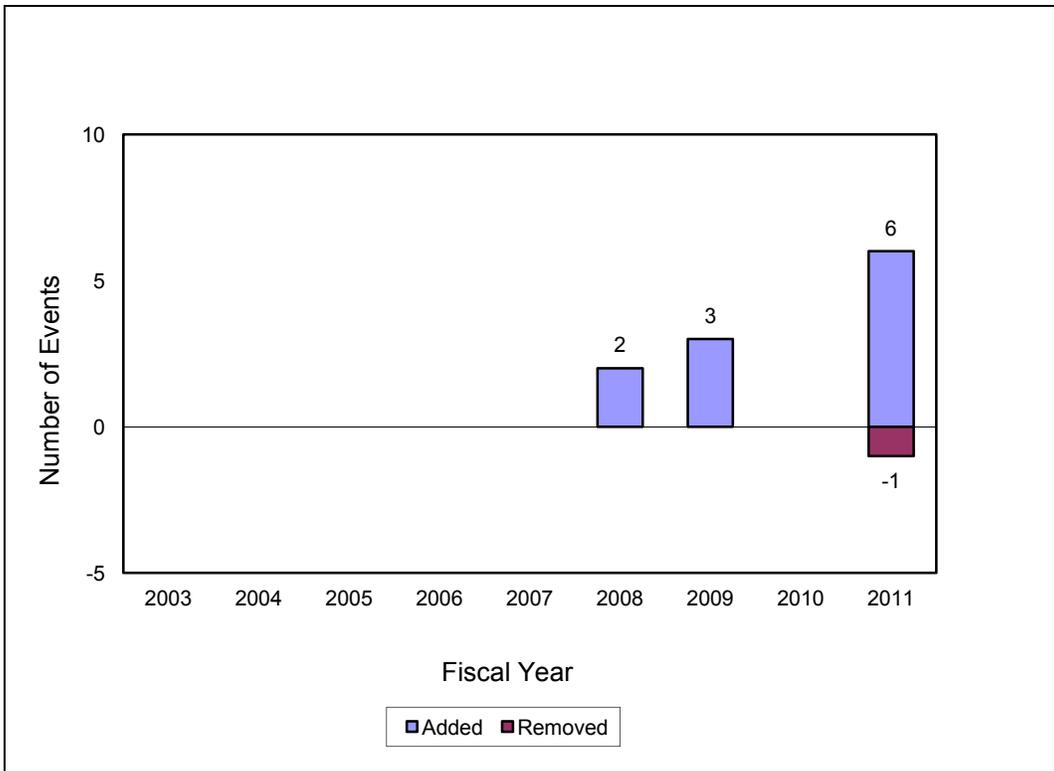


Figure D-8. Changes to TRS Data

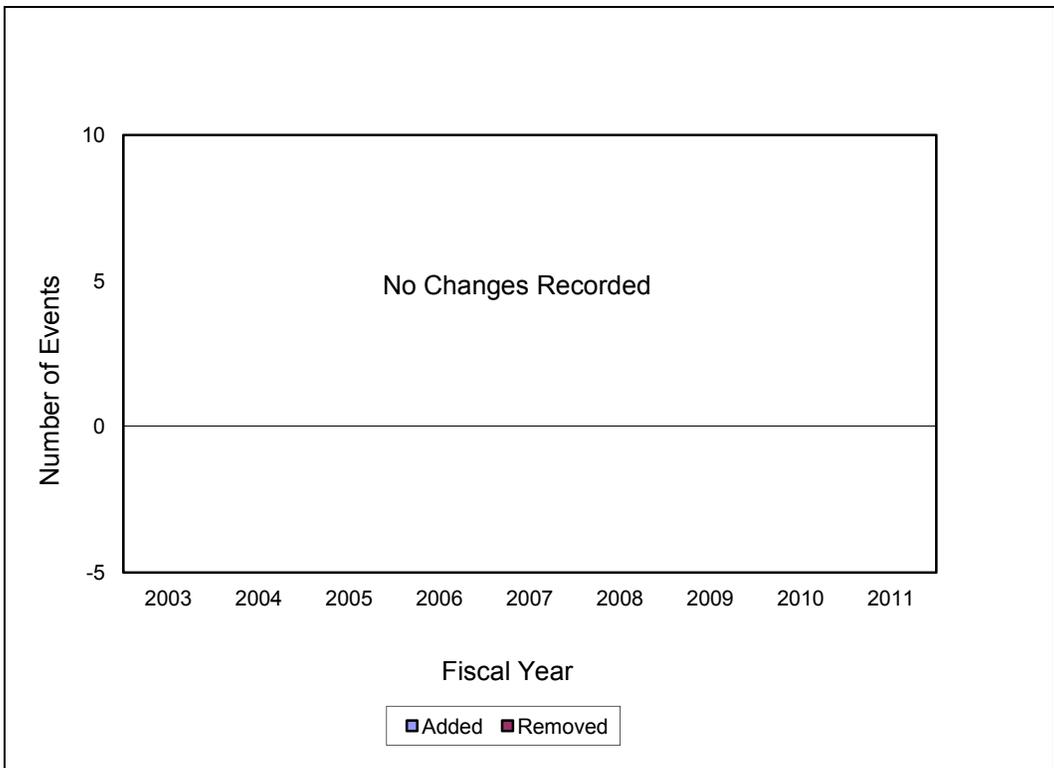


Figure D-9. Changes to FCP Data

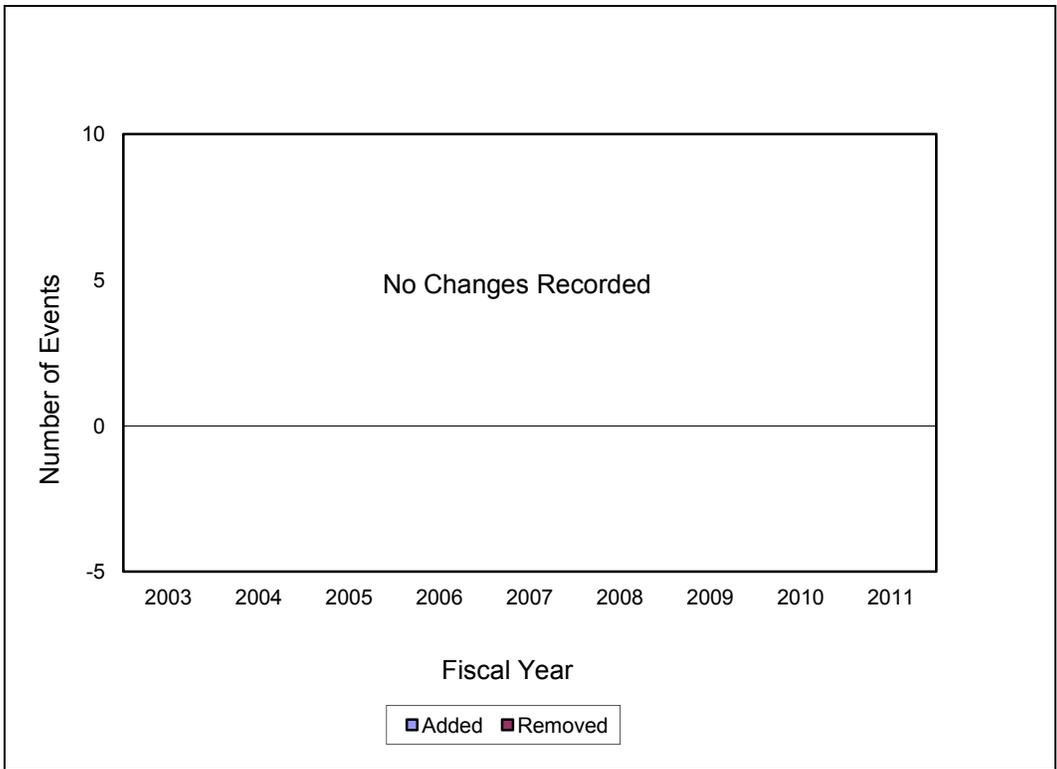


Figure D-10. Changes to OTH Data

## **SUMMARY OF LEVEL I AND II ENFORCEMENT ACTIONS FOR CALENDAR YEAR 2012**

**No Severity Level (SL) I violations were issued in calendar year (CY) 2012**

**Avera McKennan Hospital  
Sioux Falls, SD  
EA-12-090  
Docket No. 030-11252**

**Severity Level II**

On October 3, 2012, a Notice of Violation and Proposed Imposition of a Civil Penalty in the amount of \$11,200 was issued to Avera McKennan Hospital for a SL II violation involving the failure to maintain written procedures to provide high confidence that each treatment is in accordance with the physician's written directive as required by 10 CFR 35.41. Specifically, on January 16 and 17, 2012, procedures related to high dose-rate remote afterloader treatments failed to 1) verify a brachytherapy treatment was in accordance with the treatment plan and written directive as required by 10 CFR 35.41(b)(2); 2) check both manual and computer-generated dose calculations as required by 10 CFR 35.41(b)(3); and (3) verify that any computer-generated dose calculations were correctly transferred into the consoles of therapeutic medical units as required by 10 CFR 35.41(b)(4). This violation was a repeat violation resulting in radiation underexposures to the intended treatment site and exposures to an unintended site on two consecutive days. As a result of the licensee's particular poor performance, the NRC used enforcement discretion in accordance with Section 3.6 of the Enforcement Policy to double the base civil penalty for a SLII violation.

ENCLOSURE 2