February 2012

Nuclear Material Events Database

Annual Report

Fiscal Year 2011

Prepared for the U.S. Nuclear Regulatory Commission
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ENCLOSURE 1

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ABSTRACT

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

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ACRONYMS

ALARA	as low as reasonably achievable
ALI	annual limit on intake
AO	abnormal occurrence
ARF	Ammonia Recovery Facility
CAA	Controlled Access Area
CAAS	Criticality Accident Alarm System
CEDE	committed effective dose equivalent
CFR	Code Of Federal Regulations
COC	Certificate of Compliance
CT	computed tomography
DDE	deep dose equivalent
DE	dose equivalent
ECD	electron capture detector
EDE	effective dose equivalent
EQP	Equipment
EXP	Radiation Overexposure
FCP	Fuel Cycle Process
FY	fiscal year
GTCC	greater than class C
HEPA	high-efficiency particulate air
HLW	high-level waste
IAEA	International Atomic Energy Agency
IAW	in accordance with
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
NA	not applicable
NCR	non-conformance report
NMED	Nuclear Material Events Database

NR	not recovered
NRC	Nuclear Regulatory Commission
OTH	Other
PCTCD	Payload Container Transportation Certification Document
RLM	Release of Licensed Material or Contamination
SAR	safety analysis report
SDE	shallow dose equivalent
SNM	special nuclear material
SSE	error sum of squares
SSR	regression sum of squares
SST	total sum of squares
TEDE	total effective dose equivalent
TRS	Transportation
USDOT	US Department of Transportation
WDOH	Wisconsin Department of Health
WIPP	Waste Isolation Pilot Plant

EXECUTIVE SUMMARY

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

The significant events that occurred in Fiscal Year 2011 are summarized below. Note that a single event may be listed in more than one event type category.

Lost/Abandoned/Stolen Radioactive Sources/Material

Six significant events occurred involving the loss of Category 1-3 sources as defined by the *International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. No Category 1 sources, two Category 2 sources, and four Category 3 sources were lost, all of which were subsequently recovered, with the exception of one Category 2 source. The unrecovered Category 2 source was contained in a radiography exposure device that was stolen. The other events involved two radiography sources and a brachytherapy source lost during shipment, a nuclear cardiac pacemaker recovered from an individual's home, and the loss of control of a brachytherapy source.

Medical Events

Fourteen significant events occurred, all of which were classified as potential Abnormal Occurrences. Five of the events involved doses to the wrong site during high dose rate brachytherapy (one of the events involved two patients). Five events involved overdoses or doses to the wrong site during Y-90 microsphere treatments. Three events involved the incorrect placement of prostate brachytherapy seeds. The remaining event involved an I-131 administration to the wrong patient.

Two significant events classified as potential Abnormal Occurrences occurred prior to FY11 that were recently added to NMED. The first event involved the administration of too much P-32 to two patients. The other event involved incorrect prostate brachytherapy doses to three patients.

Radiation Overexposure Events

One significant event occurred. A radiography trainee received an exposure to his right hand with observable deterministic effects (blistering) corresponding to an exposure range of 20 to 30 Gy (2,000 to 3,000 rad).

Release of Licensed Material or Contamination Events

No significant events occurred.

One significant event occurred prior to FY11 that was recently added to NMED. This event involved the contamination of a student and surrounding area during an experiment performed in a university laboratory.

Leaking Sealed Source Events

No significant events occurred.

Equipment Failure Events

No significant events occurred.

A significant event occurred prior to FY11 that was recently added to NMED. This event involved the malfunction of a gamma knife unit that resulted in a medical event (patient underdose).

Transportation Events

No significant events occurred.

Fuel Cycle Process Events

Six significant events occurred, all of which involved problems maintaining double contingency criticality controls. Four of the events occurred at a gaseous diffusion plant and two at a nuclear fuel manufacturer.

Other Events

One significant event occurred, which was also classified as a potential Abnormal Occurrence. This event involved a fetal dose resulting from a treatment administered to a pregnant patient.

A significant event classified as a potential Abnormal Occurrence occurred prior to FY11 that was recently added to NMED. This event also involved a fetal dose resulting from a treatment administered to a pregnant patient.

Nuclear Material Events Database Annual Report: Fiscal Year 2011

1. INTRODUCTION

1.1 Overview and Objectives

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

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

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

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

Note that events involving irretrievable well logging sources abandoned in accordance with 10 CFR Part 39.77 were excluded from previous annual reports, but are included in this report. A description of categories addressed in this report and associated screening criteria are presented in Appendix A.

1.2 NMED Data

A single occurrence report may be captured in 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). In this report, the term "event" is used to describe an individual event category.

The data presented in this report are limited to reportable events that occurred between October 1, 2001, and September 30, 2011. The data were downloaded from the NMED on January 16, 2012. 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 Duane White (nmednrc@nrc.gov, 301-415-6272).

2. ANALYSIS OF NMED DATA

Event reports involving nuclear material submitted to the NRC are reviewed, categorized, and entered into the NMED. Charts are provided to display trends in annual data for the most recent 10-year period (FY02-11).

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.

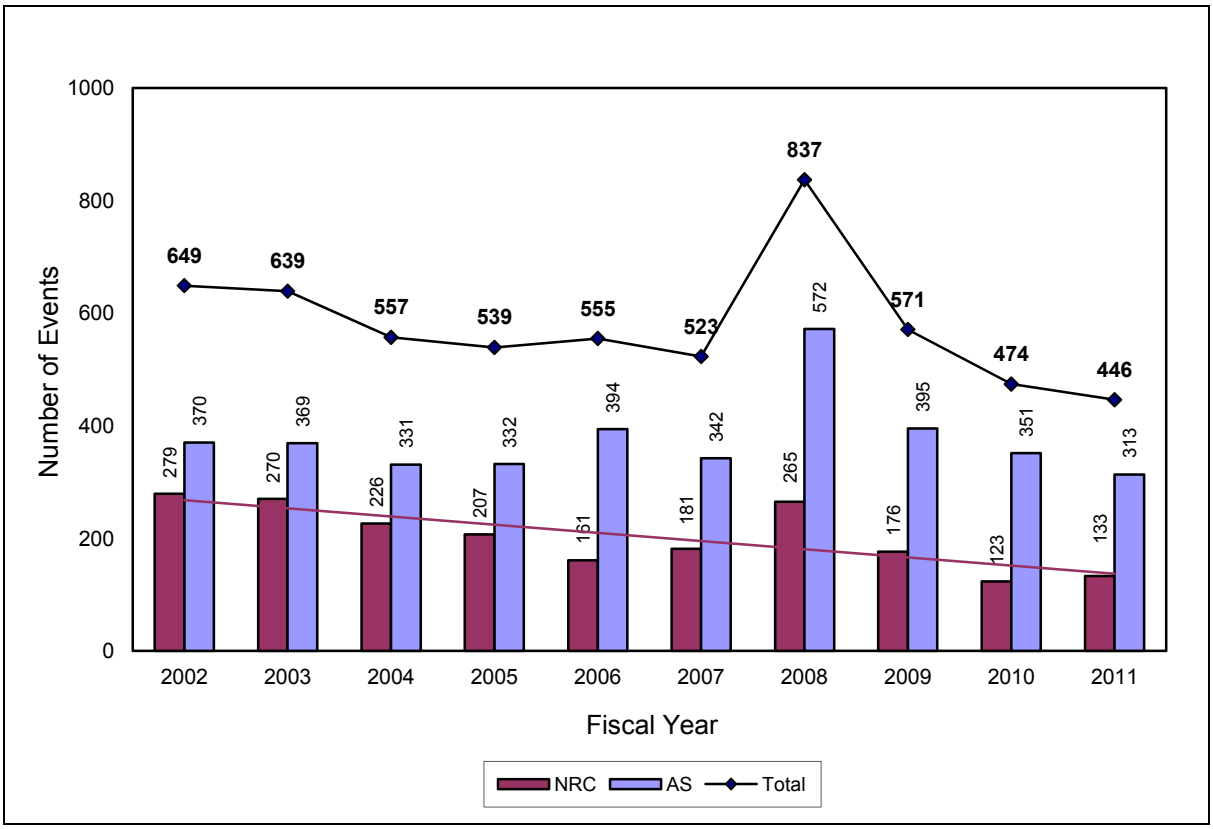

Figure 1. All NMED Events (5,790 total)

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

- In FY11, 404 occurrences accounted for 446 events; a single occurrence can be classified in different event categories.
- Note that events involving irretrievable well logging sources abandoned in accordance with 10 CFR Part 39.77 were excluded from previous annual reports, but are included in this report. Therefore, a comparison of Figure 1 against previous annual reports will show an increase in the number of events for each year.

- The FY08 and FY09 data include 272 and 65 events respectively that resulted from Wal-Mart's one-time review of their tritium exit sign inventory. If the Wal-Mart data is excluded, a statistically significant decreasing trend exists in the total remaining events.
- The most recent year's data are typically many records less than their final value when subsequent updates and late reports are received (see Appendix D, Figure D-1).
- The transition of states from NRC to Agreement State jurisdiction could result in increasing trends in Agreement State data and decreasing trends in NRC data.

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. Note that events involving irretrievable well logging sources abandoned in accordance with 10 CFR Part 39.77 were excluded from previous annual reports, but are included in this report. 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.

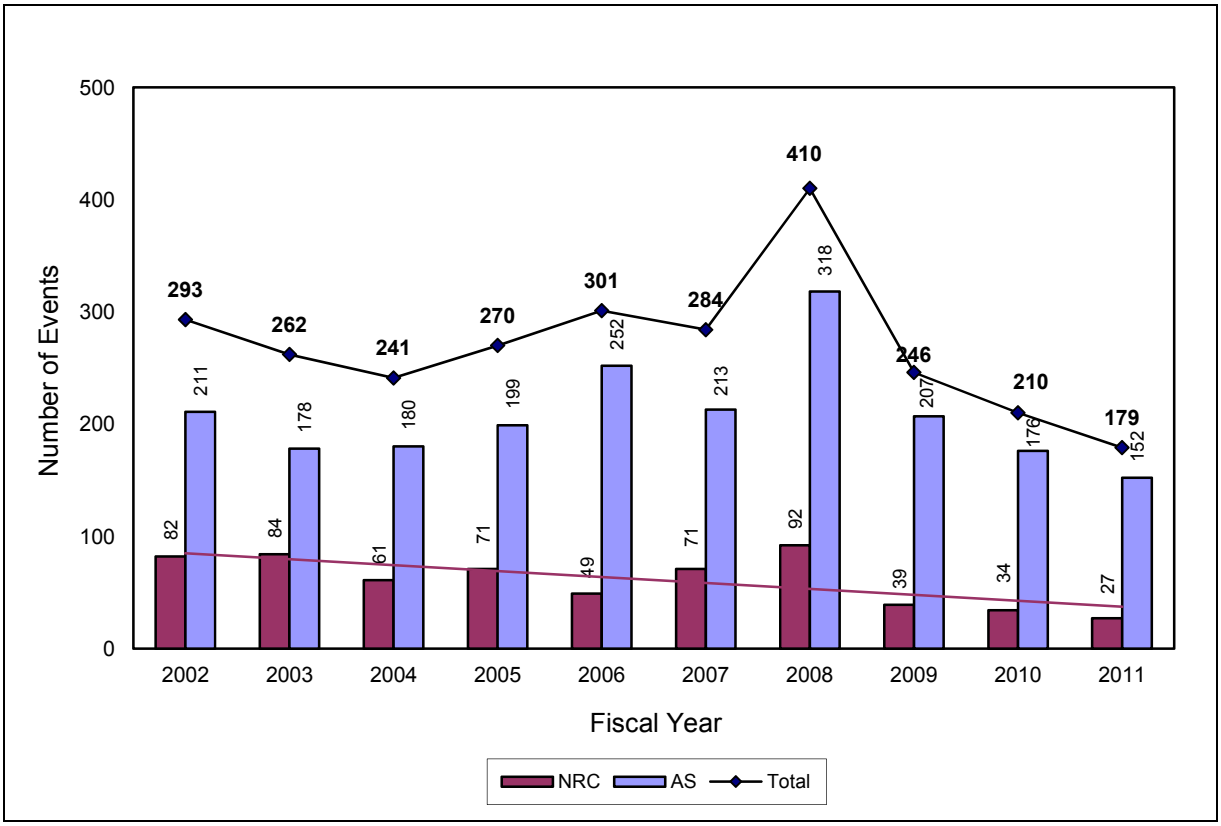

Figure 2. Lost/Abandoned/Stolen Material Events (2,696 total)

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

The 2,696 LAS events that occurred during the ten-year period involved the loss of approximately 4,610 sources (excluding irretrievable well logging sources abandoned in accordance with 10 CFR 39.77). Table 2 displays the number of sources lost during the 10-year period and the number that have not been recovered, grouped by the IAEA category where possible. During the 10-year period, no Category 1 sources, 42 Category 2 sources, and 27 Category 3 sources were lost. All of these sources were recovered, with the exception of two Category 2 and three Category 3 sources.

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

Category		Fiscal Year 2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Total
1	LAS[4]	0	0	0	0	0	0	0	0	0	0	**0**
	NR[5]	0	0	0	0	0	0	0	0	0	0	**0**
2	LAS	3	5	5	8	4	2	11	2	0	2	**42**
	NR	0	0	0	1	0	0	0	0	0	1	**2**
3	LAS	3	0	1	6	4	1	3	1	4	4	**27**
	NR	0	0	0	2	0	0	0	0	1	0	**3**
4	LAS	82	89	76	108	95	57	71	49	72	35	**734**
	NR	30	30	29	34	48	19	35	26	28	18	**297**
5	LAS	123	137	106	150	108	70	127	75	82	60	**1038**
	NR	52	58	34	57	42	20	54	22	30	11	**380**
< 5	LAS	4	2	4	7	0	2	0	2	1	1	**23**
	NR	2	1	4	4	0	0	0	2	1	0	**14**
Activity Not Known[1]	LAS	15	1	8	3	7	3	9	5	11	15	**77**
	NR	6	0	3	0	1	0	0	0	0	0	**10**
Nuclide Not Known[2]	LAS	1	1	0	3	0	0	0	0	0	11	**16**
	NR	0	1	0	0	0	0	0	0	0	11	**12**
Other[3]	LAS	307	274	253	235	257	276	430	255	174	192	**2653**
	NR	200	170	172	148	131	146	352	154	120	127	**1720**
Total	**LAS**	**538**	**509**	**453**	**520**	**475**	**411**	**651**	**389**	**344**	**320**	**4610**
	NR	**290**	**260**	**242**	**246**	**222**	**185**	**441**	**204**	**180**	**168**	**2438**

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 (FY02-11)

Radionuclide	Half Life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Aggregate IAEA Category
Ir-192	73.83 days	5	100.7	6.17	3
Total		**5**	**100.7**	**6.17**	**3**

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity). The source counts were corrected for the "aggregate" source events.
3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the "partially recovered" source events.
4. The source activities were decayed from the event date to 1/16/2012 (data download date).

Table 4. Summary of IAEA Category 1-3 Sources Not Recovered (FY11)

Radionuclide	Half Life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Aggregate IAEA Category
Ir-192	73.83 days	1	33.7	6.16	3
Total		**1**	**33.7**	**6.16**	**3**

Notes:

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

4. The source activities were decayed from the event date to 1/16/2012 (data download date).

2.2.2 FY11 Data

One hundred seventy-nine LAS events occurred in FY11, 20 of which involved irretrievable well logging sources. Excluding the irretrievable well logging sources, approximately 320 sources were lost/abandoned/stolen, 168 of which have not been recovered. Of the 320 lost sources, none were Category 1, two were Category 2, and four were Category 3. All of the Category 1-3 sources were recovered, with the exception of one Category 2 source.

Six of the FY11 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 100561 - A radiography source manufacturer reported the loss and recovery of a shipment that contained a 3.28 TBq (88.7 Ci) Ir-192 source. On 11/5/2010, the source was shipped to a radiography services company. The Ir-192 source was shipped priority overnight along with a small non-radioactive device that contained a leak test kit. However, the Ir-192 source did not arrive. On 11/9/2010, the carrier was contacted and put a trace on the shipment. The carrier stated on 11/10/2010 that the packaged was located and forwarded to its destination.

Item Number 110363 - A radiography services company reported the theft of a radiography exposure device that contained a 1.25 GBq (33.7 Ci) Ir-192 source. On the morning of 7/19/2011, radiographers discovered that the dark room on their truck had been broken into. Local law enforcement was contacted and responded to the scene. The hotel security camera was reviewed and the thief's vehicle type and manufacturer were identified. A Texas Department of Health inspector responded to the site. The dark room alarm system was tested and found to be functioning properly. However, the radiographers failed to set the alarm when they returned to their hotel from dinner. The tailgate was not locked, but the dark room was locked and the device was locked to the dark room. Several searches were conducted using portable radiation detection equipment in vehicles, but the device was not located. A fly-over survey was also conducted by the Department of Energy using a fixed wing plane. No abnormalities were noted. The radiography services company conducted a company-wide stand-down to review the incident with all employees, inspected all their trucks to verify the alarm systems were operating, and all employees were required to view a video that showed the proper way to lock and secure radioactive material. As of 7/22/2011, this incident was classified as an International Nuclear Event Scale level 2 event.

Significant Events - Category 3 Source Events
Item Number 110167 - A radiography services company reported the loss and recovery of a radiography exposure device on 4/15/2011. Two radiography exposure devices were picked up by a carrier on 4/13/2011. The devices were being shipped to the manufacturer. On 4/14/2011, the service company was notified that only one of the devices had arrived. The missing device contained a 588.3 GBq (15.9 Ci) Ir-192 source. The carrier was contacted, but could not locate the device and declared it lost. The carrier subsequently found the device on 4/15/2011 and returned it to the radiography services company. An investigation determined that the device had been held at one of the carrier's other facilities due to the loss of the original paperwork.

Item Number 110247 - A carrier reported the loss and recovery of a package that contained a 296 GBq (8 Ci) Ir-192 high dose rate afterloader source. Unknown to the driver, the rear cargo door of the transport vehicle opened and some of the contents fell out. A member of the public observed several letters on the road and stopped to pick them up. He also saw the source package across the road in a church parking lot, but did not retrieve it due to traffic. The individual took the letters to the carrier's local office and

explained what had happened. Carrier personnel went to the site and looked for the source package, but did not locate it. The source package had been found by a motorist and turned in to the fire department. The carrier retrieved the intact source package and delivered it. The Texas Department of State Health Services conducted an onsite investigation on 9/7/2011. It was determined that the driver failed to recognize that he had loaded a package containing radioactive material into his truck and failed to properly brace and block the package. The locking mechanism for the roll up door was loose and allowed the door to open while the truck was driven. The carrier's policies were updated to prevent recurrence and the driver was reprimanded.

Item Number 110308 - The New Jersey Department of Environmental Protection reported recovering a nuclear cardiac pacemaker, which contained 296 GBq (8 Ci) of Pu-238, from a private individual on 6/17/2011. The individual found the pacemaker while cleaning the residence of her deceased parent. The pacemaker had been implanted in 1973 at a hospital in New Jersey. It was removed in 1975 at an unknown location and sent to the patient's residence. A medical physicist traveled to the residence and returned the pacemaker to the hospital. The pacemaker was intact with no signs of damage.

Item Number 110634 - A medical facility reported removing a 124.32 GBq (3.36 Ci) Ir-192 source from a high dose rate unit on 4/25/2011, placing it into an approved container, and then moving it to an approved storage location pending return to the manufacturer. However, due to miscommunication, the source was not sent back to the manufacturer. The source was relocated by contractors approximately one month later to an uncontrolled and unoccupied storage room. At that time, the source had an activity of 92.5 GBq (2.5 Ci). On 10/10/2011, the storage room became the office of a new full-time physicist. The source had an activity of 25.53 GBq (0.69 Ci) on 10/10/2011. The source was discovered during a routine inspection on 10/27/2011 by the Pennsylvania Department of Environmental Protection. The source was immediately placed back into the permanent storage area. The new physicist wore a badge and received an exposure of 56 uSv (5.6 mrem). The contractor that moved the source to the office received an estimated 6 uSv (0.6 mrem). The source was returned to the manufacturer on 11/10/2011. Corrective actions taken by the medical facility included designating an individual to maintain control of all radioactive sources and modifying policies and procedures.

Events of Interest

Item Number 110016 - The U.S. Army reported that a radioluminescent light source containing 37 GBq (1 Ci) of H-3 was broken during maintenance on an M64A1 mortar sight. The event occurred in the small arms room at a National Guard maintenance shop. A National Guard employee was performing maintenance on the M64A1 mortar sight on 1/4/2011 in an attempt to remove the course azimuth scale component. During the removal of the scale, excessive force was used and the H-3 lamp was damaged, as evidenced by the sudden lack of illumination. The device was double bagged and placed in a designated storage area for future disposal. A radiation safety officer performed contamination wipes of the device and surrounding work areas on 1/4/2011. Initial wipe test results showed removable contamination on the mortar site at 52,000 dpm, with 69,000 dpm on the vice holding the mortar sight. The area was decontaminated and released from radiological restriction on 1/7/2011. The involved employee and four other people present in the room during the release were required to have an H-3 bioassay sample taken. The bioassay samples revealed that the involved employee had a committed effective dose equivalent (CEDE) of 0.01 mSv (1.0 mrem), while the other people present had CEDEs of less than 0.0005 mSv (0.05 mrem). Corrective actions included procedure modification, personnel training, and a general reminder to follow procedures when performing this activity. This event was classified as an EQP, LAS, and RLM event.

Item Number 110109 - A construction materials testing and inspection company reported that a 0.3 GBq (8 mCi) Cs-137 source was lost from a moisture/density gauge. The gauge had been used at a construction site. The source was lost sometime between 2/3/2011 and 2/8/2011. The gauge operator noticed that gauge readings had dropped significantly and thought that the computer in the gauge had malfunctioned. On 2/16/2011, a calibration facility identified that the source rod cap had broken off and

the Cs-137 source was missing. The source rod was returned to the manufacturer for inspection on 7/5/2011. The manufacturer determined that the source rod had a minor bend approximately four inches from the source. The weld attaching the source to the rod was broken with approximately half of the welding material left on the rod. The root cause of the loss was stress or other force applied to the tip of the source capsule. This event was classified as an EQP and LAS event.

Item Number 110324 - A construction materials testing and inspection company reported that a moisture/density gauge that contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source was stolen. An employee worked late on 6/24/2011 and took a company truck, which contained the gauge, to his residence. The gauge was in its transport container, which was double chained to the bed of the truck. The employee noted that the gauge was still in the truck on the morning of 6/26/2011. The gauge was determined to be missing the morning of 6/27/2011. Both chains had been cut to steal the gauge. Local police were notified of the theft. The Cs-137 source was subsequently recovered from a load of scrap metal that set off radiation monitor alarms at steel mill in a neighboring state. Using the source's model and serial number, the gauge manufacturer identified it as the Cs-137 source from the stolen gauge. The Am-Be source has not been located. The construction materials testing and inspection company will properly dispose of the Cs-137 source and now requires that gauges be returned to their permanent storage location. This event was classified as an EQP and LAS event.

Item Number 110468 - A mining company reported finding two fixed nuclear gauges in a remote, back lot area of their plant property. Each gauge contained a 1.11 GBq (30 mCi - 9/21/2001) Cs-137 source. The gauges were found during site cleanup activities performed on 9/8/2011. The gauges were clamped to piping located among various discarded metal parts. An inspector from the West Virginia Radiological Health Program responded to the site. The inspector performed radiation surveys and measured dose rates on contact with the gauges of approximately 4 uSv/hour (0.4 mrem/hour). Dose rates inside of the pipes that the gauges were mounted to revealed approximately 400 uSv/hour (40 mrem/hour), which indicated that the shutters on both gauges were open. The mining company intends to place the gauges in a locked gang box and will take steps to have the gauges removed from the site. In addition to these two gauges, an additional gauge is missing from the site. A company that previously removed scrap metal from the facility in 2010 was contacted regarding the missing gauge. They reported that the removed material was surveyed and no radioactive material was identified. Additionally, steel mills that receive scrap from this company employ radiation monitors on all incoming shipments of metal and no shipments had been rejected based on radiation levels. This event was classified as an EQP and LAS event.

2.2.3 Events Recently Added to NMED That Occurred Prior to FY11

Forty-one LAS events were recently added to NMED that occurred prior to the current fiscal year and have not been included in any previous annual report. 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
None.

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

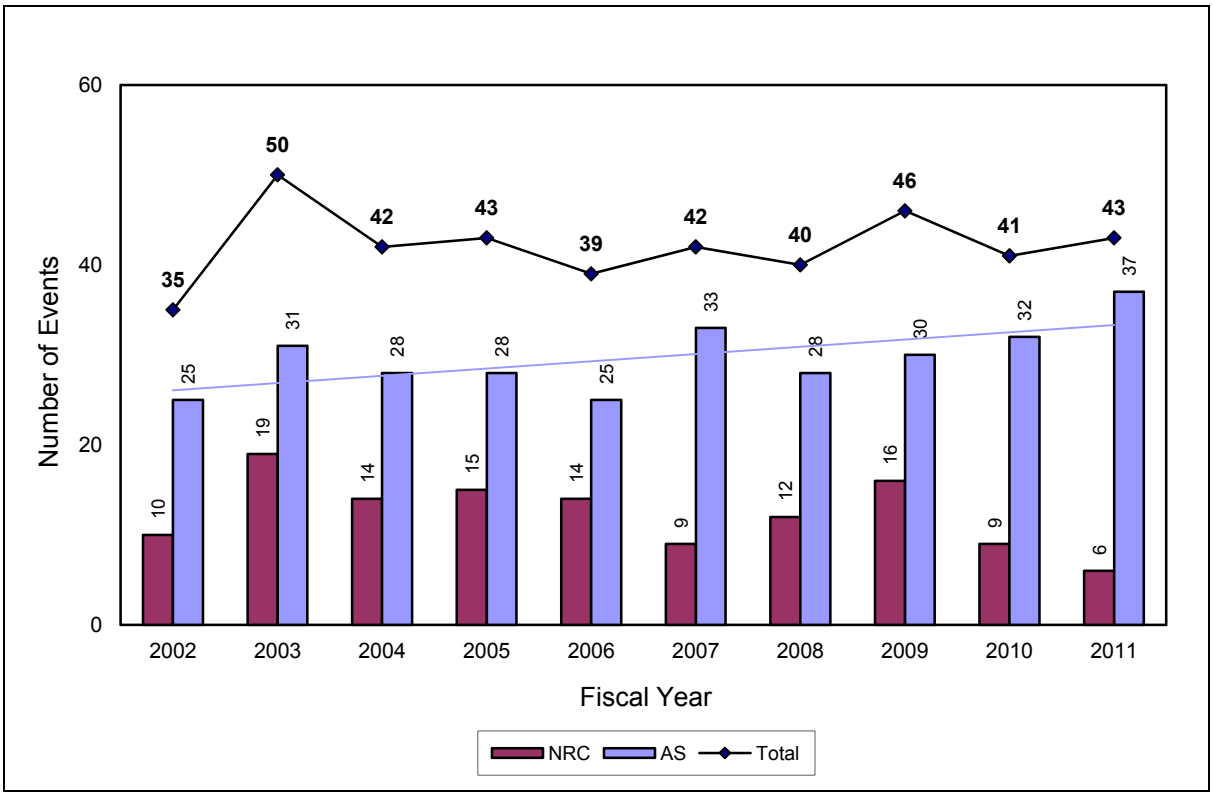

Figure 3. Medical Events (421 total)

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										
	2002	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**Total[1]**
Medical	6	10	12	9	7	11	12	15	12	14	**108**
Embryo[2]	0	1	1	1	3	2	2	2	2	1	**15**
Total	**6**	**11**	**13**	**10**	**10**	**13**	**14**	**17**	**14**	**15**	**123**

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.

2.3.2 FY11 Data

Forty-three MED events occurred in FY11, 14 of which were classified as significant events.

Significant Events - AOs or Potential AOs

Item Number 100506 - A patient received excessive dose to a treatment site and unintended dose to tissues other than the treatment site on 10/6/2010. The patient was receiving treatment to the post-surgical cavity in the left breast following excision of a cancerous tumor. The treatment involved a high dose rate unit with a 340.4 GBq (9.2 Ci) Ir-192 source. The written directive prescribed a total dose of 3,400 cGy (rad) to breast tissue at 1 cm from the cavity to be delivered over 10 fractions, with each fraction delivering 340 cGy (rad). Following the 8th fraction, an error was discovered in the treatment plan when the medical physicist remembered that he had not changed a default entry in the treatment planning system. Specifically, the medical physicist did not switch the "start at" position from "connector end" to "tip end". This caused the source placement to be flipped 180 degrees along the applicator's long axis; therefore, a portion of the treatment site at the tip end of the applicator did not receive the prescribed dose, and a portion of the treatment site at the connector end of the applicator received more dose than prescribed. The patient's treatment plan was modified to make up for the underdosed area. During the first eight fractions, the high-dose location of the treatment site received 26,600 cGy (rad) instead of the intended 4,624 cGy (rad). The skin's high-dose location received 10,488 cGy (rad) instead of the expected 2,880 cGy (rad), and the muscle's high-dose location received 100,160 cGy (rad) instead of the expected 3,024 cGy (rad). No long-term medical effects are expected for the patient. The patient was notified of the event on 10/7/2010. An NRC medical consultant determined that the overall impact to the patient is likely small. Corrective actions included personnel training and procedure modification to add a step in the planning process to verify that the catheter position is correct.

Item Number 100543 - A patient received dose to an unintended location during the administration of 3.959 GBq (107 mCi) of Y-90 microspheres on 10/26/2010. Approximately three weeks prior to the treatment, the patient was scanned for extrahepatic shunting through injection of Tc-99m MAA into the hepatic artery. No shunting to the duodenum was identified during that test. A post-procedure scan for the Y-90 microsphere treatment identified significant activity in the duodenum. Initial estimates indicated that approximately 0.37 GBq (10 mCi), or about 10% of the microspheres, ended up in the duodenum. The estimated dose to the duodenum was calculated to be approximately 9,000 cGy (rad). The patient was hospitalized for observation and possible intervention as a result of dose to the duodenum. Corrective actions included generating new procedures and modifying existing procedures.

Item Number 100554 - A patient received high dose rate endobronchial brachytherapy to the wrong location on 10/22/2010. The high dose rate unit contained a 199.8 GBq (5.4 Ci) Ir-192 source. The patient was prescribed two fractions of 1,000 cGy (rad) to the target volume as defined in their planning computed tomography (CT) scan. The first treatment was delivered to the wrong site due to errors in defining the starting positions of the source. During treatment planning, the locations of two catheters were correctly identified in the CT images. The direction of the catheters was mistakenly reversed afterwards, which changed the starting position of the source. Therefore, instead of the patient being treated to the left-sided airways, she was treated more proximal, to the larynx area. Although the plan was checked by a number of qualified physicists, the subtle orientation error was missed. The error was identified by the planning physicists when they were working on another patient case, about one hour after this patient's administration. The estimated dose to the patient's larynx region was between 1,500

and 2,000 cGy (rad). The patient was contacted and returned to the facility for observation and prophylactic treatments. The patient underwent fiber optic laryngoscopy 36 hours after her treatment, which showed minor edema of the supraglottic larynx, but no airway compromise. She then received the correct treatment. The hospital conducted a root-cause analysis of the event, generated a more detailed standard operational procedure for this type of administration, edited their existing quality assurance form to add extra check levels, generated a new verification procedure, and provided additional training to personnel. In addition, involved personnel were reprimanded.

Item Number 110005 - A patient received between 500 and 5,000 cGy (rad) to her skin on 12/22/2010, instead of the prescribed treatment to breast cancer tissue. The patient was receiving treatment with a high dose rate unit connected to an accelerated partial breast irradiation device. The source punched through the catheter and moved along the skin surface during the treatment. The patient did not notice that the source was outside the catheter. The source retracted normally into the shielded position. The physicist estimated that the patient's skin received 500 cGy (rad) if the source moved along the skin's surface. However, if the source stuck in one position, the patient's skin received 5,000 cGy (rad). The hospital stated that the catheter is easily kinked, which can cause this type of failure.

Item Number 110032 - A patient prescribed to receive 14,500 cGy (rad) during prostate seed brachytherapy treatment only received an estimated dose of 4,400 cGy (rad) to the prostate gland. The patient had undergone treatment on 11/23/2010 using 102 I-125 seeds, each containing an apparent activity of 16.65 MBq (0.45 mCi) for a total apparent activity of 1.7 GBq (45.9 mCi). Ultrasound-guided placement of the needle template was utilized. A post-implant C-arm X-ray scan was performed. Visualization of seed placement revealed that the seeds were inferior to ideal placement, but still acceptable. However, engorgement of the prostate and surrounding tissue due to the procedure made visualization difficult. As the patient healed, additional scans were scheduled at the four-week post-treatment date. Those scans revealed seed placement to be four to five cm inferior to the prescribed location. The dose to the prostate was determined suboptimal. Regions receiving elevated dose were the soft tissue at the base of the penis and the penile bulb. The patient was notified of the error. Corrective actions included procedure modification to reconfirm positioning of the patient using ultrasound and fluoroscopy throughout seed placement.

Item Number 110052 - A patient prescribed to receive 1.42 GBq (38.4 mCi) of Y-90 microspheres to the left lobe of the liver, received approximately 4.73 GBq (127.8 mCi) on 1/19/2011. As a result, the left lobe of the liver received 25,700 cGy (rad) instead of the intended 11,900 cGy (rad). The cause of the event was determined to be human error. There was a transcription error when preparing the order form. The error was not recognized upon receipt of the Y-90, because the received activity (as measured in a dose calibrator) was compared to the activity indicated on the order form rather than on the written directive. The incident may result in an increased risk of atrophy to the treated liver lobe. Corrective actions included generating a computer spreadsheet that populates fields based on initial calculations, written directive, order form, etc. Additionally, several procedure modifications were implemented to ensure the correct dosage is ordered and received.

Item Number 110088 - A patient undergoing high dose rate brachytherapy received an underdose during three fractions. The incident involved a remote afterloading unit and a 318.2 GBq (8.6 Ci) Ir-192 source. The wrong transfer tubes were used on three of four catheters during the first three of ten fractions. The incident resulted in a 59% underdose to the intended site and an overexposure to a small area of skin. The intended site received 3,400 cGy (rad) and the unintended site received 8,000 cGy (rad). The cause of the incident was identified as inadequate training of new staff and failure of the physicist to check all transfer tubes. A new plan was implemented to ensure that the intended site will receive the correct total dose. In addition, the hospital will conduct an in-service for all staff involved in high dose rate treatment and implement a time-out procedure to recheck all parameters before the treatment is delivered.

Item Number 110133 - A patient received a calculated dose of 159.4 Gy (15,940 rad) to the left lateral lobe of the liver instead of the prescribed 74.4 Gy (7,440 rad). An authorized user planned two liver infusion treatments for a patient with non-resectable hepatocellular carcinoma, using Y-90 microspheres. The first treatment to the right lobe and left medial segment of the patient's liver was successfully performed on 12/15/2010. The authorized user then ordered a 74.4 Gy (7,440 rad) dose to the left lateral lobe of the patient's liver. The medical physicist calculated a corresponding activity of 2.24 GBq (60.5 mCi) of Y-90 to be infused into the patient's left liver lobe. The treatment was performed on 3/9/2011. However, in determining the Y-90 activity needed, the physicist used the liver segment volumes for the right lobe and left medial segment instead of that for the left lateral lobe. Had the correct volume been used, the Y-90 activity would have been about one-third of that calculated. That error resulted in a dose of approximately 114.25% more than prescribed. No permanent damage to the patient's liver and no further loss of function is anticipated due to this event. This event was caused by inadequate communication between the prescribing physician and the medical physicist. Corrective actions included procedure modification to improve communication and documentation. An NRC medical consultant concurred with the hospital's assessment.

Item Number 110144 - A Y-90 microsphere therapy patient was administered 1.66 GBq (44.82 mCi) instead of the intended 1.11 GBq (29.97 mCi) on 3/17/2011. This resulted in a dose to the liver of 4,593 cGy (rad) instead of the intended 3,072 cGy (rad). This event was discovered on 3/18/2011 when the radiation oncologist determined that the amount of Y-90 microspheres delivered was 150% of the prescribed dose rather than the intended 105%. An investigation determined that the medical physicist had not read the written directive correctly. Contributing factors to this error included difficulty discerning the prescribed activity on the written directive and the lack of a secondary check of the activity worksheet after manually transcribing the prescribed activity from the written directive. Corrective actions included implementing a new procedure, modifying the written directive to display the prescribed activity more clearly, and instituting a second check of the activity worksheet. The patient will receive follow-up testing to track her status.

Item Number 110254 - A significant number of seeds were inadvertently implanted inferior to a patient's prostate during a procedure on 4/4/2011. The error was identified when the patient returned to the hospital on 5/3/2011 for a follow-up visit and post-implant CT scan. The patient was prescribed to receive 101 I-125 seeds, with activities of 0.44 mCi/seed, for a dose of 14,400 cGy (rad). Final post-implant dosimetry calculations revealed that the D90 dose to the prostate was 3,750 cGy (rad). Approximately 47 seeds were placed inferior to the prostate and 25 seeds lateral to the prostate. The maximum dose to the rectum was estimated based upon 1.0 cc and 0.1 cc rectal volumes. Those values were calculated as 12,500 and 17,000 cGy (rad), respectively. The maximum dose to the bladder was estimated based on a 1.0 cc volume. That value was calculated as 2,500 cGy (rad). Also, approximately 31 cc of normal tissue inferior to the prostate volume received at least 14,400 cGy (rad). The patient agreed to receive supplemental external beam radiation treatment. The permanent prostate seed implant program was placed on temporary hold pending review of procedures. An internal departmental review was conducted, including all steps from planning to implantation. Immediate changes were made to the implantation procedure to ensure proper verification of needle placement and location of deployed seeds. The implant program will resume once procedure changes are implemented.

Item Number 110296 - Two high dose rate medical events occurred involving partial breast treatments, starting on 5/9/2011. Both patients were prescribed to receive 3,400 cGy (rad) to the intended treatment site. A remote afterloader unit with Ir-192 sources was used for the treatments. For both patients, treatment was delivered twice a day for five consecutive days. It was later determined that, for both patients, when the physicist determined the catheter lengths, the source marker wire stopped approximately 4.5 cm from the end of each lumen, at the point of maximum curvature of the applicator. Consequently, the wrong length was entered into the treatment planning software and both treatments were shifted approximately 4.5 cm in the proximal direction as compared to the treatment plan. It was

concluded that the first patient received 1,105 cGy (rad) or 67.5% less dose than prescribed. Dose reconstruction revealed that the patient only received the planned dose to 26% of the target volume. It was also determined that the patient received a skin dose over the course of the treatment that exceeded 6,750 cGy (rad) above the planned skin dose. The second patient received 1,246.6 cGy (rad) or 63.3% less than prescribed. Dose reconstruction revealed that the patient only received the planned dose to 33% of the target volume. The hospital suspended these treatments until the root cause was identified. The cause was determined to be inadequate procedures, in addition to human error and inadequate training. Corrective actions included acquiring a new marker wire, changing the applicator treatment protocol, and developing a new policy and procedure.

Item Number 110351 - A patient received 3.75 GBq (101.3 mCi) of I-131 on 7/8/2011 instead of the prescribed dosage of 0.74 GBq (20 mCi) of I-131 for Grave's Disease. The 3.75 GBq (101.3 mCi) dosage was intended for another patient. The patient was prescribed to receive a total dose of approximately 34,000 cGy (rad) to the thyroid gland, but instead received approximately 172,200 cGy (rad). The patient was discharged from the hospital before the error was discovered. The patient was subsequently given additional instructions regarding contact with members of the public. The cause of the incident was determined to be failure to follow the written directive. Corrective actions included reprimanding involved personnel, providing improved personnel supervision, and providing additional personnel training.

Item Number 110402 - A patient received 1.05 GBq (28.38 mCi) of Y-90 microspheres on 7/7/2011 to the wrong side of the liver as documented in the written directive. The patient was prescribed to receive 1.04 GBq (28.11 mCi) for multinodlar hepatocellular cancer to the left lobe of the liver. A treatment plan was created for the left lobe, but during the procedure the right lobe was treated with the prescribed dose for the left lobe. It was determined that the interventional radiologist forgot about the conclusions to treat the patient's left lobe and completed the treatment to the right lobe. The error was not discovered until the patient returned to the facility on 8/8/2011. The hospital determined that a double check of both the dose and the targeted organ should be performed in the interventional radiology procedure room.

Item Number 110505 - A patient only received three of 71 I-125 seeds in the target during a prostate implant performed on 9/13/2011. Seven seeds were discovered in the bladder and were immediately removed. A number of seeds were also placed in the bowel wall, bladder wall, and lumen of the bowel. The patient was prescribed 14,500 cGy (rad) to the prostate gland and was allowed up to 14,500 cGy (rad) to the prostatic urethra and 21,750 cGy (rad) to the rectum. Preliminary estimates revealed that the D90 dose to the prostate was 220 cGy (rad). Estimates also revealed a dose of 1,530 cGy (rad) to the prostatic urethra and 6,390 cGy (rad) to the rectum. Segments of the large bowel, small bowel, and bladder were also believed to have received 4,919 cGy, 2,070 cGy, and 2,380 cGy (rad), respectively. The patient and referring physician were notified of the event on 9/14/2011. Imaging of the patient on 9/15/2011 suggested that the patient expelled eight seeds since the implant. The patient will undergo another seed placement procedure to treat the cancer. The hospital stated that fluoroscopy was not used during needle placement and no medical physicist was present during administration, both required by procedure.

Events of Interest

Item Number 110646 - Bracco Diagnostics (BD) reported increased radiation exposure in patients who underwent cardiac positron emission tomography (PET) scans with Rb-82 chloride injection from the CardioGen-82 rubidium generators. This event was discovered after two individuals who previously underwent Rb-82 PET myocardial perfusion imaging 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) and BD, BD voluntarily recalled all of the 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 BD began collecting and analyzing data to determine the extent of condition. Nevada Heart

and Vascular Center reported that three out 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. As of February 2012, BD 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 BD and shall adopt BD's updated policy 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

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 FY11 and was classified as a potential AO.

Item Number 110073 - A pregnant patient received 3.63 GBq (98.1 mCi) of I-131 on 1/12/2011 for thyroid ablation. The patient was unaware that she was pregnant and a pregnancy test administered approximately two hours prior to the dose administration had a negative result. Late in the evening of 1/26/2011, the patient was seen in an emergency room complaining of nausea and vomiting. A pregnancy test confirmed that she was pregnant. It was determined that the patient became pregnant during the period of 1/7/2011 to 1/10/2011. A dose calculation performed by the medical center estimated that the dose to the embryo/fetus was 24.68 cGy (rad). An NRC medical consultant concluded that the dose to the embryo/fetus was 27 cGy (rad). Because thyroid tissue capable of concentrating I-131 is formed between 10 and 12 weeks of gestation, this tissue was not formed at the time of treatment. Corrective actions included procedure revision to stress the importance of discussing sexual abstinence prior to therapeutic doses. This event was classified as a potential AO.

2.3.3 Events Recently Added to NMED That Occurred Prior to FY11

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

Significant Events - AOs or Potential AOs

Item Number 110108 - Two patients were administered 88.5% and 153.3% more than their prescribed doses of P-32 chronic phosphate colloid to treat Cystic Craniopharyngioma (cranial cysts). Those rare procedures were performed on 7/16/2010 and 9/16/2010. The first patient was prescribed 30,000 cGy (rad), but received 56,546 cGy (rad) and the second patient was prescribed 20,000 cGy (rad), but received 50,667 cGy (rad). The patients were prescribed to receive a total P-32 activity of approximately 23.68 and 10.88 MBq (0.64 and 0.294 mCi), respectively. However, they received approximately 44.4 and 27.57 MBq (1.2 and 0.745 mCi), respectively. The incidents were discovered when the authorized user noticed an area of inflammation surrounding a patient's cyst and along the track of the patient's drainage catheter. The accuracy of the P-32 calibration from the supplier was investigated. It was concluded that the two shipped dosages were more concentrated than labeled. To prevent recurrence, the hospital will obtain future doses that have been calibrated to National Institute of Standards and Testing traceable standards. They will also perform verification assays at their facility, as well as assessing dose volume to a specific activity.

Item Number 110341 - Three medical events occurred involving prostate therapy and Pd-103 brachytherapy seeds. The events were discovered during an inspection on 1/14/2011 and all three

incidents were the result of one doctor. On 2/18/2008, a patient was prescribed to receive 10,000 cGy (rad), but was administered 7,024 cGy (rad). On 4/8/2008, a patient was prescribed to receive 12,500 cGy (rad), but received 7,160 cGy (rad). On 3/17/2009, a patient was prescribed to receive 10,000 cGy (rad), but received 16,080 cGy (rad). The first two events (underdoses) were not significant, but the third event (overdose) was significant and classified as a potential AO.

Events of Interest

Item Number 110573 - A patient received 48% more dose than prescribed during high dose rate treatment delivered on 6/29/2011. The patient was treated intraoperatively following surgical removal of a metastatic lesion in the sacral region. The patient was prescribed 15,000 cGy (rad) at a position 1 cm from the source plane. The physicist incorrectly entered the distance between treatment planes as 3 cm, instead of 3 mm. The treatment plan was generated using the larger distance, corresponding source stopping positions, and dwell times. That resulted in large dwell times and an overdose to two treatment planes. Calculations revealed a delivered dose of 22,200 cGy (rad). The event was discovered during chart rounds when a supervising physicist noticed the difference between prescribed dose and the iCheck results. Corrective actions included procedure modifications, retraining in cases of non-standard geometry, disciplinary actions of personnel involved, annual documented training on appropriate quality assurance procedures, and modifications to the cover sheet for brachytherapy treatments to include iCheck calculations and quality assurance verifications. It was determined that the dosimetrist informed the physicist of the discrepancy prior to treatment. However, the physicist believed the iCheck results to be in error.

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

Item Number 110305 - A pregnant patient was administered 3.52 GBq (95 mCi) of I-131 on 9/22/2006 for thyroid ablation therapy. The hospital had interviewed the patient on 9/8/2006, explained precautions, and warned of becoming pregnant. A pregnancy test was performed on 9/21/2006 and results were negative. It was determined on 12/22/2006 that the patient was pregnant and the conception date was estimated to be between 9/1 and 9/6/2006. Estimates reveal that the embryo/fetus received approximately 25 cGy (rad). The patient was advised to see a genetic specialist to discuss possible consequences. Corrective actions included procedure modification. It was concluded that the hospital had followed acceptable protocols prior to administration.

2.4 Radiation Overexposure

2.4.1 Ten-Year Data

Figure 4 displays the annual number and trend of EXP events that occurred during the 10-year period. The trend analysis determined that the Total events and Agreement State-regulated events represent statistically significant decreasing trends (indicated by the trend lines). However, the NRC-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line). Therefore, variations within the NRC-regulated values represent random fluctuation around the average of the data.

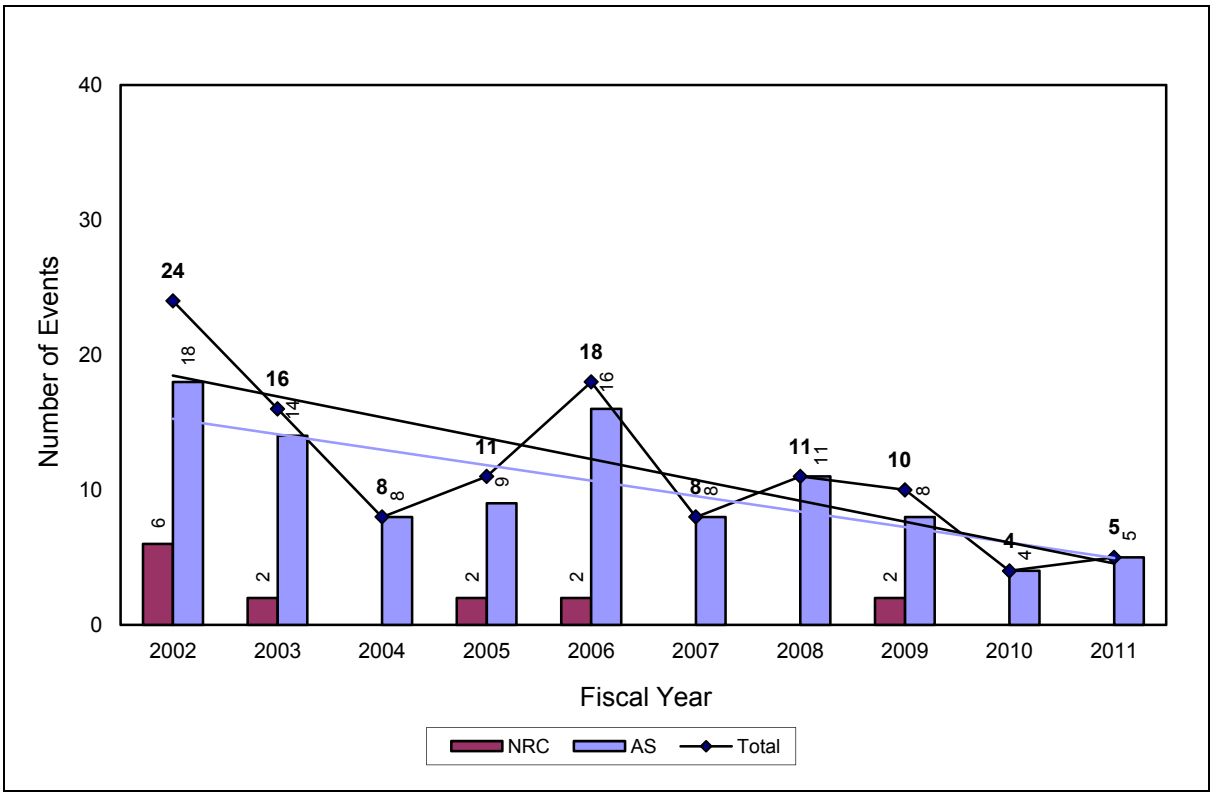

Figure 4. Radiation Overexposure Events (115 total)

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

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

Table 6. EXP Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Total
Immediate	1	2	1	0	1	1	0	0	0	1	**7**
24-Hour	0	1	1	1	3	1	3	1	1	1	**13**
30-Day	23	13	6	10	14	6	8	9	3	3	**95**
Total	**24**	**16**	**8**	**11**	**18**	**8**	**11**	**10**	**4**	**5**	**115**

2.4.2 FY11 Data

Five EXP events occurred in FY11, one of which was considered a significant event.

Significant Events - Immediate Reports

Item Number 110504 - A radiography trainee received an overexposure to his right hand during operations on 9/19/2011. The trainee removed the guide tube from the exposure device and saw that the 2.7 TBq (73 Ci) Ir-192 source was protruding from the device. The individual sought medical attention at a hospital. The individual's fingers indicated observable deterministic effects, including blistering of the thumb, index, and middle fingers. Effects correspond to an exposure range between 20 and 30 Gy (2,000 and 3,000 rad). The trainee's whole body dosimeter was sent for immediate processing and results revealed 14 mSv (1.4 rem). The radiography company is conferring with the Radiation Emergency Assistance Center/Training Site. As of 9/23/2011, this incident was classified as an International Nuclear Event Scale level 3 event. This event is classified as a potential AO.

Significant Events - Within 24-Hour Reports

None.

Events of Interest

Item Number 110484 - A radiographer exceeded the 5 cSv (rem) total effective dose equivalent (TEDE) limit for 2011. While operating a radiography exposure device on 9/12/2011, which contained a 2.48 TBq (67 Ci) Ir-192 source, the radiographer failed to fully retract the source after completing three shots on a weld. A radiographer trainee discovered that the locking mechanism was in the unlocked position when he went to unlock the mechanism for the next set of shots. Their radiation survey meter was turned off and no radiation monitors alarmed. Both radiographers noted that their pocket dosimeters (0 - 200 mR) were off scale. They then fully retracted the source and notified their radiation safety officer. Their badges were sent for emergency processing and the results were received on 9/14/2011. The radiographer's badge results revealed 3.361 cSv (rem) deep dose equivalent (DDE) and the trainee's revealed 2.787 cSv (rem). The radiographer's TEDE for the year was 5.152 cSv (rem). An investigation determined that survey meter had not been turned on during the first three shots or during the survey conducted after the source was incorrectly secured in the device. Corrective actions included personnel training and removing the radiographer from duty.

2.4.3 Events Recently Added to NMED That Occurred Prior to FY11

No EXP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. 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 Agreement State-regulated events represent a statistically significant decreasing trend (indicated by the trend line). However, the Total events and NRC-regulated events do not represent statistically significant trends (indicated by the absence of trend lines). Therefore, variations within the Total and NRC-regulated values represent random fluctuation around the average of the data.

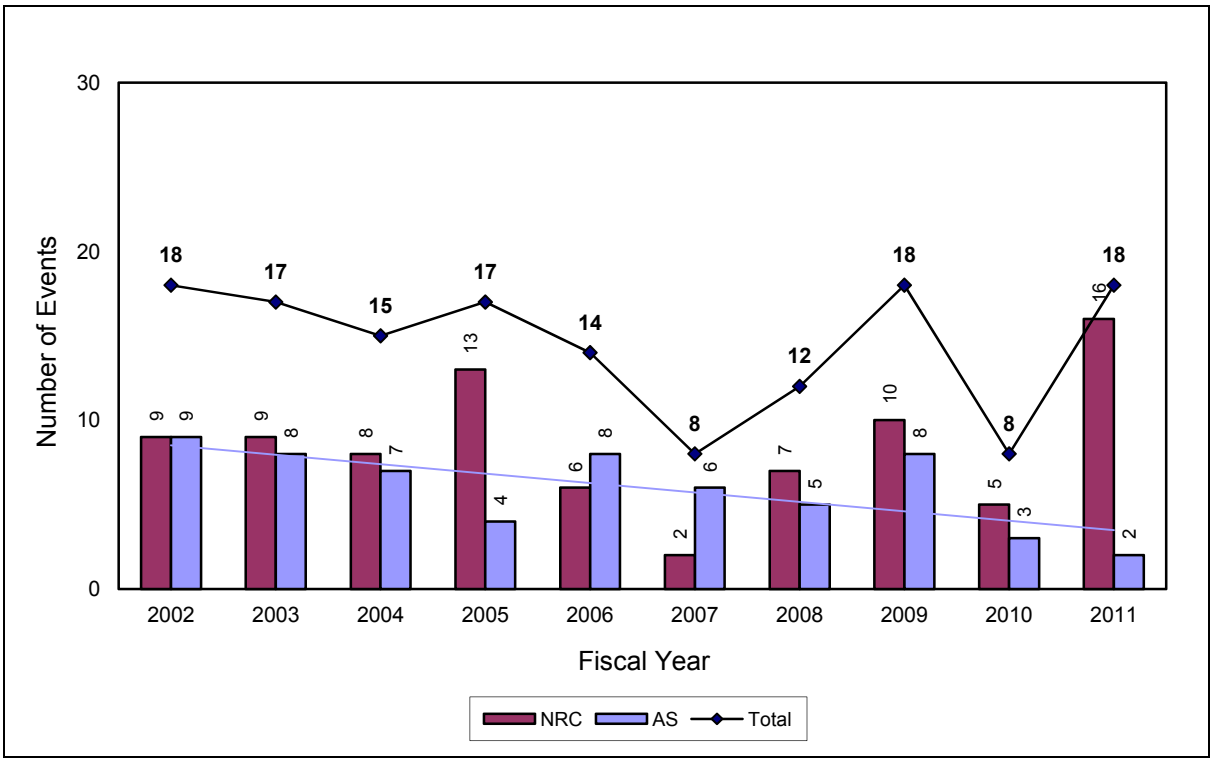

Figure 5. Release of Licensed Material or Contamination Events (145 total)

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

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

Table 7. RLM Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Total
Immediate	0	0	2	0	0	0	2	1	2	0	**7**
24-Hour	15	16	13	17	12	8	8	12	3	18	**122**
30-Day	3	1	0	0	2	0	2	5	3	0	**16**
Total	**18**	**17**	**15**	**17**	**14**	**8**	**12**	**18**	**8**	**18**	**145**

2.5.2 FY11 Data

Eighteen RLM events occurred in FY11, none of which were classified as significant events.

Significant Events - Immediate Reporting
None.

Events of Interest
None.

2.5.3 Events Recently Added to NMED That Occurred Prior to FY11

One RLM 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 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 100198 - A university reported a contamination event that occurred on 4/13/2010. A student, under the supervision of an authorized user, was conducting an electroplating experiment using 925 MBq (25 mCi) of Ni-63 under a fume hood in a radioactive material room. At the end of the experiment, the student took two smears inside the fume hood, one on the source, and one on the floor in front of the fume hood. The results of these smears were below 100 dpm (action level). The next day the Office of Radiological Safety took swipes of the room and identified 22,643 dpm on the fume hood lip, 11,364 dpm on the radioactive material room floor, 1,200 dpm on a public hallway floor outside the room, and contamination in an adjacent radioactive material room. All areas were cordoned off to control access and decontamination was performed from 4/14 through 4/16/2010. The cause of the event was determined to be that the authorized user directed the student to use an inappropriate procedure during the experiment. The authorized user's authorization to use Ni-63 was suspended. A urine bioassay was performed for the student and no Ni-63 activity was identified.

Events of Interest
None.

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.

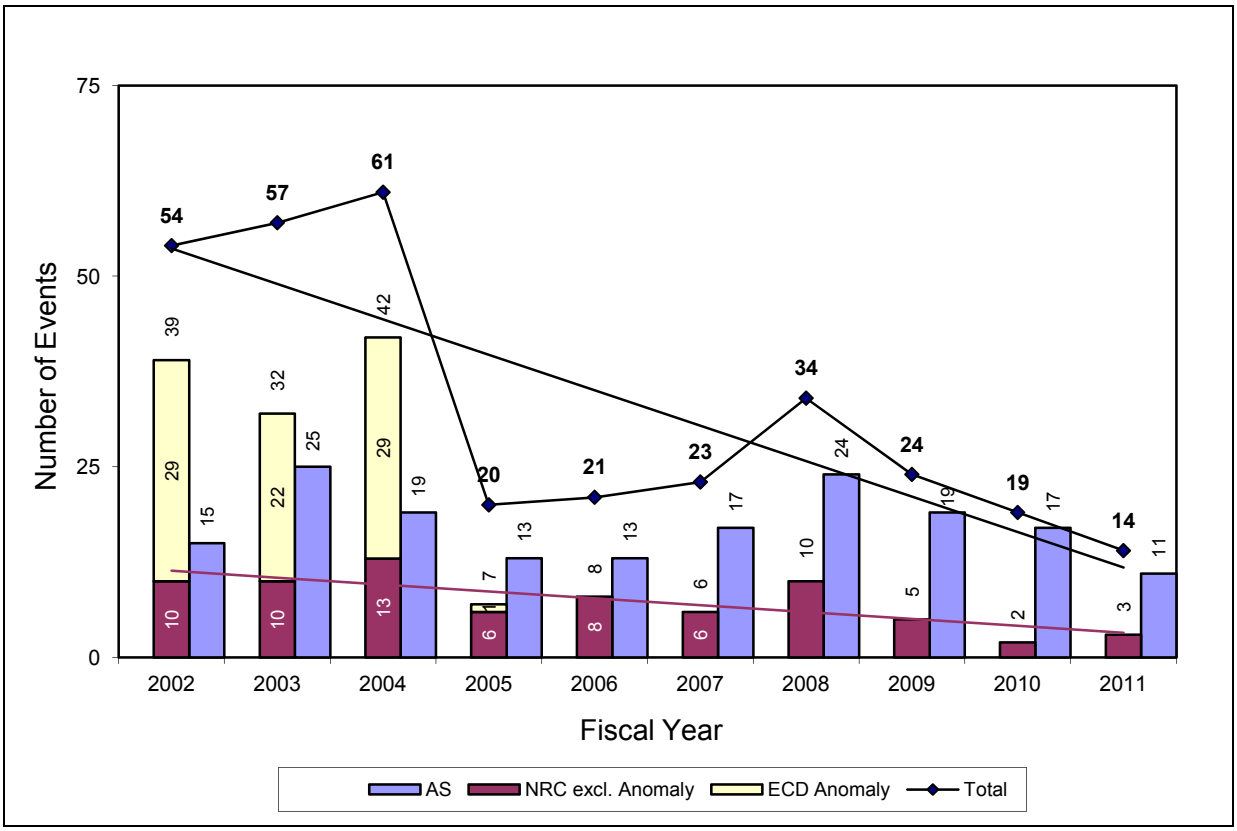

Figure 6. Leaking Sealed Source Events (327 total)

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. Thus, significance of these events is determined using a qualitative review of the event consequences.

2.6.2 FY11 Data

Fourteen LKS events occurred in FY11, none of which were classified as significant events.

Significant Events
None.

Events of Interest
None.

2.6.3 Events Recently Added to NMED That Occurred Prior to FY11

One LKS 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
None.

Events of Interest
None.

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.

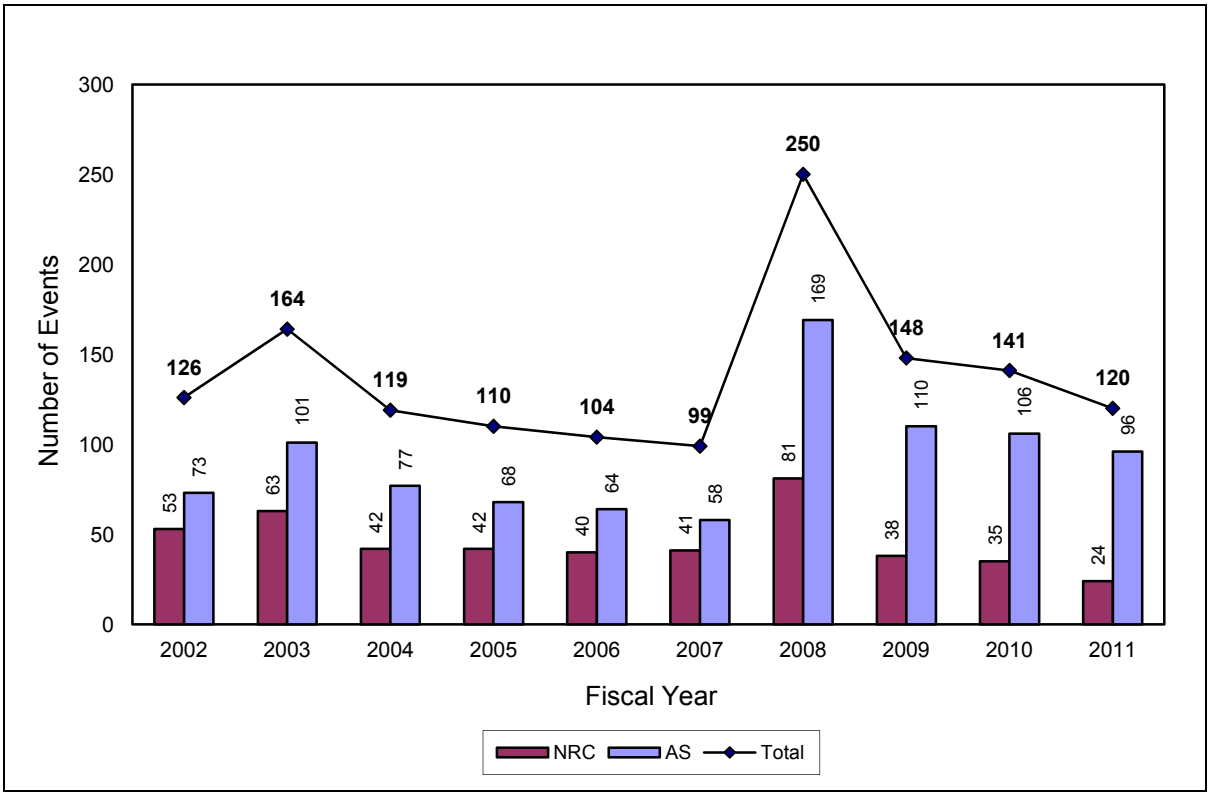

Figure 7. Equipment Events (1,381 total)

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. Thus, significance of these events is determined using a qualitative review of the event consequences.

2.7.2 FY11 Data

One hundred-twenty EQP events occurred in FY11, none of which were classified as significant events.

Significant Events
None.

Events of Interest
Item Number 100505 - A moisture/density gauge that contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source was run over by a front end loader at a construction site on 10/8/2010. The gauge was damaged and the source rod was bent. After performing surveys that indicated normal

levels, the gauge was placed into its storage container and returned it to their storage facility. The following day, New Jersey Department of Environmental Protection personnel visited the storage facility and determined that the gauge was significantly damaged and the shielding had been compromised. A small piece of shielding had broken off from the side and the shutter mechanism fell off the bottom of the gauge. The radiation exposure rate on contact with the gauge and identified 70 mR/hour. In the shipping container, with the lid closed, the measurement was 50 mR/hour on contact and 2.5 mR/hour at three feet. A wipe test revealed no removable contamination. Pieces of the shielding were reassembled and taped into place, which resulted in a reduced contact reading of 25 mR/hour. A lead pig was sent to the site for transportation of the gauge. The gauge will be shipped to a licensed service provider for repair/disposal.

Item Number 100511 - A steel mill reported that the shutter on a slab detection gauge that contained a 37 GBq (1 Ci) Cs-137 source would not close. The failure was identified during a semi-annual wipe test performed on 10/18/2010. The radiation safety officer was contacted and responded to the site. Radiation surveys were conducted and results were compared to prior surveys and no significant difference in radiation levels were noted. Melted metallic material was noted adjacent to the gauge. That material was analyzed and determined to be 90 to 95% lead. It is believed some shielding may have overheated and blocked the shutter open, or debris entered the shutter arm and prevented it from closing. The radiation safety officer removed the gauge from service and shipped it to the manufacturer for inspection.

Item Number 110016 - The U.S. Army reported that a radioluminescent light source containing 37 GBq (1 Ci) of H-3 was broken during maintenance on an M64A1 mortar sight. The event occurred in the small arms room at a National Guard maintenance shop. A National Guard employee was performing maintenance on the M64A1 mortar sight on 1/4/2011 in an attempt to remove the course azimuth scale component. During the removal of the scale, excessive force was used and the H-3 lamp was damaged, as evidenced by the sudden lack of illumination. The device was double bagged and placed in a designated storage area for future disposal. A radiation safety officer performed contamination wipes of the device and surrounding work areas on 1/4/2011. Initial wipe test results showed removable contamination on the mortar site at 52,000 dpm, with 69,000 dpm on the vice holding the mortar sight. The area was decontaminated and released from radiological restriction on 1/7/2011. The involved employee and four other people present in the room during the release were required to have an H-3 bioassay sample taken. The bioassay samples revealed that the involved employee had a committed effective dose equivalent (CEDE) of 0.01 mSv (1.0 mrem), while the other people present had CEDEs of less than 0.0005 mSv (0.05 mrem). Corrective actions included procedure modification, personnel training, and a general reminder to follow procedures when performing this activity. This event was classified as an EQP, LAS, and RLM event.

Item Number 110041 - A moisture/density gauge was damaged on 1/5/2011. As the gauge operator removed the gauge from its transportation case and turned the gauge upright, the base of the gauge dropped to the ground, damaging the plastic on one corner around the electronic readout. The handle separated from the base and the 0.33 GBq (9 mCi) Cs-137 source rod was exposed for a few seconds. The operator immediately returned the handle to the base, securing the Cs-137 source. There was no damage to the source. The gauge was placed back into its storage container. The gauge was tagged out of service pending inspection and repair. The gauge also contained a 1.63 GBq (44 mCi) Am-Be source. The radiation safety officer stated that the incident occurred due to the loose screw on the handle. The gauge was repaired and placed back into service.

Item Number 110109 - A construction materials testing and inspection company reported that a 0.3 GBq (8 mCi) Cs-137 source was lost from a moisture/density gauge. The gauge had been used at a construction site. The source was lost sometime between 2/3/2011 and 2/8/2011. The gauge operator noticed that gauge readings had dropped significantly and thought that the computer in the gauge had malfunctioned. On 2/16/2011, a calibration facility identified that the source rod cap had broken off and the Cs-137 source was missing. The source rod was returned to the manufacturer for inspection on

7/5/2011. The manufacturer determined that the source rod had a minor bend approximately four inches from the source. The weld attaching the source to the rod was broken with approximately half of the welding material left on the rod. The root cause of the loss was stress or other force applied to the tip of the source capsule. This event was classified as an EQP and LAS event.

Item Number 110146 - A hospital reported that a 377.4 GBq (10.2 Ci) Ir-192 source failed to extend on a newly installed high dose rate afterloader on 3/23/2011. Following troubleshooting by the manufacturer, it was determined that the active source wire became stuck in the wedge block, which is part of the emergency retract mechanism. The active source wire was removed and the emergency retract mechanism was replaced. The technician received 2 uSv (0.2 mrem) during the repair work. An analysis of the wedge block failed to determine the reason for the blockage of the active source wire. The shipping regime and active source wire were also checked, but no issues were identified. Engineering evaluation performed by the manufacturer identified a very small amount of material in the wedge block, which has a small bore that the source wire passes through. Otherwise, nothing remarkable was identified. There is no history of similar events with new units of this type. The manufacturer concluded that the bore of the wedge block was not properly designed to tolerate any debris or residue to ensure that the source wire will not become jammed. The manufacturer issued a technical bulletin and is investigating a new design for the wedge block, with a goal of implementing the new design by 4/30/2012.

Item Number 110324 - A construction materials testing and inspection company reported that a moisture/density gauge that contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source was stolen. An employee worked late on 6/24/2011 and took a company truck, which contained the gauge, to his residence. The gauge was in its transport container, which was double chained to the bed of the truck. The employee noted that the gauge was still in the truck on the morning of 6/26/2011. The gauge was determined to be missing the morning of 6/27/2011. Both chains had been cut to steal the gauge. Local police were notified of the theft. The Cs-137 source was subsequently recovered from a load of scrap metal that had set off radiation monitor alarms at steel mill in a neighboring state. Using the source's model and serial number, the gauge manufacturer identified it as the Cs-137 source from the stolen gauge. The Am-Be source has not been located. The construction materials testing and inspection company will properly dispose of the Cs-137 source and now requires that gauges be returned to their permanent storage location. This event was classified as an EQP and LAS event.

Item Number 110353 - A uranium fuel fabrication facility reported inaudible Criticality Accident Alarm System (CAAS) horns. The failures occurred during regularly scheduled audibility tests conducted on 7/14/2011. The failures actually occurred during regularly scheduled audibility tests conducted in May and June 2011, but were not adequately identified until 7/14/2011, nor reported until 7/15/2011. The test performed on 7/14/2011 was conducted for those CAAS horns covering the Controlled Access Area (CAA). The test was conducted as a result of an event reported on 7/13/2011 (NMED Item 11350). The test revealed that the installed CAAS failed to immediately activate the horn signal generators as expected. Activation of the associated warning horns was delayed approximately three minutes. That response time did not meet the design requirement. The complex fissile material process operations were suspended on 7/14/2011 and personnel were evacuated. The emergency organization was activated and investigations started. Personnel entry was withheld into the CAA and all production activities were shutdown pending completion of a root cause analysis and recovery plan. The cause of the incident was identified as a hardware failure. Specifically, a capacitor on a circuit board failed. The CAAS was repaired and a comprehensive testing plan was developed. This event was classified as an EQP and FCP event.

Item Number 110361 - A load of scrap steel set off their radiation monitor alarms on 7/14/2011 at a scrap yard. Scrap yard personnel were able to identify the item and isolate it. Virginia Radioactive Material Program personnel went to the site on 7/15/2011. Investigation determined that the scrap steel had come from the demolition site of a former textile company that closed in 2008. A gauge was recovered that

contained a Kr-85 source. The source originally contained an activity of 3.7 GBq (100 mCi) and the estimated activity at the time of recovery was 0.48 GBq (13 mCi). The mount for the gauge was badly disfigured and the shutter was missing. The source shield was intact, but the source aperture was visible. The aperture was covered by a Mylar-like material. Radiation surveys revealed maximum results between 4.5 and 6 mR/hour near contact with the aperture. Results were 150 uR/hour at approximately 30 cm. The textile company had owned three gauges and the State is working with the scrap yard and demolition company to search for the other two gauges. This event was classified as an EQP and LAS event.

Item Number 110374 - A recycling facility reported that a load of scrap metal set off their radiation monitor alarms on 7/5/2011. The radiation reading exceeded 5 mR/hour (maximum reading for the instrument used) and background was 9 uR/hour. A California Health and Human Services Agency inspector identified the radionuclide as Cs-137. A 17-inch source rod was identified, which came from a gauge. The only identifying mark on the rod was the number 7405. Surveys revealed 20 uSv/hour (2 mrem/hour) at 36-inches, with 6 uSv/hour (0.6 mrem/hour) at 60-inches (background was 7 urem/hour). Leak tests revealed negative results. The source contained an activity of approximately 0.18 GBq (4.86 mCi). The source was transferred to a State storage facility. This event was classified as an EQP and LAS event.

Item Number 110468 - A mining company reported finding two fixed nuclear gauges in a remote, back lot area of their plant property. Each gauge contained a 1.11 GBq (30 mCi - 9/21/2001) Cs-137 source. The gauges were found during site cleanup activities performed on 9/8/2011. The gauges were clamped to piping located among various discarded metal parts. An inspector from the West Virginia Radiological Health Program responded to the site. The inspector performed radiation surveys and measured dose rates on contact with the gauges of approximately 4 uSv/hour (0.4 mrem/hour). Dose rates inside of the pipes that the gauges were mounted to revealed approximately 400 uSv/hour (40 mrem/hour), which indicated that the shutters on both gauges were open. The mining company intends to place the gauges in a locked gang box and will take steps to have the gauges removed from the site. In addition to these two gauges, an additional gauge is missing from the site. A company that previously removed scrap metal from the facility in 2010 was contacted regarding the missing gauge. They reported that the removed material was surveyed and no radioactive material was identified. Additionally, the steel mills that the scrap company provides material to employ radiation monitors on all incoming shipments of metal and no shipments had been rejected based on radiation levels. This event was classified as an EQP and LAS event.

Item Number 110646 - Bracco Diagnostics (BD) reported increased radiation exposure in patients who underwent cardiac positron emission tomography (PET) scans with Rb-82 chloride injection from the CardioGen-82 rubidium generators. This event was discovered after two individuals who previously underwent Rb-82 PET myocardial perfusion imaging 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) and BD, BD voluntarily recalled all of the 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 BD began collecting and analyzing data to determine the extent of condition. Nevada Heart and Vascular Center reported that three out 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. As of February 2012, BD 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 BD and shall adopt BD's updated policy 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.

2.7.3 Events Recently Added to NMED That Occurred Prior to FY11

Fifteen 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 110340 - A hospital reported that a patient did not receive their intended gamma knife treatment due to equipment malfunction on 10/25/2007. The patient was prescribed 20,000 cGy (rad) to 10 brain lesions of 2,000 cGy/lesion (rad/lesion). However, following treatment of the third lesion, the gamma knife couch failed. The first three lesions received their treatment, but the remaining seven did not. The physicist and neurosurgeon had to enter the room and manually pull the couch out of the gamma knife unit. The unit contained Co-60 sources with a total activity of 111.4 TBq (3,011.7 Ci). The physicist's badge revealed 10 uSv (1 mrem) deep dose equivalent and 20 uSv (2 mrem) shallow dose equivalent. The neurosurgeon was not wearing his badge at the time of the incident. This event was classified as an EQP and MED event.

Events of Interest

Item Number 070659 - A licensee reported the theft and recovery of a moisture/density gauge that contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. The gauge was stolen from a pickup truck parked at an employee's residence on 10/28/2007. The gauge and locks were stolen, but the cables were not cut. Corrective actions included 1) developing a steel strap that fits tightly around each transport case and a steel rod that runs through the handle of each case and through both ends of the steel straps and locked with a padlock, 2) replacing cables with thicker, heavier chains, 3) providing instructions to all users on the revised security procedures, 4) increased emphasis on gauge security during internal training sessions, and 5) reduced visibility of gauges in open bed pickup trucks by using tarps to cover them. The gauge was recovered from a local scrap facility on 7/23/2010. The scrap facility discovered the damaged gauge, contained in a 55-gallon drum, and contacted the licensee. The licensee retrieved both sources and the broken base pieces. The sources were found intact. The damaged gauge and both sources were returned to the manufacturer. This event was classified as an EQP and LAS event.

Item Number 100481 - A radiography services company reported that during their last radiographic exposure on 9/22/2010, the source did not fully retract. The radiography exposure device contained a 2.63 TBq (71 Ci) Ir-192 source. The workers did not perform a survey and did not have their rate alarms turned on. They noticed that their pocket dosimeters were off scale and discovered the problem. The assistant radiographer's badge revealed an exposure of 7.42 mSv (742 mrem) and the lead radiographer's badge revealed an exposure of 114.4 cSv (rem). However, the lead radiographer's badge showed an uneven surface reading, which is an indication that it had been damaged by being dropped. Calculations performed by the radiography services company revealed exposures of 1.11 and 1.06 cSv (rem) for both individuals. The lead radiographer was sent for a blood test and results were normal. A Florida Bureau of Radiation Control investigation concurred with the company's findings. Corrective actions included additional personnel training.

Item Number 110405 - While unloading a source from a high dose rate afterloader into a transport container on 1/20/2009, the drive mechanism failed to fully deploy the source into the transport container or retract it back into the safe. The emergency motor was unable to retract the source. The engineer was also unable to manually retract the source. The engineer removed the transfer tube from the indexer, cut the exposed source cable, and manually inserted the source into an emergency container. The equipment

was returned to the manufacturer for a root cause investigation on 6/15/2009. The manufacturer found no logical explanation for the failure. Corrective actions included retraining involved personnel, since operator error was a possible cause.

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.

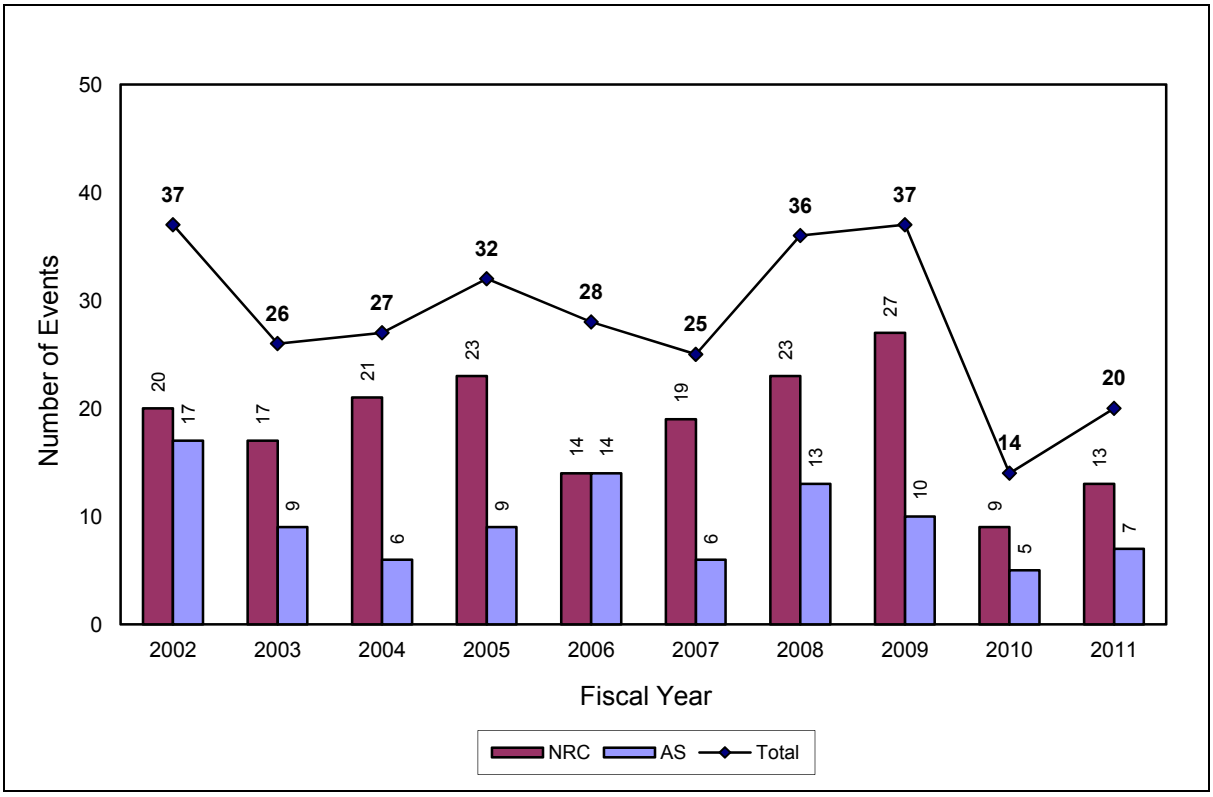

Figure 8. Transportation Events (282 total)

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

2.8.2 FY11 Data

Twenty TRS events occurred in FY11, none of which were considered significant.

Significant Events
None.

Events of Interest
None.

2.8.3 Events Recently Added to NMED That Occurred Prior to FY11

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

Significant Events
None.

Events of Interest
Item Number 110046 - The conditions in a Certificate of Compliance (COC) were not followed during shipments involving the Advanced Test Reactor Fresh Fuel Shipping Container package. The container is used to ship uranium-aluminum elements and uranium-silicide elements. On 11/23/2010, a review determined that the COC's channel spacing requirement of 0.082 inches for the uranium-aluminum elements was more restrictive than the design limits for the elements (which ranged from 0.0823 to 0.0845 inches). This prompted a follow-up review, which determined that three out of six fuel elements shipped on 2/1/2010 and 4/27/2010 violated the COC channel spacing limit. The review also identified a shipment of four uranium-silicide elements on 9/27/2010 that exceeded the COC U-234 limit of 0.21 weight percent (the actual values ranged from 0.215 to 0.217 weight percent U-234). The review was unable to determine if this shipment complied with the COC channel spacing limit. There were no safety consequences as a result of these conditions. This event was caused by inadequate procedures. Corrective actions included procedure modification and revision of the COC.

Item Number 110186 - The conditions in a Certificate of Compliance for the TNF-XI package were not followed during shipments. On 9/3/2010, a nuclear fuel manufacturer discovered that all shipments of low-enriched uranium dioxide powder shipped from their Richland, Washington, fuel manufacturing plant to two nuclear fuel manufacturing plants in Japan using the TNF-XI package were in violation of the USDOT Competent Authority Certification USA/0653/AF-96. From late 2003 to 8/27/2010, 110 shipments were made during which the uranium dioxide powder in the inner pails was contained in polyethylene bags, which is prohibited. Criticality analysis determined that k-eff never reached or exceeded the upper subcritical limit. Corrective actions included suspending future shipments until other suitable bags are identified.

Item Number 120026 - The conditions of approval in a Certificate of Compliance for a RAJ-II package were not followed during shipments. For the RAJ-II package, fuel assemblies must contain a specific number of burnable poison (gadolinia) rods and prescribed weight percent of gadolinia for a given bundle lattice average U-235 enrichment. Fuel manufacturing allows a tolerance on the lattice average U-235 enrichment, which was not included in the original safety analysis report (SAR) analysis basis. In March and April 2010, 52 fuel assemblies were shipped to a reactor site. If allowed manufacturing tolerances are included, these shipments may have failed to meet the RAJ-II SAR requirements for gadolinia and lattice average enrichment. The safety significance of this deficiency is low since there is sufficient conservatism in the assumptions for the enrichment tolerance. Corrective actions include revising the fuel assembly design process to incorporate the enrichment tolerance as part of existing lattice average design verification.

Item Number 120028 - The conditions of approval in the Certificates of Compliance for a TRAVELLER package and an MCC package were not followed during shipments. On three occasions, non-conforming fuel pellets marked as scrap were loaded into fuel rods. Between 8/24/2010 and 9/18/2010, an MCC package was shipped with fuel assemblies containing a pellet with a diameter of 0.2 mils less than the minimum manufacturing tolerance. Between 1/7/2009 and 2/11/2009, a TRAVELLER XL package was shipped with fuel assemblies containing a pellet with a diameter that exceeded the maximum allowed diameter by 2.2 mils. Between 7/19/2010 and 9/27/2010, a TRAVELLER XL package was shipped with fuel assemblies containing a pellet with a diameter that exceeded the maximum allowed diameter by 0.3 mils. In each case, the non-conforming pellet diameter resulted in small increases in reactivity, but there was no adverse impact on the package safety basis. Corrective actions included procedure revision.

2.9 Fuel Cycle Process

2.9.1 Ten-Year Data

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

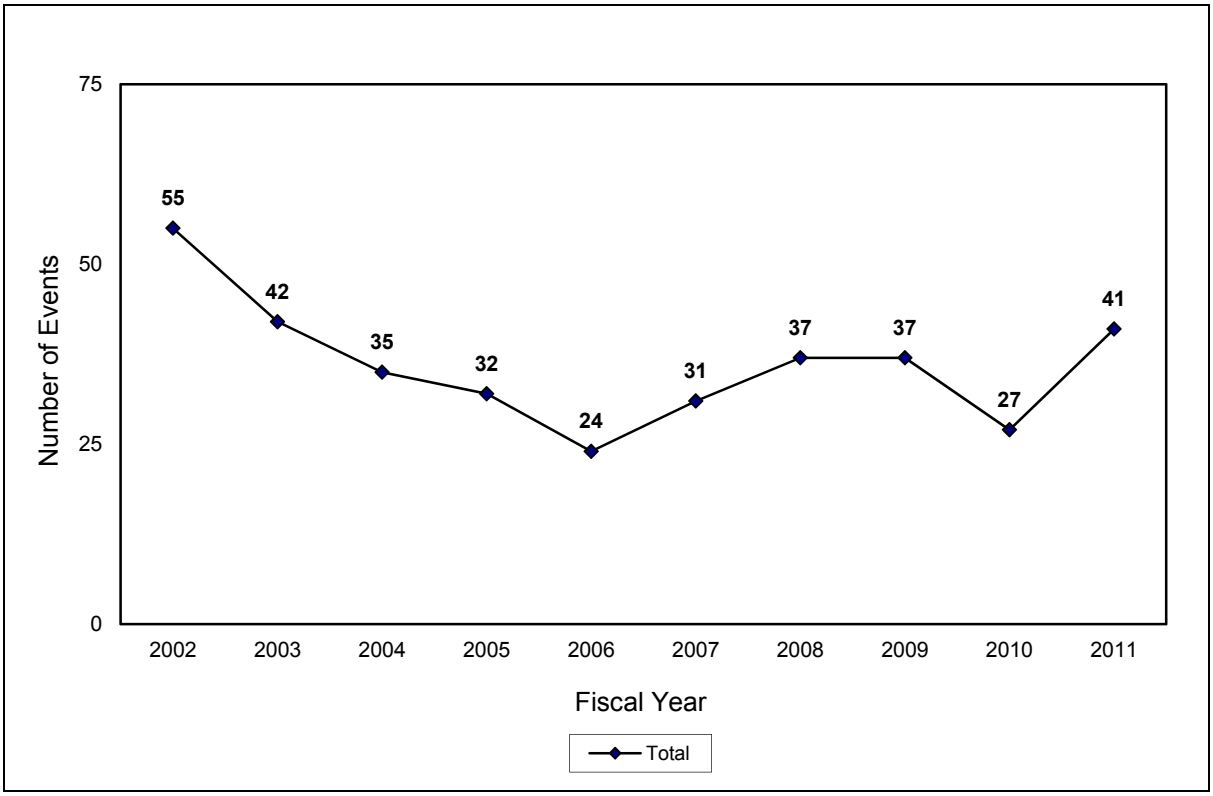

Figure 9. Fuel Cycle Process Events (361 total)

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

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

Table 8. FCP Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Total
Immediate	37	22	23	12	6	5	9	7	4	6	**131**
24-Hour	13	19	11	19	16	25	26	29	22	33	**213**
30-Day	5	1	1	1	2	1	2	1	1	2	**17**
Total	**55**	**42**	**35**	**32**	**24**	**31**	**37**	**37**	**27**	**41**	**361**

2.9.2 FY11 Data

Forty-one FCP events occurred in FY11, six of which were classified as significant events.

Significant Events - Immediate Reports

Item Number 100493 - A gaseous diffusion plant reported that the independent verification of cylinder cool down time had not been completed on some uranium hexafluoride (UF_6) cylinders. Upon discovery of the violation, it was determined that the cylinders had met the required cool down period prior to movement, but the independent verification had not been completed. Since the independent verification had not been completed, the second leg of double contingency had been violated. The assay of any material involved was less than or equal to 5.5 weight % of U-235. The cylinders involved were 10-ton cylinders. An investigation subsequently determined that independent verification of the cool down time had been performed prior to cylinder movement, but the verification was not documented.

Item Number 110077 - A gaseous diffusion plant reported the failure to establish double contingency in the crawl space above the C-310 Product Withdrawal room. After identifying water leaking into the C-310 Product Withdrawal room on 2/3/2011, personnel determined that a steam condensate line had broken in the crawl space above the room, allowing water to leak through the ceiling and into the room on the ground floor. The flooded area in the C-310 Product Withdrawal room was roped off and posted as a contamination control area. An investigation revealed large unsafe geometry collection points in the crawl space capable of accumulating liquid greater than a depth of 0.5 inches of water. The water actually accumulated to a depth of approximately 3.4 inches. The investigation also determined that the fire sprinkler heads in the area were designed to activate at 160 degrees F instead of the required minimum activation temperature of 200 degrees F. Activation of the fire sprinklers in the event of a UF_6 release in the area was credible and would provide both fissile material and moderator to the unsafe geometry collection points. Corrective actions included revision of the nuclear criticality safety analysis to address the crawl space, adding drain holes to the crawl space, replacing the sprinkler heads with higher temperature heads, and training personnel. This event was classified as an FCP and RLM event.

Item Number 110126 - A nuclear fuel manufacturer reported that greater than a safe mass of Uranium dioxide (UO_2) had accumulated in the UO_2 Sinter Test Grinding Station HEPA filter housing transition. On 2/1/2011, personnel replaced the pre-filter due to high differential pressure indications. At that time, approximately 4 kg of UO_2 powder was removed from the pre-filter. On 2/5/2011, personnel replaced the HEPA filter that had been in service for approximately two years. Approximately 26.9 kg of UO_2 was removed from the HEPA filter. On 3/1/2011, personnel removed approximately 15.3 kg of UO_2 powder from the transition section of the HEPA filter enclosure. Therefore, the total amount of UO_2 powder present in the exhaust filter system was approximately 46.2 kg, which is greater than the facility limit of 25 kg and the safe mass limit of 31 kg of dry UO_2 powder. This failure to maintain mass control resulted in the loss of double contingency for the filter housing. The manufacturer shut down the grinding station and other grinders in the facility to assess the event. No other examples of excessive material accumulation were identified. The sinter test grinder HEPA filter was replaced and the UO_2 was transferred into favorable geometry three-gallon cans per procedure. An investigation determined that

this event was caused by inadequate differential pressure monitoring at the test grinder due to smaller UO_2 particle sizes and inadequate procedures for identifying UO_2 powder accumulation. Corrective actions included procedure modification and equipment/process changes.

Item Number 110128 - A nuclear fuel manufacturer reported that a failed material transaction led to a can of powder being placed in the wrong station. The can was present on the conveyor in the UO_2 Press Feed Area, resulting in the loss of one criticality control. It was discovered on 3/7/2011 that the can contained three vacuum bags of UO_2 powder, for a total of 13.6 kg. The second control parameter (mass of uranium in each can) was maintained. The can was subsequently transferred to an approved storage location. Special nuclear material movements were suspended pending investigation and implementation of additional corrective actions. Corrective actions included new instructions and personnel training for handling vacuum bags.

Item Number 110414 - A gaseous diffusion plant reported that during disassembly of a Seal Exhaust/Wet Air pump, the pump's two piston slides and cam were placed within two feet of the internal oil separators. Nuclear criticality safety requirements specify a minimum edge-to-edge spacing of 2 feet. Therefore, the interactive parameter was not maintained and one leg of double contingency was lost. Access to the area was controlled and the items were moved such that spacing was greater than two feet. The exclusion zone was then removed. Product withdrawal assay at the time of the event revealed less than 4.95% U-235.

Item Number 110513 - A gaseous diffusion plant reported the loss of one leg of double contingency on 9/30/2011. Water was observed in the #5 Withdrawal Position Scale Pit during the completion of the monthly test of the C-310 scale pit water detection system alarm module. The alarm module was found with the visual alarm on at the local panel in the Withdrawal Position Room. In response to the alarm, the scale pit hatch was opened and the water detection sensor cable was observed to be partially submerged. Investigation found that the sump pump breaker was tripped. When the breaker was reset, the pump actuated and water was immediately removed. At the time of the occurrence, product withdrawal was in progress in the #3 and #4 Withdrawal Position Room and no cylinder was present in the #5 Withdrawal Position Room. The water was determined to be from a leaking steam condensate valve. Assay of product withdrawal operations during the incident remained no higher than 2.0 weight % U-235. No UF_6 release occurred. With the alarm out of service, continued ingress of water into the pit could have resulted in exceeding the geometry parameter limit for water depth before detection and mitigation. It was assumed credible that the geometry parameter limit was violated during the time the alarm was not functional. The #5 Withdrawal Position Scale Pit will be checked twice per shift beginning on 9/30/2011.

Events of Interest

Item Number 100487 - A nuclear fuel manufacturer reported that boats of fuel pellets had become stacked in a UO_2 sintering furnace. On 10/1/2010, an operator received a pusher overload alarm on the furnace. On 10/2/2010, it was discovered that boats of fuel pellets had become stacked, jamming the line. The furnace was shutdown to perform a full investigation. Although 22 pellet boats (approximately 330 kg net weight) were in the furnace at the time, five pellet boats (approximately 75 kg net weight) were involved in the jam. Approximately 15 kg of UO_2 pellets were found outside the limits of the pellet boats. The jam condition was a result of pellet boat misalignment inside the pre-heat section of the furnace. The cause of the pellet boat misalignment was determined to be a misaligned charge pusher, which allowed a pellet boat to strike the entrance doorframe and become misaligned on top of a pellet boat skid. The misalignment of the charge pusher was caused by maintenance procedures that lacked sufficient detail on how to verify alignment. The geometry control was compromised, but the moderation control remained intact. Corrective actions included modifying maintenance procedures and verifying that charge pushers were aligned.

Item Number 100581 - A nuclear fuel manufacturer reported the accumulation of a greater amount of fissile material than expected in a stripper column in the Ammonia Recovery Facility (ARF) when an acid

wash recovered 8 kg of uranium on 12/2/2010. An acid wash of the gas stripper was initiated as a result of concerns over the differences in the inlet and outlet pressures of the system, which indicated that the system was becoming less efficient. The Integrated Safety Analysis (ISA) summary for the process states that only minute quantities of radioactive material are present in the feed to the ARF. The 8 kg is less than 25% of a minimum critical mass in a spherical geometry and constitutes an approximate 10-year accumulation. The system was down for maintenance at the time of discovery. Maintenance activities were suspended pending identification of an appropriate processing path for the material and the establishment of appropriate controls. The incident resulted in a review of the adequacy of the ISA treatment for the ARF stripper column. This event was caused by the failure to identify that a gradual accumulation of uranium in the ARF stripper column and its ancillary equipment was a credible mechanism for creating a nuclear criticality hazard. Corrective actions included procedure changes to require periodic washing of the equipment, the establishment of appropriate Items Relied On For Safety (IROFS), and changes to the ISA summary.

2.9.3 Events Recently Added to NMED That Occurred Prior to FY11

One FCP 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
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.

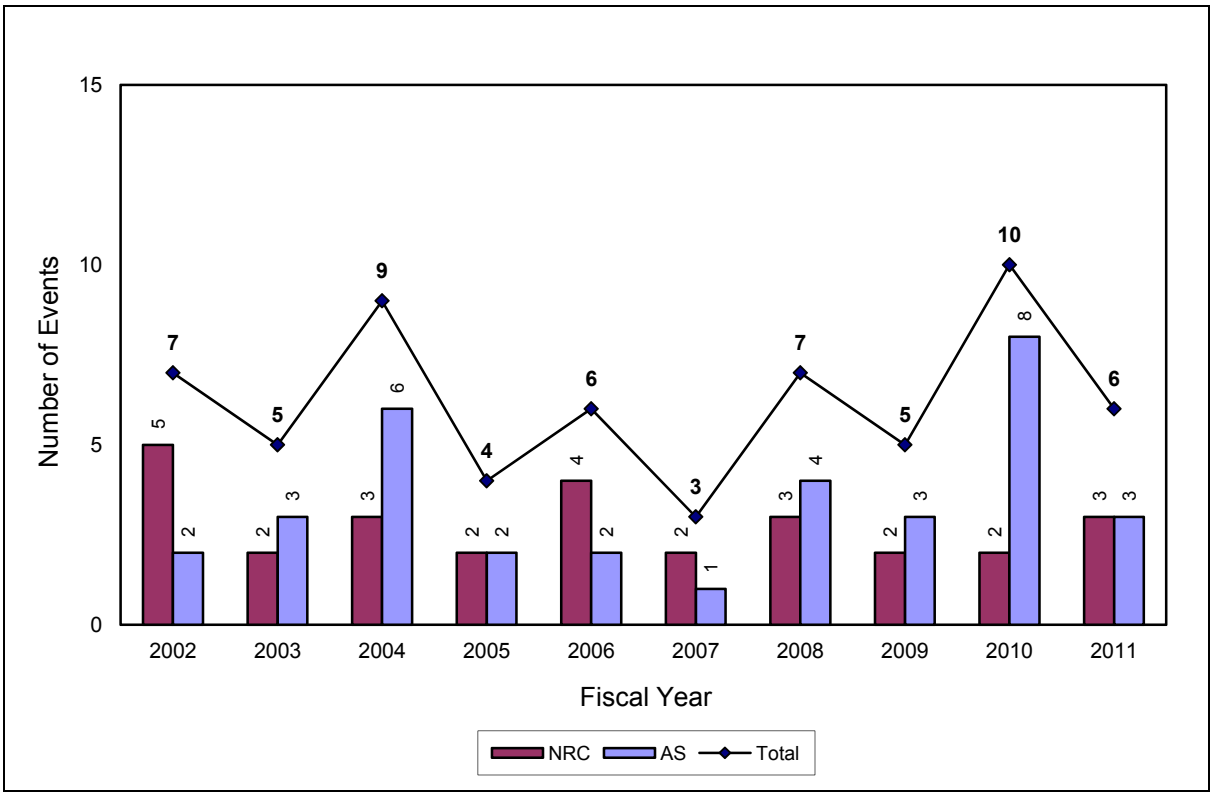

Figure 10. Other Events (62 total)

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

2.10.2 FY11 Data

Six OTH events occurred in FY11, one of which was considered significant.

Significant Events - AOs or Potential AOs

Item Number 110073 - A pregnant patient received 3.63 GBq (98.1 mCi) of I-131 on 1/12/2011 for thyroid ablation. The patient was unaware that she was pregnant and a pregnancy test administered approximately two hours prior to the dose administration had a negative result. Late in the evening of 1/26/2011, the patient was seen in an emergency department complaining of nausea and vomiting. A pregnancy test confirmed that she was pregnant. It was determined that the patient became pregnant during the period of 1/7/2011 to 1/10/2011. A dose calculation performed by the medical center estimated that the dose to the embryo/fetus was 24.68 cGy (rad). An NRC medical consultant concluded that the dose to the embryo/fetus was 27 cGy (rad). Because thyroid tissue capable of concentrating I-131 is formed between 10 and 12 weeks of gestation, this tissue was not formed at the time of treatment. Corrective actions included procedure revision to stress the importance of discussing sexual abstinence prior to therapeutic doses. This event was classified as a potential AO.

Events of Interest

Item Number 100576 - A specialty paper company reported that 14 individuals (contractors and subcontractors) worked near a fixed level gauge while the source shutter was in the open position. The gauge contained a 34.1 GBq (921 mCi) Cs-137 source, which had an original activity of 59.2 GBq (1.6 Ci) in November 1986. The level gauge was mounted to Digester #7, in which the 14 individuals worked for approximately 48 hours starting on 10/11/2010. The Wisconsin Department of Health (WDOH) sent a special inspection team to the facility on 10/14/2010. Five individuals that worked in the digester were interviewed. The longest time any of the five were inside the digester was approximately five hours. A dose re-enactment inside the digester determined that the radiation field two feet from the source holder was approximately 20 mR/hour. WDOH estimated that individuals within two feet of the source holder for five hours would receive a maximum dose of 1 mSv (100 mrem). WDOH required that the company perform an investigation into the doses received by the 14 individuals. WDOH estimated that the highest exposed individual received 0.91 mSv (91 mrem). The company's consultant determined that the highest exposure received was 0.745 mSv (74.5 mrem). The cause of the event was determined to be an inadequate lockout procedure. Contributing factors included poor communication. Corrective actions included writing new policies and procedures, generating new training programs, and providing additional training to personnel.

Item Number 100606 - A radiography services company initially reported that the locking mechanism on a radiography exposure device containing a 3.59 TBq (97 Ci) Ir-192 source failed to activate. It was later determined that the locking mechanism had not failed, but that the radiographers had failed to fully retract and lock the source. The incident occurred on 12/10/2010 when a radiography crew finished operations at one site location and were moving to a new location. The assembled exposure device, crank assembly, and guide tube were placed in the dark room of their truck. They stated that a radiation survey had been conducted to verify the source was fully shielded and in the locked position. As they drove to their new location, they passed nearby another radiography crew and caused their dosimeters to alarm. The radiographers then retracted the source approximately one-quarter of a turn. The radiographers did not notify their management until 12/16/2010. The company performed an investigation, including reenactments of the incident, to determine personnel exposure. Initial estimates revealed that both radiographers were eight feet from the source for approximately 10 minutes and each received 1.7 cSv (rem). Their dosimeters were sent for processing and results revealed that neither radiographer exceeded exposure limits. The company also stated that several pieces of radiography film were lying on the seat of the truck when the event occurred. That film was developed and indicated an exposure of approximately 1.7 cSv (rem). On 12/23/2010, the Texas Department of Health Services performed an onsite investigation and determined that the locking mechanism had not failed, but that the incident was due to human error. Corrective actions included terminating the employment of involved personnel and providing additional training to other personnel.

Item Number 110455 - On 7/8/2011, a radiography services company reported that a member of the public received a dose greater than 2 mR in any one hour. The event occurred during radiography operations on 6/22/2011 at drilling site. The radiography exposure device contained a 2.63 TBq (71.2 Ci) Ir-192 source. A member of the public removed a radiation sign and entered the restricted area. Upon being observed by the radiographers, the source was immediately returned to the shielded and locked position, all radiographic operations were halted, the member of the public was escorted back outside of the controlled area, and the site radiation safety officer was contacted. The dose to the member of the public was estimated to be 33 uSv (3.3 mrem). Corrective actions included re-training radiographers on maintaining surveillance of the controlled area.

Item Number 110598 - A radiography services company reported that there had been a breach in a radiography boundary by two maintenance employees during operations on 9/11/2011. The radiographers were using a 3.5 TBq (94.7 Ci) Ir-192 source and the incident occurred during the seventh exposure of the day. Upon seeing the two individuals in the radiography area, the radiographer

immediately escorted them outside the roped off area. The radiographer then secured the source inside the exposure device. At the time of the incident, the source was on a scaffold platform approximately nine feet above ground level. The two individuals were approximately 12 feet from the source for five seconds. The barricade had fallen to the ground where the individuals entered the area. The barricade rope had come in contact with a hot flange, which caused it to melt and created a 10 to 15 foot breach in the boundary. The estimated exposure to the individuals was 56.8 uSv (5.68 mrem). Corrective actions included procedure modifications and personnel training.

2.10.3 Events Recently Added to NMED That Occurred Prior to FY11

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

Significant Events - AOs or Potential AOs

Item Number 110305 - A pregnant patient was administered 3.52 GBq (95 mCi) of I-131 on 9/22/2006 for thyroid ablation therapy. The hospital had interviewed the patient on 9/8/2006, explained precautions, and warned of becoming pregnant. A pregnancy test was performed on 9/21/2006 and results were negative. It was determined on 12/22/2006 that the patient was pregnant and the conception date was estimated to be between 9/1 and 9/6/2006. Estimates reveal that the embryo/fetus received approximately 25 cGy (rad). The patient was advised to see a genetic specialist to discuss possible consequences. Corrective actions included procedure modification. The New York City Bureau of Radiological Health investigated the incident on 6/16/2011. They concluded that the hospital had followed acceptable protocols prior to administration.

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 × or 1,000 × 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 ≥ 1,000 × 10 CFR Part 20 Appendix C quantity.
20.2201(a)(1)(ii)	Aggregate activity > 10 and < 1,000 × 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(I)(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 <= 100 μCi of other beta and/or gamma emitting material,
- Sources containing <= 10 μCi 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 μCi of removable radioactive material. The leaking source is then removed from service, disposed of or returned to the manufacturer for repair, and a report is sent to the NRC or Agreement State with the details of the leaking source.

For regulatory reporting purposes, a leaking source is generally considered a failed device under 10 CFR 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.
NRCB 91-01	Loss of criticality safety controls, including: 1. The complete loss of a controlled parameter. This criteria includes the loss or inoperability of the criticality alarm system. 2. The substantial degradation of a controlled parameter. This criteria can be used for a malfunction of the criticality alarm system, similar to criteria 1, listed above. 3. Failure of a controlled parameter previously identified by the Commission or the licensee's criticality safety specialists as requiring reporting upon failure. 4. Determining that a criticality safety analysis was deficient in evaluating actual plant conditions and necessary controlled parameters were not established. 5. An unusual event or condition for which the severity and remedy are not readily determined. (Note: This criteria would include any major hazardous chemical releases that occur at the facility.)
S.E.A	Safety equipment actuation.

Other (OTH)

The OTH event category includes the following types of events:

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

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

Table A-10. OTH Reporting Requirements

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

Appendix B

Statistical Trending Methodology

Appendix B
Statistical Trending Methodology

General

The following is a general discussion of statistical trending techniques.

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

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

Fitting a Straight Line to Data

Consider a linear function

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

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

- Each yi is an observed value of a random quantity that is normally distributed [with mean f(xi)], and
- All the observations yi are of variables with a common variance, σ2.

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

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

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

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

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

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

and an estimate of σ is

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

Testing for Trend

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

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

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

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

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

One can show by algebra that

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

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

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

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

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

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

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

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

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

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

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

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

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

Applying the Model to the NMED Data

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

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

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

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

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

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

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

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

Appendix C

IAEA Radionuclide Categorization

Appendix C
IAEA Radionuclide Categorization

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

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

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

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

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

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

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

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

Notes

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

Appendix D

Revision of Data

Appendix D
Revision of Data

The NMED is a dynamic database with new reports and revisions to previous reports being added on a continuing basis. 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 quarters 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.

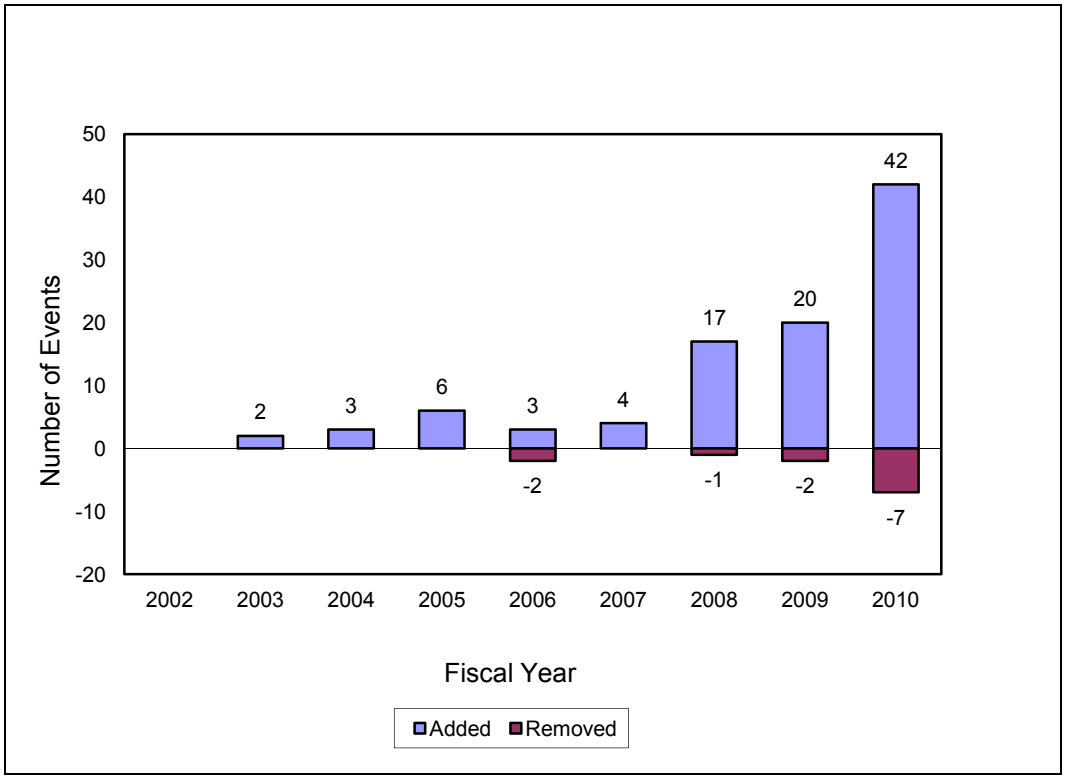

Figure D-1. Changes to All NMED Event Data

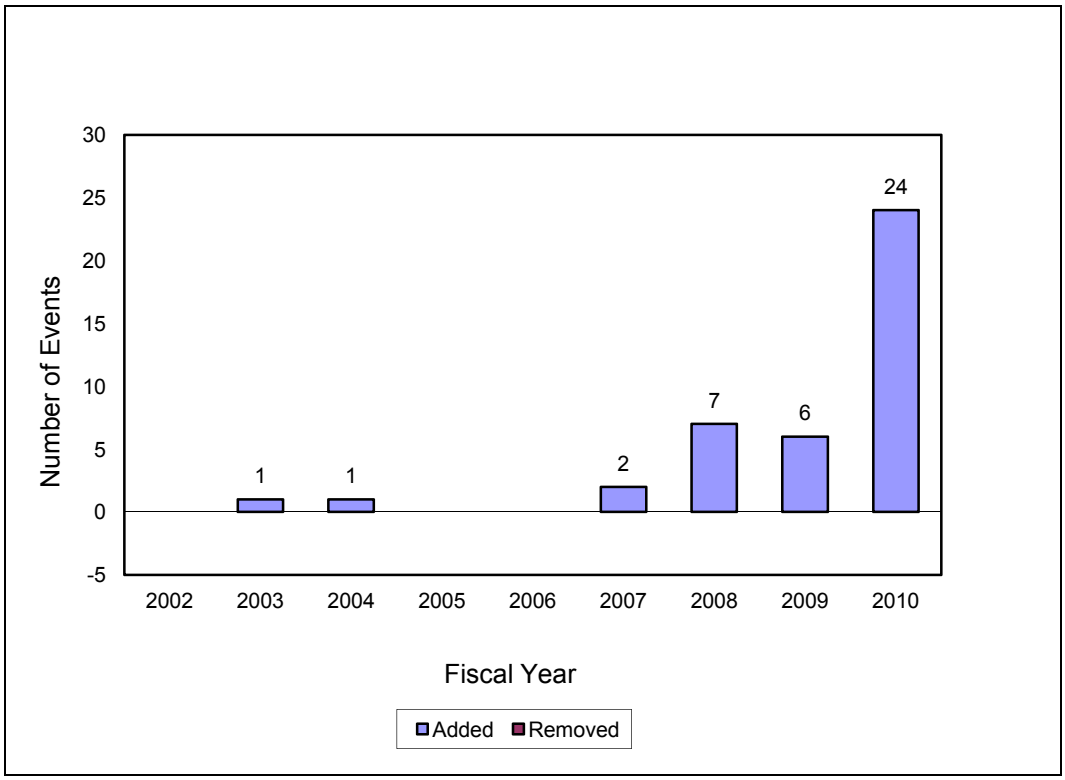

Figure D-2. Changes to LAS Data

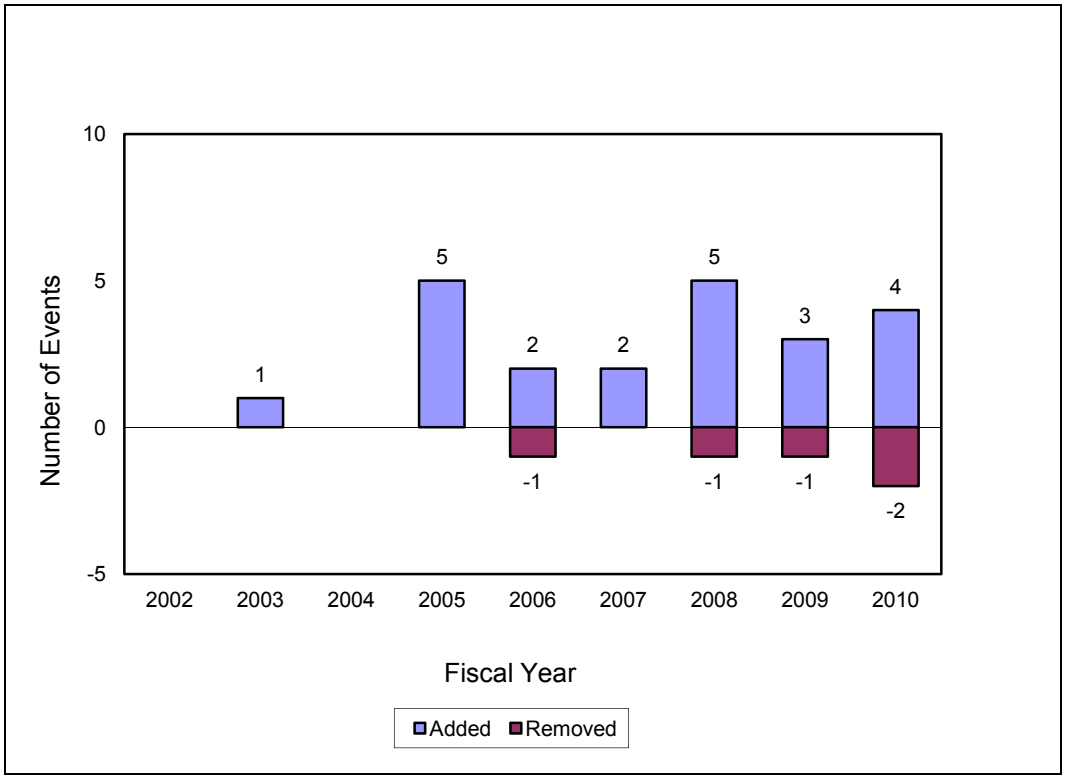

Figure D-3. Changes to MED Data

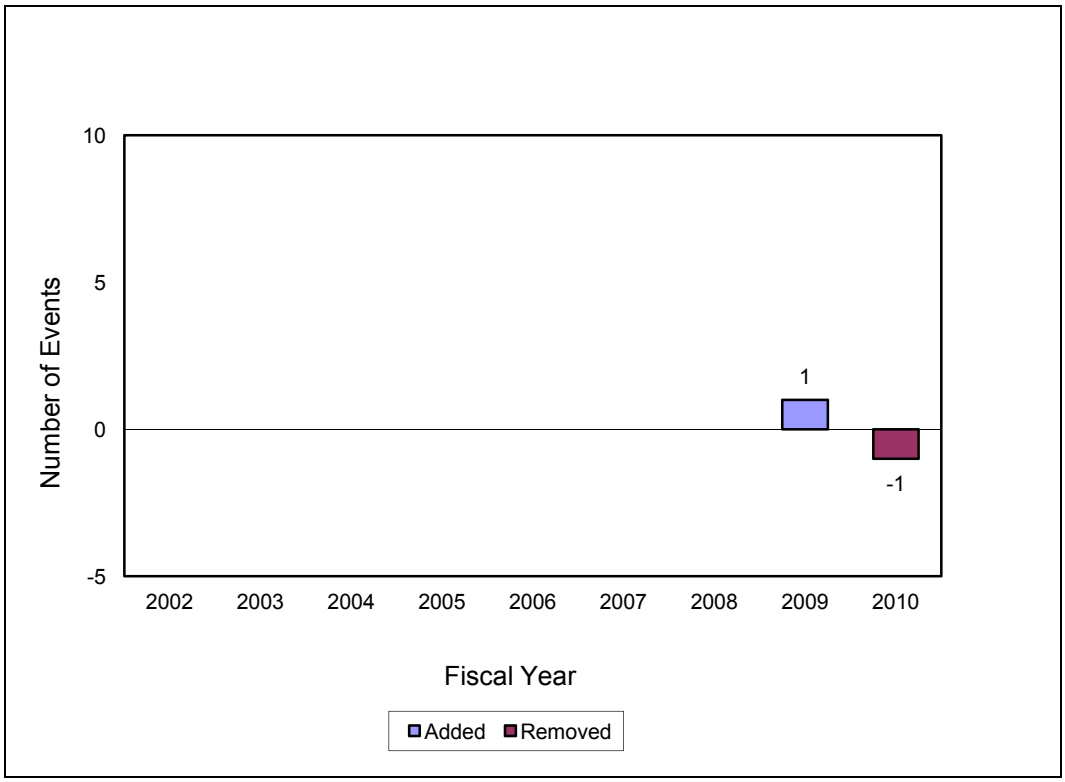

Figure D-4. Changes to EXP Data

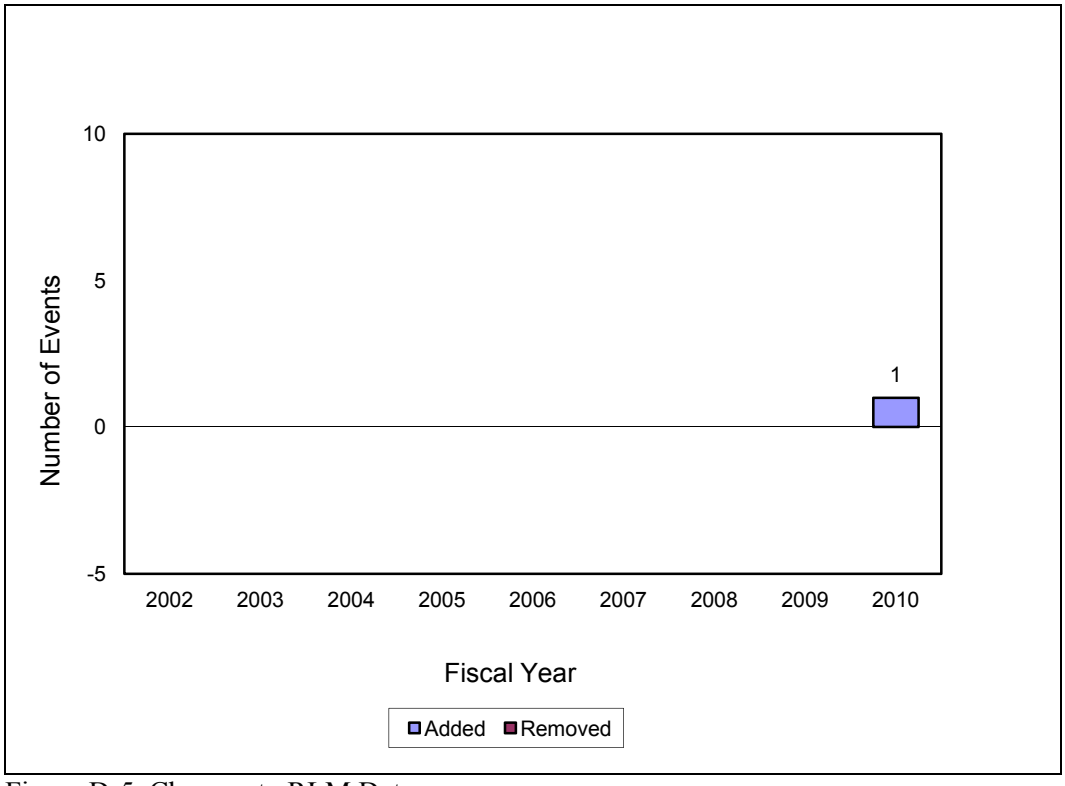

Figure D-5. Changes to RLM Data

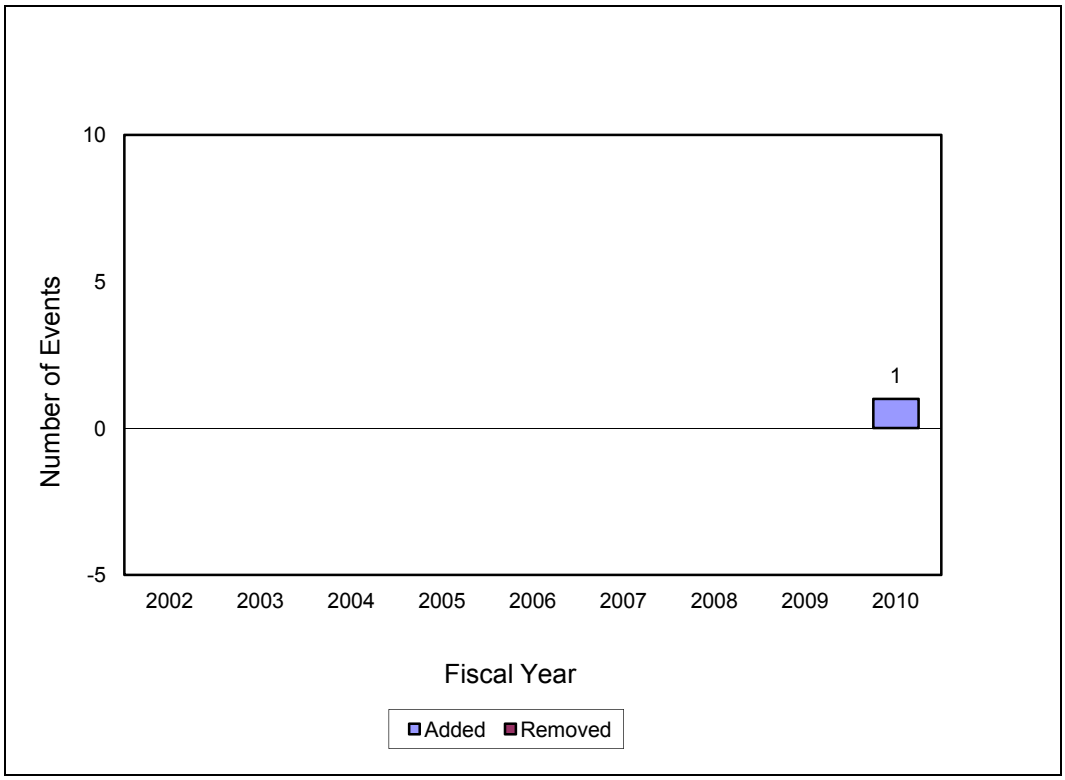

Figure D-6. Changes to LKS Data

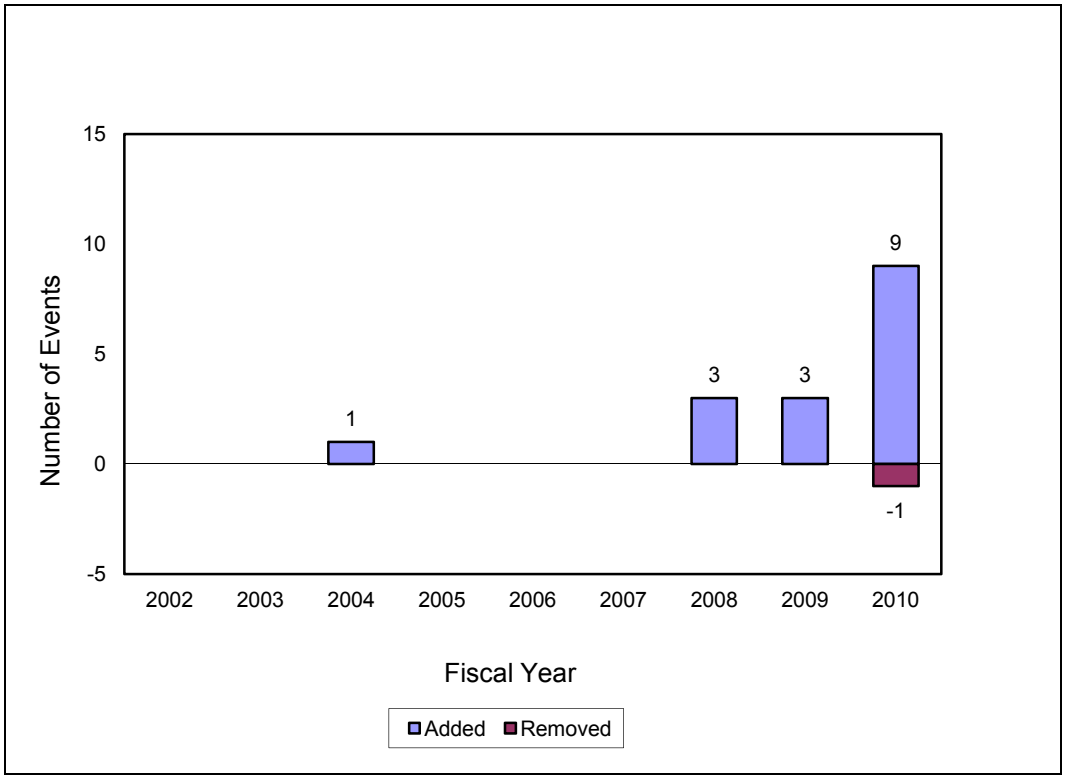

Figure D-7. Changes to EQP Data

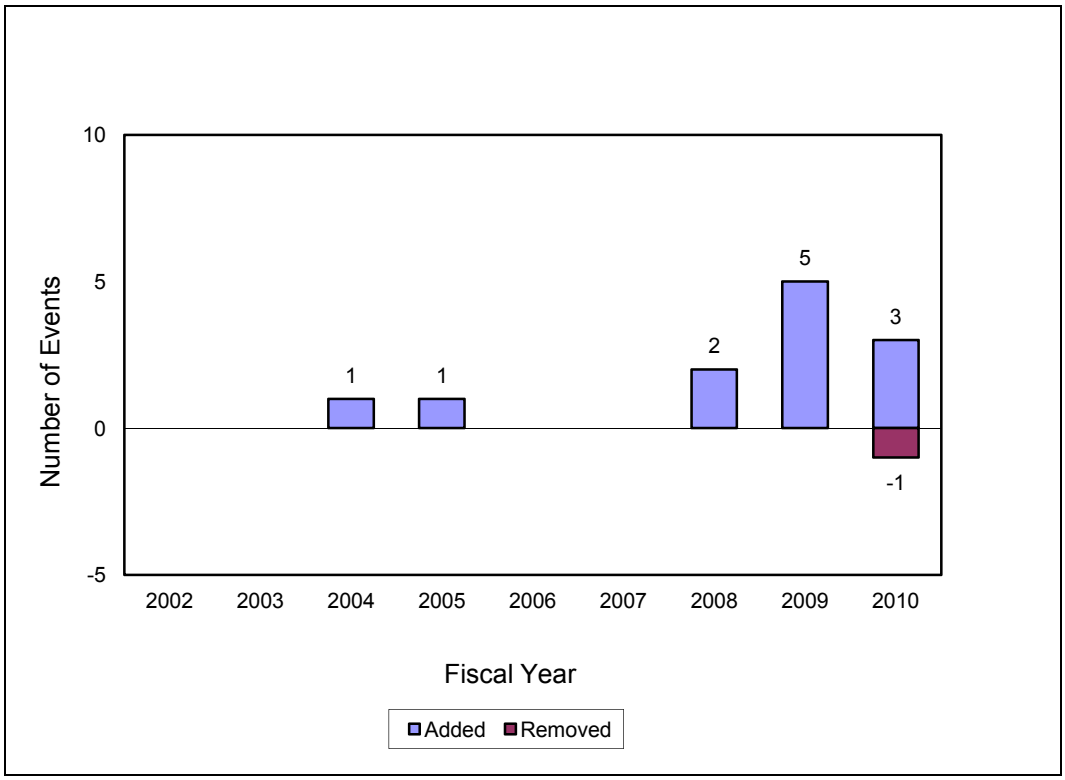

Figure D-8. Changes to TRS Data

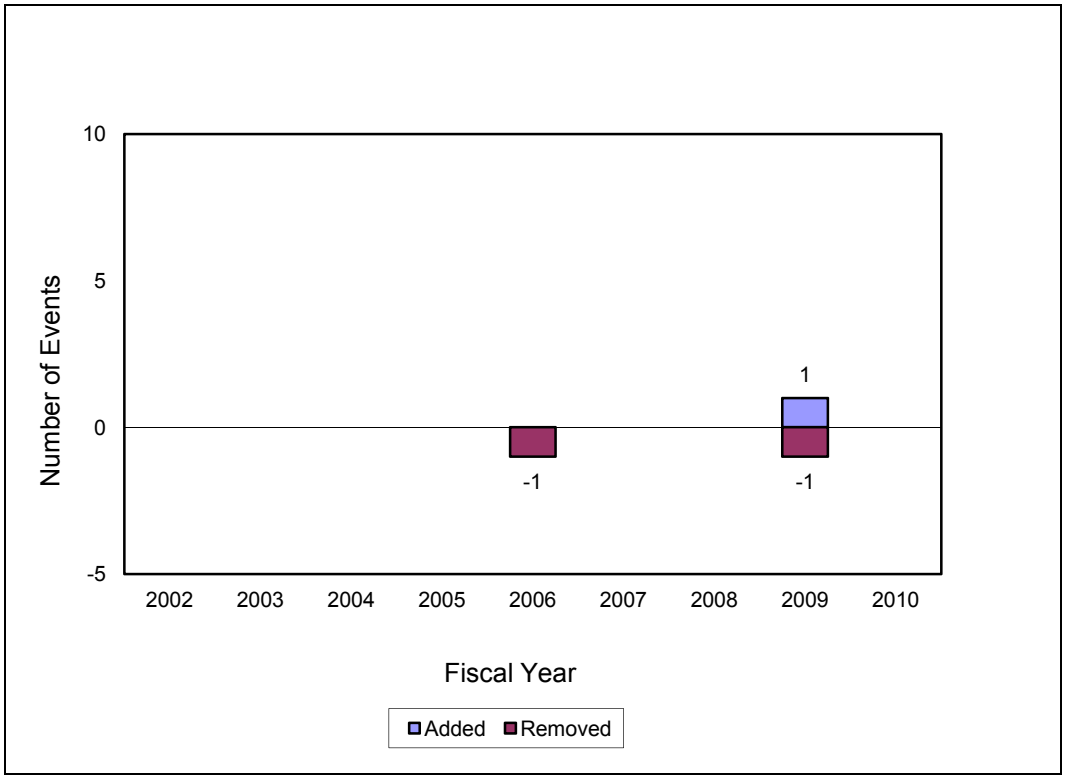

Figure D-9. Changes to FCP Data

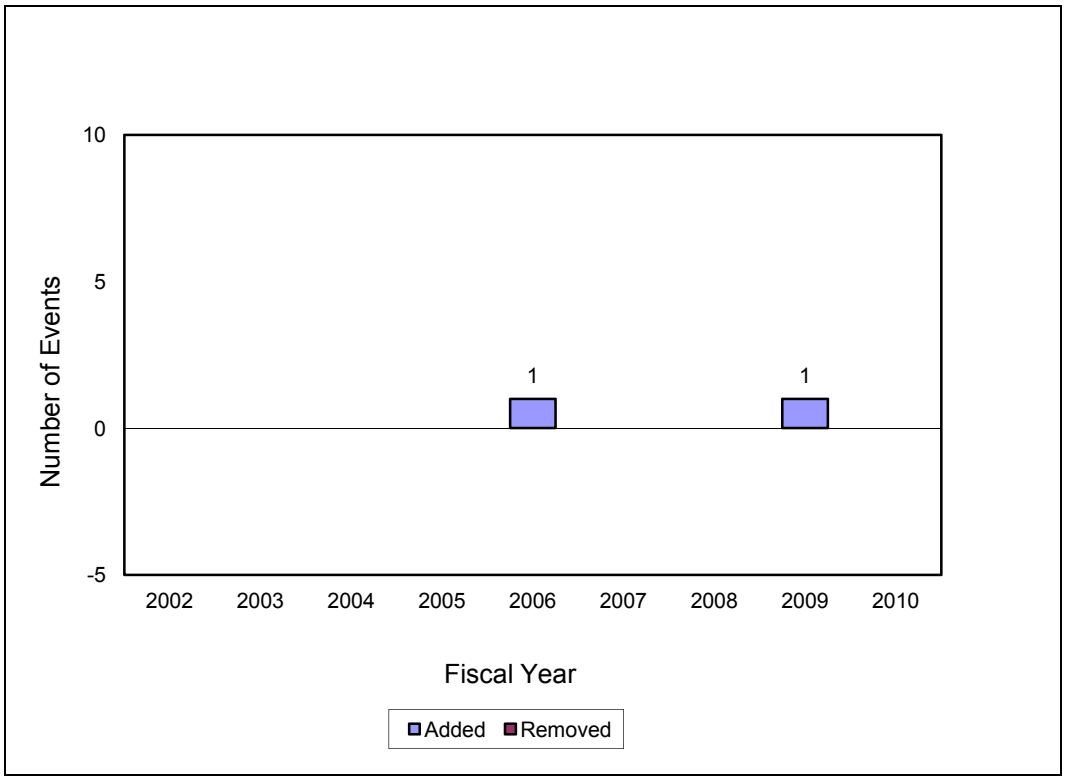

Figure D-10. Changes to OTH Data