

POLICY ISSUE
(Information)

April 7, 2008

SECY-08-0048

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE
PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS
(FISCAL YEAR 2007)

PURPOSE:

The purpose of this paper is to provide the sixth annual report on significant nuclear materials issues and adverse licensee performance trends in the Materials and Waste Programs pursuant to Staff Requirements Memorandum (SRM) SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated February 25, 2003 (ML030560328), and SRM SECY-07-0066, "Annual Report to the Commission on Licensee Performance in the Materials and Waste Programs – Fiscal Year 2006," dated June 20, 2007 (ML071710239). This report covers Fiscal Year (FY) 2007. This paper does not address any new commitments or resource implications.

SUMMARY:

The staff evaluated significant nuclear materials issues and performance trends based on aggregated information obtained from operating experience associated with reportable events and generic issues affecting the industry. With the exception of the review of escalated enforcement actions, this evaluation included both U.S. Nuclear Regulatory Commission (NRC) and Agreement State licensees. The staff concluded, from the assessment of the overall performance data, that there are no discernable trends or generic issues. For FY 2007, there were no nuclear material licensees that met the criteria of significant nuclear materials issues and adverse licensee performance.

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However, an update on the status of Nuclear Fuel Services (NFS), which met the criteria last FY, is provided to discuss ongoing corrective actions.

BACKGROUND:

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

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

In addition, this paper addresses the Commission's SRM of June 20, 2007, concerning the FY 2006 materials and waste programs annual licensee performance report (SECY-07-0066). The SRM directed staff to eliminate direct comparison of high and low risk-significant events, and to specifically make the International Atomic Energy Agency (IAEA) Code of Conduct the central focus on matters of lost, abandoned, and stolen material in future Nuclear Materials Events Database (NMED) quarterly reports and annual licensee performance reports. In response to this SRM, the staff created a new NMED annual report that replaces the NMED fourth quarter report, which was used for previous materials and waste programs annual licensee performance reports. In comparison to the previous NMED fourth quarter report, the new NMED annual report provides the following features:

- Revised the executive summary and individual sections to provide a summary of the risk-significant events;
- Removed performance metrics to eliminate confusion with metrics presented elsewhere in the SECY paper;
- Removed the pie charts for all events to eliminate direct comparison of high and low risk-significant events;
- Resorted the order of the sections within the report to present event types of more interest first;
- Provided a new format for the charts to improve readability and to show comparison between NRC and Agreement State events;
- Removed short-term quarterly data to focus on long-term and annual summary data to better support the annual licensee performance report; and
- Added the IAEA Categorization of Sources to focus the definition of risk-significant lost source data to the IAEA definitions.

DISCUSSION:

The evaluation of significant adverse performance issues and performance trends is based on aggregated information on operating experience associated with reportable events and generic issues affecting the industry. As committed to in SECY-02-0216 (ML022410435), staff has developed a process for providing the Commission with annual updates on significant issues and performance trends that builds on existing processes and systems and has minimal impact on staff resources.

The aggregated information used to evaluate significant adverse performance issues and performance trends was obtained through existing processes and systems and includes the following: (1) Abnormal Occurrences (AO) data; (2) strategic outcomes and performance measures data; (3) data derived through escalated enforcement actions; (4) annual report data based on assessment of events reported to the NMED; (5) generic and special event study results; and (6) significant issues that were identified based on significant issues criteria.

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

(1) Abnormal Occurrences Data:

The staff determined that 11 of the events reported to the NRC in FY 2007, involving the Materials and Waste Programs, met the criteria for AO. The FY 2007 AO Report is scheduled to be published in April 2008. The AO events included five events at NRC-licensed facilities and six events at facilities licensed in Agreement States. All of the five events at NRC-licensed facilities were medical events (including one involving a dose to an embryo fetus). Also, the six Agreement State licensee events were medical events. There is no discernable trend in the number of AO events when data from FYs 1998 through 2007 are compared. A breakdown of the AO events by type of events and jurisdiction of the event (NRC vs. Agreement State) may be found in Enclosure 1 of this paper.

The staff's analysis and evaluation of these events resulted in the finding that human error, including failure to adhere to procedures, was a contributor to the root cause for every event reported as a FY 2007 AO. For 10 of the 11 AO events reported, human error was the primary cause. For these 10 medical events, five of the events involved incorrect input into computer treatment planning software, three of the events involved failure to verify that the sources were placed in the correct position, and two of the 10 events involved not verifying the prescribed dosages (activity). The event that was not primarily due to human error involved a dose to an embryo fetus because of a false negative pregnancy test.

However, given the small number of events reported versus the very large number of total medical treatments and diagnostic procedures performed by medical-use licensees per year, the staff does not believe that these events represent a generic concern.

Also, no significant performance trends or generic concerns were identified when the data for FYs 1998 through 2007 was analyzed.

(2) Strategic Outcomes and Performance Measures Data:

NRC staff focused on verification and validation of data generated by NRC and the Agreement States to determine the impact on strategic outcomes and performance measures, as reported in NRC's "Fiscal Year 2007 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero, and there were no events reported during FY 2007 that met any of the strategic outcomes. Also, the number of events for each performance measure did not exceed 80 percent of the metric.

(3) Data Derived Through Escalated Enforcement Actions:

In past annual materials and waste licensee performance reports, escalated enforcement data was provided by NRC's Office of Enforcement (OE) for a given FY. In 2005, OE began tracking and reporting the agency's enforcement activities by calendar year (CY). In an effort to be consistent with OE current reporting methods, this report will begin providing enforcement information on a CY basis. The current report will cover a 15 month period covering October 1, 2006, through December 31, 2007.

For the period October 1, 2006, through December 31, 2007, NRC issued 84 escalated enforcement actions involving NRC materials licensees, with 74 of these actions in CY 2007. Escalated enforcement in the Materials and Waste Programs includes civil penalties, Orders, and Notices of Violation for Severity Levels I, II, and III violations. Also in this period, there was one enforcement action that resulted in a Severity Level II violation. In the past 6 years, the average for Severity Level I or II violations was about three per year.

There were three in FY 2002, five in FY 2003, five in FY 2004, four in FY 2005, two in FY 2006, and one in FY/CY 2007. Summaries of Severity Level I or II violations for FY/CY 2007 are described in Enclosure 2. No significant performance trends were identified.

(4) Assessment of Data Reported to NMED:

The NMED contains records of events involving nuclear material reported to NRC by its licensees, Agreement States, and non-licensees. These reported events are sorted by event-reporting requirements defined in NRC regulations. The event reports are evaluated to identify any safety-significant events and their causes. NMED data are analyzed for the main event types, and are presented in an annual summary report, in which historical data are aggregated for evaluation of potential trends. The NMED Annual Report is posted on the NMED Web site at <https://nmed.inl.gov> and is directly available to NRC and Agreement State staff. Using event analysis and reviews published in the NMED Annual Reports, performance trends can be identified.

A copy of the FY 2007 NMED Annual Report may be found in Enclosure 3. For the 10 year period covering October 1, 1997, through September 30, 2007, a total of 5,053 events (1,903 NRC and 3,150 Agreement State) associated with materials licensees were reported to the NRC, versus a total of 5,260 events that were reported for the previous 10-year period, covering October 1, 1996, through September 30, 2006. For the current 10-year period, the NMED annual report indicated a slight downward trend for all NMED events.

There could be several possible reasons for this trend including, change in technology, change in regulations, and NRC's change to a performance based inspection program, which results in improved licensee programs. However, a specific reason could not be determined for the trend. Also, after evaluating the NMED, enforcement, and performance metrics data, the staff did not identify any performance issues that were associated with the trend. For several of the individual event types, the NMED annual report also indicated downward trends for NRC events while Agreement State events showed no trend or an upward trend. These trends are believed to be due to the shifting of licensees from NRC jurisdiction to Agreement State jurisdiction.

For FY 2007, 15 of the 393 total reportable events were considered safety significant events. There were three lost radioactive source events, 11 medical events, and one radiation overexposure event. The three radioactive sources that were lost are rated under the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (2004) as Category 2 and 3 sources; two of the sources were Category 2 sources and the other source was a Category 3 source. All three of the sources, however, were recovered. No Category 1 sources were lost in FY 2007. For the 11 medical events, all of the events were abnormal occurrences, and approximately half of these events did not result in significant adverse effects to the patient. One radiation overexposure resulted in a member of the public receiving a calculated dose between 5,000 and 10,000 mrem, which exceeds the public dose limit of 100 mrem and the occupational dose limit of 5,000 mrem.

(5) Generic and Special Event Study Results:

The staff performed a special study to evaluate portable gauge losses and thefts. The data was reviewed to determine any trends in the area of portable gauge losses and thefts in general, and any measurable results from the 10 CFR 30.34(i) rulemaking that became effective in July 2005.

Portable gauges generally contain Americium-241/Beryllium (Am/Be) or Cesium 137 (Cs-137) sources. Based on portable gauge event data from 2002 thru 2007, the total amount of unrecovered Am/Be reported lost or stolen was 7.38 Curies (Ci), which would be rated as IAEA Category 3 amount of material. And, there was 1.81 Ci of unrecovered Cs-137, which would be rated as IAEA Category 4 amount of material.

Analysis of the portable gauge event data also determined the following:

- Theft of gauges from a vehicle occurs more often when at a residence or other location than at a hotel;
- More gauges are stolen (69%) than missing (31%), and a missing gauge is more likely to be recovered than a stolen gauge; and
- More gauges appear likely to be recovered if stolen from a vehicle (average ~ 50%) than from a jobsite (44%).

From examining the data described above, the data does not show a clear trend or indication of the effectiveness of the 10 CFR 30.34(i) rulemaking. The long term data for the period 1998 through 2007 show no trend, but the data after 2005 show a possible drop in portable gauge losses and thefts.

Since there is some indication of a possible drop in the data after 2005, staff will continue to watch the data to see if a definite trend develops over the next 2 to 3 years.

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

Table 1 of SECY-02-0216 defines the criteria to identify those issues and licensees that warrant the highest level of NRC management attention. The criteria target the most critical issues involving: (1) very serious events (those triggering the strategic level measures); (2) significant licensee performance or program issues; or (3) NRC program gaps or failures that have been identified. For FY 2007, there were no nuclear material licensees that met the criteria.

In FY 2006, NFS met the significant-issues criteria, and an update is being provided in Enclosure 4. The staff's analysis outlines the issues and describes the regulatory actions being taken to improve licensee performance.

Overall Performance Conclusions:

Based on the review of events data and assessment of key events, the staff concludes that the Materials and Waste Programs are functioning effectively to protect public health and safety. Based on the significant-issues criteria, there were no licensees that were identified through event evaluations, or other follow-up reviews, as having significant performance issues, during FY 2007. Corrective actions are ongoing for significant issues identified last year.

COORDINATION:

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

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosures:

1. Annual Trend in AO Events from FYs 1999-2007
2. Summary of Severity Level I and II Enforcement Actions for FYs 2002-2007
3. FY 2007 Nuclear Material Events Database Annual Report
4. Update of Nuclear Fuel Services, Inc.

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OFFICE	FSME/DMSSA	FSME/DWMEP	NMSS	NMSS/FCSS	NMSS/SFST	NMSS/DHLW	RGN I
NAME	DWhite	LCamper	YChen	RPierson	BWhite for EWBrach	LKokajko	JKinneman for SCollins
DATE	02/15/08	03/03/08	02/29/08	02/29/08	02/27/08	02/15/08	02/27/08
OFFICE	RGN II	RGN III	RGN IV	NSIR	OGC	OE	OI
NAME	DCollins for VMcCree	SReynolds for JCaldwell	LWert for ECollins	MShaffer for RZimmerman	BJones (NLO)	CCarpenter	GCaputo
DATE	03/03/08	02/29/08	02/27/08	03/04/08	02/27/08	03/03/08	03/04/08
OFFICE	FSME/DMSSA	NMSS	TechEditor	FSME	EDO		
NAME	RLewis	MWeber	CPoland	CLMiller	LAReyes		
DATE	03/12/08	03/19/08	03/21/08	03/28/08	04/07/08		

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ANNUAL TREND IN ABNORMAL OCCURRENCE EVENTS FROM FY 1998 - 2007

Table 1 shows the number of events reported annually that were determined to meet the Abnormal Occurrence (AO) criteria. A total of 98 events were found to meet the AO criteria for the 10-year period 1998 - 2007. Of these 98 events, 34 of the events were by U.S. Nuclear Regulatory Commission (NRC) licensees and 64 of the events were by Agreement State (AS) licensees. Eighty percent of the AO events are medical events. However, the relative higher number of medical events determined to be AOs is not necessarily an indication of relative performance between the medical industry and other industries. One reason why medical events make up a large fraction of AOs is that medical therapy procedures use large sources of radiation in very close proximity to or within the body. Due to the close proximity of the sources, small errors in source location can cause high radiation doses to unintended locations, resulting in unintended doses that exceed the AO criteria. There is no discernable trend in the total number of AO events when data from FYs 1998 through 2007 are compared. Also, there were no discernable trends when analyzing NRC AO data and AS AO data separately.

It is noteworthy that although events involving the loss or theft of material account for about 45 to 50 percent of the number of events reported to NRC each year, only 1 loss/theft event in 9 years have been found to meet the AO criteria. The average number of AOs per year over the last 10 years is 9.8.

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

Year	Lost/Stolen		Medical		Personnel Overexposure		Fuel Cycle Facility		Totals	
	NRC	AS	NRC	AS	NRC	AS	NRC	AS	NRC	AS
1998	0	0	3	1	1	0	1	0	5	1
1999	0	0	3	7	0	2	1	0	4	9
2000	0	0	1	6	1	0	0	0	2	6
2001	0	0	0	0	1	1	0	0	1	1
2002	0	1	1	3	1	3	0	0	2	7
2003	0	0	5*	7	0	2	0	0	5	9
2004	0	0	2	12*	0	1	2	0	4	13
2005	0	0	3	6*	0	0	0	0	3	6
2006	0	0	2*	5*	0	1	1	0	3	6
2007	0	0	5*	6	0	0	0	0	5	6
Totals	0	1	25	53	4	10	5	0	34	64

*Include events involving a dose to embryo/fetus.

SUMMARY OF LEVEL I AND II ENFORCEMENT ACTIONS FOR FY/CY 2007

**Alpha Omega Services
Bellflower, CA
EA 07-215
Docket Nos. 71-5979, 71-0086**

Severity Level II

On December 20, 2007, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$19,200 were issued for a Severity Level II violation. In January 2003, the company deliberately provided materially inaccurate information to an NRC licensee and to a contractor for the licensee in violation of 10 CFR 71.8(b)(2). The company Operations Manager/Assistant Radiation Safety Officer signed a maintenance checklist indicating that a package was in compliance with the NRC Certificate of Compliance and approved for use, when he knew it was not. Additionally, in violation of 10 CFR 71.8(b)(1), Alpha Omega Services deliberately caused the NRC licensee to violate NRC requirements for a license when the licensee exported licensed material in nonconforming packages.



February 2008

Nuclear Material Events Database

Annual Report

Fiscal Year 2007

Prepared for the U.S. Nuclear Regulatory Commission
by the Idaho National Laboratory (INL/EXT-08-13749)

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Nuclear Material Events Database

Annual Report

Fiscal Year 2007

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Robert L. Sant, INL

Published February 2008
<https://nmed.inl.gov>

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Idaho Falls, Idaho 83415**

Prepared for the
U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs
Under U.S. Department of Energy-Idaho Operations Office
Contract DE-AC07-99ID13727

ABSTRACT

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

Copies of this report are available on the NMED website at <https://nmed.inl.gov>.

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EXECUTIVE SUMMARY

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

The safety significant events that occurred in Fiscal Year 2007 are summarized below.

Lost/Abandoned/Stolen Radioactive Sources/Material

No Category 1 sources were lost, abandoned, or stolen. Two Category 2 sources were lost (both of which were recovered) and one Category 3 source was lost (which was recovered).

Medical Events

Eleven medical events were classified as potential Abnormal Occurrences.

Radiation Overexposure Events

One overexposure event was classified as a safety significant event and resulted in a 5-10 rem whole body dose to a member of the public.

Release of Licensed Material or Contamination Events

There were no safety significant release of licensed material or contamination events.

Leaking Sealed Source Events

There were no safety significant leaking sealed source events.

Equipment Failure Events

There were no safety significant equipment failure events.

Transportation Events

There were no safety significant transportation events.

Other Events

There were no safety significant other events.

Nuclear Material Events Database Annual Report: Fiscal Year 2007

1. INTRODUCTION

1.1 Overview and Objectives

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

A database for tracking nuclear material events was developed by the Nuclear Regulatory Commission (NRC) in 1981. In 1993, using existing material events databases, the NRC developed a new and more comprehensive database for tracking material events. This database, designated the Nuclear Material Events Database (NMED), contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by the Idaho National Laboratory (INL) and contains approximately 18,000 records of material events submitted to the NRC from approximately January 1990 through December 2007.

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

1. Lost/Abandoned/Stolen Material (LAS),
2. Medical (MED),
3. Radiation Overexposure (EXP),
4. Release of Licensed Material or Contamination (RLM),
5. Leaking Sealed Source (LKS),
6. Equipment (EQP),
7. Transportation (TRS), and
8. Other (OTH).

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

1.2 NMED Data

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

The data presented in this report are limited to reportable events that occurred between October 1, 1997, and September 30, 2007. The data were downloaded from the NMED on December 6, 2007. Because the NMED is a dynamic database that is updated daily, variations in data may be encountered over time. Furthermore, even though many events were reported and entered in the database for operational experience purposes, only those events required to be reported by 10 CFR are addressed in this report.

This report displays annual trend data for each of the event categories for a 10-year period. A trend analysis was performed on each event category to identify the existence or absence of a statistically

significant trend. If a statistically significant trend exists, the display indicates the direction and approximate rate of change with a trend line. For the purposes of this report, a statistically significant trend exists if the analysis indicates that the computed fit and slope of a least squares linear model is valid at a 95% confidence level. A primer on the statistical methods employed in the trend analysis is presented in Appendix B.

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

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

For assistance on searches or other questions, contact Michele Burgess (mlb5@nrc.gov), (301) 415-5868.

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 (FY98-07).

2.1 All NMED Events

Figure 1 displays the annual number and trend of the 5,053 NMED events that occurred during the 10-year period. The trend analysis determined that the data represent a statistically significant decreasing trend in the number of Total and NRC-regulated events (indicated by the trend lines). However, the Agreement State-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line). Therefore, variations within the annual Agreement State values represent random fluctuation around the average of the data.

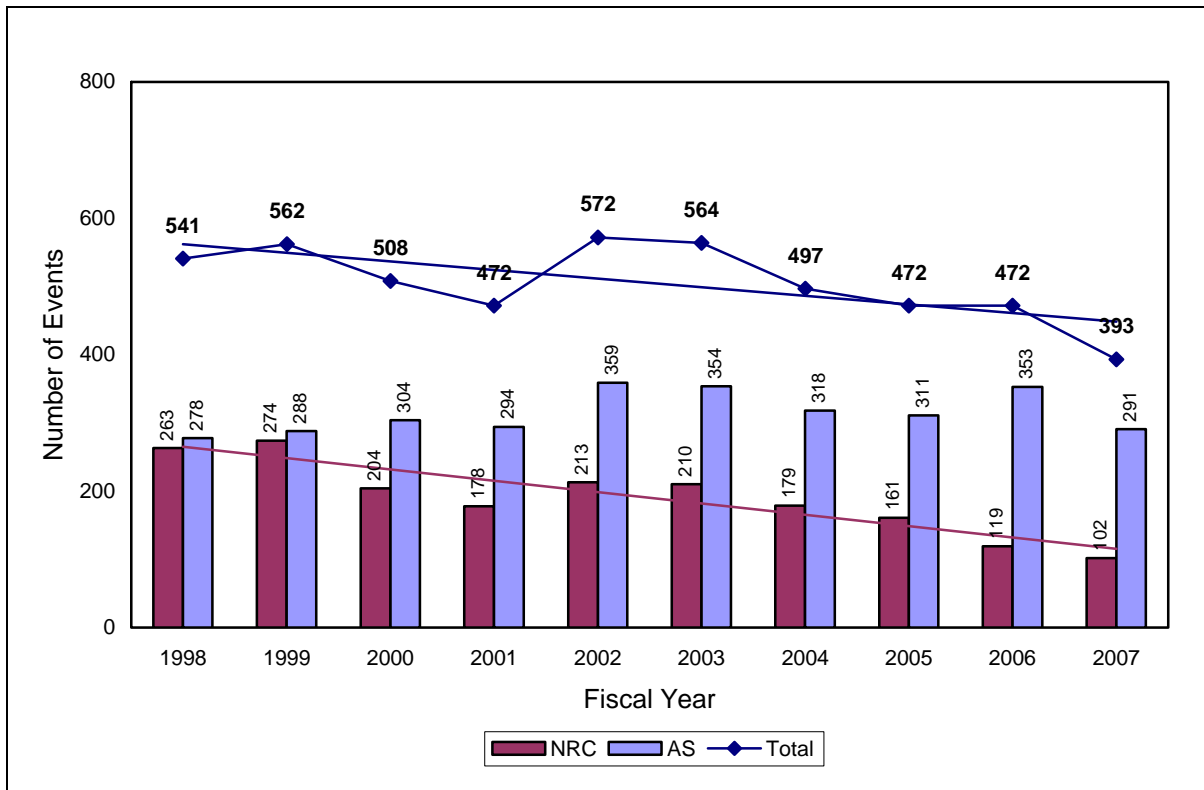


Figure 1. All NMED Events (5,053 total)

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

1. The most recent year's data are typically several records less than their final value when subsequent updates and late reports are received. This effect may exaggerate the slope of a decreasing trend.
2. The NRC's Sensitive Information Screening Process (SISP) reduced the number of public documents available in ADAMS for input into NMED since FY05, but did not necessarily reduce the number of NMED event records.
3. The revised 10 CFR 35 became effective October 2002. This revision relaxed previous reporting requirements and could result in a decreased number of reportable medical events.
4. The transition of states from NRC to Agreement State jurisdiction could result in increasing trends in Agreement State data and decreasing trends in NRC data.

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

Table 1. Summary of Trending Analysis

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

Notes:

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

2.2 Lost/Abandoned/Stolen Material

2.2.1 Ten-Year Data

Figure 2 displays the annual number and trend of the 2,350 LAS events that occurred during the 10-year period, excluding irretrievable well-logging sources abandoned in accordance with 10 CFR 39.77. The trend analysis determined that the data do not represent statistically significant trend in the Total number of events (indicated by the absence of a trend line). Therefore, variations within those annual values represent random fluctuation around the average of the data. However, the NRC-Regulated events represent a statistically significant decreasing trend, while the Agreement State-regulated events represent a statistically significant increasing trend (indicated by the trend lines).

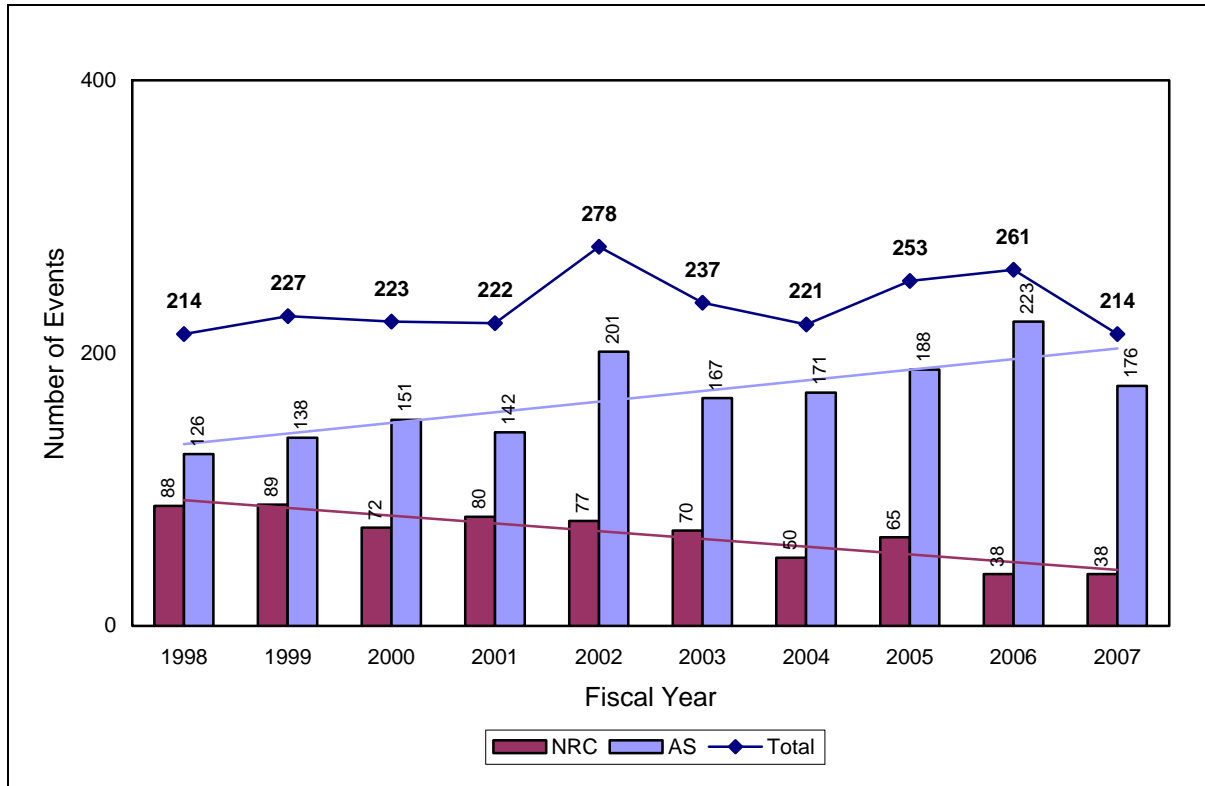


Figure 2. Lost/Abandoned/Stolen Material Events (2,350 total)

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

The 2,350 LAS events that occurred during the ten-year period involved the loss of approximately 4,363 sources. Table 2 displays the number of sources lost during the 10-year period and the number that have not been recovered, grouped by the IAEA category where possible. During the 10-year period, no Category 1 sources, 55 Category 2 sources, and 18 Category 3 sources were lost. All but five of the Category 2 and six of the Category 3 sources were recovered.

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

Category		Fiscal Year										Total
		1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	
1	LAS ⁵	0	0	0	0	0	0	0	0	0	0	0
	NRec ⁶	0	0	0	0	0	0	0	0	0	0	0
2	LAS	9	10	3	7	3	5	5	8	3	2	55
	NRec	1	1	0	1	0	0	0	1	0	0	4
3	LAS	2	0	1	0	3	0	1	6	4	1	18
	NRec	1	0	1	0	0	0	0	4	0	0	6
4	LAS	66	74	71	83	82	86	76	108	95	54	795
	NRec	31	38	25	32	31	29	30	34	49	21	320
5	LAS	109	99	89	131	123	137	107	148	108	64	1115
	NRec	69	54	38	62	53	61	36	55	43	22	493
<5	LAS	1	1	2	2	4	2	4	7	0	2	25
	NRec	0	1	2	2	2	1	4	4	0	0	16
Activity Not Known ¹	LAS	17	8	2	3	15	1	8	3	7	3	67
	NRec	15	7	0	2	6	0	3	0	1	0	34
		0										
Nuclide Not Known ²	LAS	3	2	1	1	1	1	0	3	0	0	12
	NRec	1	0	0	0	0	1	0	0	0	0	2
Other ³	LAS	173	196	251	149	307	262	249	221	238	230	2276
	NRec	99	123	179	92	200	158	170	134	116	104	1375
Total	LAS	380	390	420	376	538	494	450	504	455	356	4363
	NRec	217	224	245	191	292	250	243	232	209	147	2250

Notes:

1. The “Activity Not Known” category includes sources containing radionuclides listed in Appendix C for which the activity was not reported. Therefore, the sources were not included in Categories 1 thru 5.
2. The “Nuclide Not Known” category includes those sources for which the radionuclide was not reported. Therefore, the sources were not included in Categories 1 thru 5 or Other.
3. The “Other” category includes sources containing radionuclides not included in Appendix C.
4. Tables 3 and 4 provide more detail regarding the 10-year and current year “not-recovered” data highlighted in yellow and green, respectively. If printed in black and white, these highlights show as lighter and darker shading, respectively.
5. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a vial of brachytherapy seeds may be entered as a single

source with a total combined activity). The Category 1 thru 3 source counts were corrected for the “aggregate” source events.

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

Table 3 displays radionuclide data pertaining to the 331 IAEA Category 1 thru 4 sources lost during the 10-year period that have not yet been recovered. The Decayed Activity values are conservative estimates in that the values are typically decayed from the loss date instead of the manufacture’s assay date. As a result, the actual decayed activities (based on manufacture’s assay date) are less than the estimates. Table 4 is similar to Table 3, but limited to the current fiscal year.

Table 3. Summary of IAEA Category 1 thru 4 Sources Not Recovered (Fiscal Years 1998 thru 2007)

Radionuclide	Half Life ¹	Number of Sources Not Recovered ²	Total Activity (Ci)	Total Decayed Activity (Ci) ³	Aggregate IAEA Category ⁴
Am-241	432.7 years	44	4.414475	4.367596	3
Am-Be	432.7 years	252	14.3193	14.192378	3
Cm-244	18.1 years	4	0.29	0.250282	4
Cs-137	30.07 years	20	4.019	3.45791	3
Ir-192	73.83 days	8	236.01	0.010972	5
Pu-238	87.7 years	1	3	2.774181	3
Sr-90	28.78 years	1	0.997	0.855258	4
Total		330	263.049775	25.908577	2

Notes:

- Half-life values from the Chart of the Nuclides, 16th Edition.
- Events involving a large number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a vial of brachytherapy seeds may be entered as a single source with a total combined activity). Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The Category 1 thru 3 “aggregate” and “partially recovered” source counts were corrected; the Category 4 data was not corrected.
- The source activities were decayed from the event date to 12/06/2007 (data download date).
- The equivalent IAEA Category based on the decayed activity if all of the sources were in a single location (unrealistic worst-case).

Table 4. Summary of IAEA Category 1 thru 4 Sources Not Recovered (Fiscal Year 2007)

Radionuclide	Half Life ¹	Number of Sources Not Recovered ²	Total Activity (Ci)	Total Decayed Activity (Ci) ³	Aggregate IAEA Category ⁴
Am-241	432.7 years	3	0.28	0.27961	4
Am-Be	432.7 years	16	0.678	0.677377	4
Cs-137	30.07 years	2	0.33	0.327348	4
Total		21	1.288	1.284335	4

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a large number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a vial of brachytherapy seeds may be entered as a single source with a total combined activity). Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The Category 1 thru 3 “aggregate” and “partially recovered” source counts were corrected, the Category 4 data was not corrected.
3. The source activities were decayed from the event date to 12/06/2007 (data download date).
4. The equivalent IAEA Category based on the decayed activity if all of the sources were in a single location (unrealistic worst-case).

2.2.2 FY07 Data

Two hundred fourteen LAS events occurred in FY07, involving the loss of approximately 356 sources, 148 of which have not been recovered. Of the 356 lost sources, none were Category 1, two were Category 2 (both of which were recovered), and one was Category 3 (which was recovered).

Significant Events—Category 1 Source Events

None.

Significant Events—Category 2 Source Events

Event 070050 involved the loss and recovery of a radiography exposure device that contained a 3.7 TBq (100 Ci) Ir-192 source. On 1/21/2007, a radiographer was traveling in his truck with a dark room on the back. The device was secured in a yellow box in the dark room. When the radiographer attempted to cross moving water, the truck engine stalled. The radiographer exited the truck, which was subsequently swept away. Oklahoma Emergency Management, local law enforcement, and Oklahoma State Police were notified and initiated a search for the truck. The truck was located on 1/22/2007 and the licensee recovered the exposure device on 1/24/2007.

Event 070260 involved the loss and recovery of a radiography exposure device that contained a 1.15 TBq (31 Ci) Ir-192 source. The device was lost during shipment from Anchorage, Alaska, to Baton Rouge, Louisiana, where it was being shipped for source replacement. Three devices were shipped, but only two arrived as scheduled on 4/26/2007. The device owner’s RSO was notified of the missing shipment by the receiving company on 4/30/2007. The shipping company’s tracking system confirmed that the device was in Oakland, California. The device was delivered to its intended destination on 5/1/2007.

Significant Events—Category 3 Source Events

Event 070426 involved the loss and recovery of a 222 GBq (6 Ci) Ir-192 brachytherapy source during a shipment from Twin Falls, Idaho, to Edgerly, Louisiana. During transit, a label that was on the source

shipping bucket was torn off and affixed to another package containing an aircraft part. When the receiving company received the aircraft part with the source mailing label attached, they assumed the source had been lost, and reported the incident. However, the receiving company had actually received the source bucket on 07/09/2007, two days before reporting the lost source. The bucket had a smaller barcode label that enabled FedEx to deliver the package without the original handwritten label. The company's receipt procedures appeared to have been followed on 07/09/2007, the bucket had been surveyed and wiped for contamination, then placed in storage.

Events of Interest

Event 070116 involved the loss of a 25.9 GBq (700 mCi) Cs-137 well logging source that caused personnel to receive radiation dose in excess of the limit for members of the public. The source dose rate was determined to be 264 R/hr skin dose at one inch. On 2/22/2007 at approximately 0600 CST, the well logging crew unknowingly dropped the source in the motor pool parking lot while loading it into a pig. At approximately 0900 CST, the source was picked up by a mechanic who placed it in his jacket pocket. The mechanic wore the jacket for about four hours. He visited several businesses and later hung the jacket on a bollard in an area where individuals were working. The jacket was later moved to a break room overnight. On 2/23/2007, the mechanic put the jacket back on. The well logging crew returned to the facility at approximately 0600 CST and discovered the source missing when they unpacked their equipment. The source was not discovered missing earlier because it was not needed in the field. The crew immediately started searching for the source. The mechanic produced the source when he heard it was missing. In total, the mechanic wore the jacket approximately 5.5 hours. The mechanic and a couple of co-workers were taken to a local hospital for examination. No abnormalities were noted. The mechanic was seen by a physician at the Oklahoma University Health Sciences Center (OUHSC). The physician believed that the mechanic would suffer from radiation burns on his abdomen and possibly on his finger tips. A blood sample was taken and shipped to RPA in London, England, for cytogenetic analysis. Their report cited damage that is slightly above normal background, perhaps indicating an exposure of 10 cGy (rad) averaged whole body dose. The report included uncertainties due to sampling statistics such that the upper and lower 95% confidence limits are 20 cGy (rad) and zero, respectively. The NRC and the Oklahoma Department of Environmental Quality calculated a dose of between 5 and 10 cSv (rem). It was stated that the only symptom displayed by the mechanic was some gastrointestinal upset, which could have been caused by emotional stress related to the incident. The mechanic denied any radiation burn symptoms. Regarding others who may have received dose in excess of limits due to this event, a co-worker who rode to lunch with the mechanic was identified as being most at-risk. This event was caused by the failure to conduct surveys during transfer of the source and the failure of the source handling tool and pig to positively secure the source. To prevent recurrence, the licensee removed similar sources from service pending upgrade of the source handling sticks, modified their procedures, retrained personnel. This event was classified as an EXP and LAS event.

Event 070277 involved the loss of a small amount of special nuclear material (SNM) from a commercial nuclear power plant. As part of preparations for an NRC inspection of the licensee's SNM Control and Accounting Program, documentation concerning the recovery of two pieces of a broken fuel rod was obtained. The documentation revealed the existence of potential fuel particles estimated to be less than 1 gram in aggregate located in the spent fuel pool. The location of those particles cannot be positively identified at this time. The particles were created during a 1990 refueling outage while inspecting a leaking fuel bundle. To identify the leaking rod, the bundle was disassembled and rod-by-rod electronic sorting was performed. Ultrasonic examination identified the leaking rod; however, during the inspection the rod bent and snapped while being guided through a fuel inspection funnel. A procedure was approved and successfully executed to recover the broken rod sections. Following the recovery, an inspection was performed with an underwater camera to determine if any fuel pellets had been released as part of the evolution. No fuel pellets were identified; however, a small dark particle of material surrounded by smaller black particles was observed in a stainless steel bucket which had been positioned under the broken fuel rod pieces. It is believed that the bucket containing the particles was suspended off the west

wall of the spent fuel pool, north of the work table. The location of the particles within the bucket cannot be positively identified at this time. The contents of the bucket were described as a small particle of material roughly the size of a fingernail clipping surrounded by a few black particles the size of ground pepper. An underwater survey indicated a radiation level of greater than 400 R/hr on contact. The total amount is believed to be considerably less than 10 percent of a single pellet worth of material, or less than 1 gram. Energy Northwest is continuing to investigate the event. Based on the information gathered to date, the nature of the particles, and the existence of radiation monitoring, a high degree of confidence exists that the particles are located in the bottom of the spent fuel pool or in an otherwise radiologically controlled location such that the health and safety of the public would not be adversely affected. In addition, there is no evidence of theft or diversion.

Event 070416 involved the loss of two fuel pellets and a number of in-core detectors (less than one gram of fuel material total) from a commercial nuclear power plant. The discovery was made during a review of the station's SNM accounting records. According to a 1977 report, the fuel pellets were placed in the spent fuel pool, but they could not be located during the May 2007 inspection. During this same review, personnel determined that some records for storing and shipping in-core detectors were missing. These issues are not expected to result in a safety or security hazard because the fuel pellets could not have been removed by individuals without alarming the radiation monitoring equipment. The fuel pellets and in-core detectors are believed to be on-site or they could have been shipped to an NRC-regulated disposal site. An NRC inspection in June 2007 found that the station failed to keep complete records, conduct adequate inventories, and have procedures sufficient to account for SNM. Corrective actions include revising material accountability and control procedures, visual verification of SNM on an annual basis for required locations, and retaining SNM records for the lifetime of the station.

Event 070502 involved a fire at a military warehouse. A security patrol on 8/6/2007 noticed smoke coming out of the building. Firefighters extinguished the fire using chemical extinguishers and the least amount of water possible in order to reduce the spread of contamination. The firefighters wore respiratory protection and only entered the building after extinguishing the majority of the fire and forcing most of the remaining smoke out with a large fan. The fire involved a worktable and wooden storage bins, which contained several H-3 sources awaiting disposal. Many of the sources burst due to the heat. Surveys of firefighting personnel and equipment revealed no contamination. Personnel (including the firefighters) submitted bioassay samples the following day to ensure no uptake occurred, and the resulting doses were all less than 0.01 mSv (1 mrem) total effective dose equivalent (TEDE). Initial radiation surveys of the sealed floor area, approximately 10 foot by 10 foot, revealed levels between 8,000 and 28,000 dpm/100 cm². The RSO performed an inventory of the contents of the building and calculated a release of approximately 25.9 TBq (700 Ci) of H-3 from 92 devices. The ruptured devices included 32 aiming posts, 40 muzzle reference sensors, 10 elbow telescopes, and 10 various other devices (rifle and pistol sights, etc.). An assessment of the offsite dose indicated that doses beyond the immediate area of the building were less than 0.001 mSv (0.1 mrem) TEDE at 0 to 10 miles. The cause of the fire was determined to be a chemical reaction involving oily paper towels and hydrogen peroxide in a sealed plastic bag that were used to decontaminate H-3 on 8/4/2007 after a forklift crushed three fire control devices. Corrective actions included discontinuing the use of hydrogen peroxide as a decontamination agent, no longer storing decontamination materials with radioactive materials, and retraining staff. This event was classified as an EQP and LAS event.

2.3 Medical

2.3.1 Ten-Year Data

Figure 3 displays the annual number and trend of the 383 MED events that occurred during the 10-year period. The trend analysis determined that the Total and Agreement State-regulated events do not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data. However, the NRC-regulated events represent a statistically significant decreasing trend (indicated by the trend line).

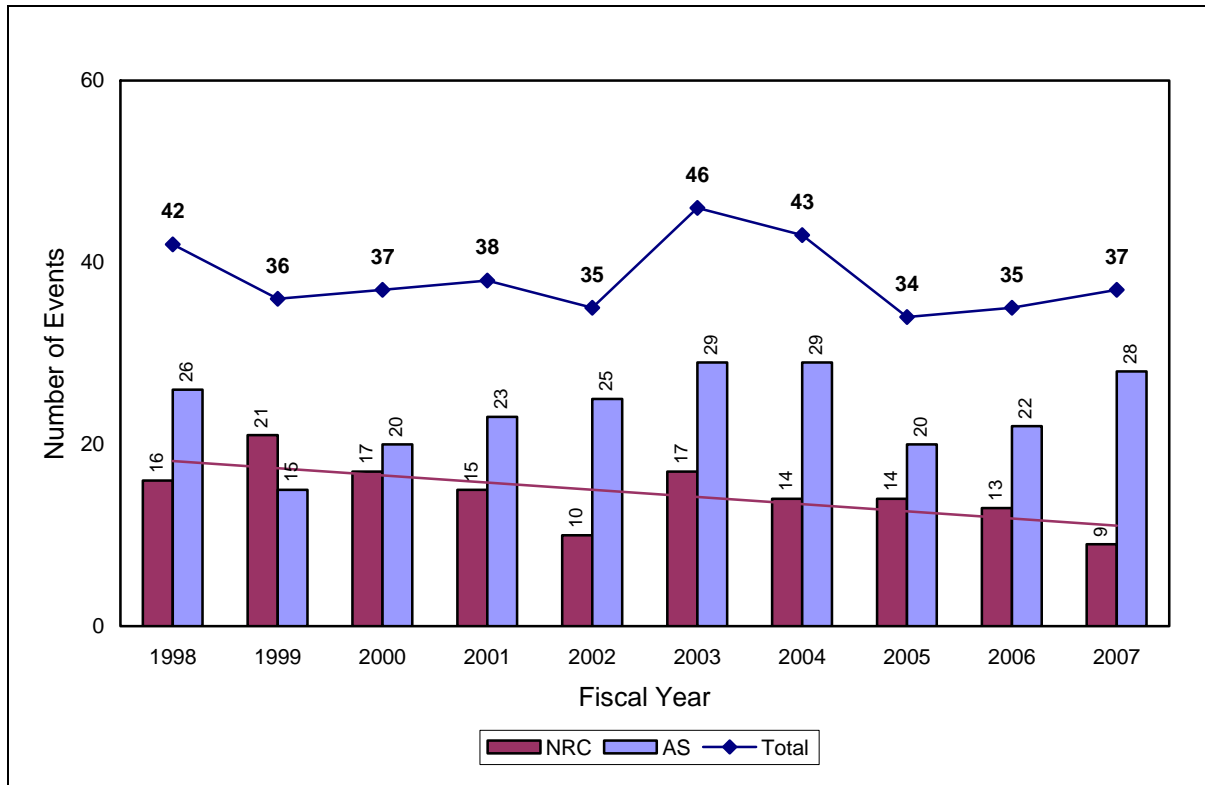


Figure 3. Medical Events (383 total)

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

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

Table 5. Medical AO Events

	Fiscal Year										Total
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007 ¹	
Events	4	5	5	2	6	9	12	7	6	11	67

Notes:

1. Events in FY07 are currently marked as potential AOs, because the AO determination process has not yet been completed for this year. In 2008 (typically April or May), the final AO determination will be made and the events published in NUREG 0090.

2.3.2 FY07 Data

Thirty seven MED events occurred in FY07, 11 of which were classified as potential AOs and are described below.

Significant Events—Potential AOs

Event 060659 involved a patient that received a high dose rate (HDR) afterloader breast therapy (mammosite) treatment. At the time of the event, the HDR contained approximately 144.3 GBq (3.9 Ci) of Ir-192. While the physicist was verifying the source positions and dwell times prior to treatment number eight of ten, it was noted that the first (most distal) source position was different from the previous treatments. A subsequent investigation by the licensee revealed that the usable catheter length entered into the treatment planning computer was 93 cm rather than the correct value of 95 cm. This error in catheter length was used for the first seven treatments beginning on 10/23/2006, which resulted in an unplanned dose to tissue proximal to the mammosite balloon. The patient was prescribed to receive 340 cGy/fraction (rad/fraction) to the specified site, or 2,380 cGy (rad) for the first seven fractions, but received only 700 to 1,000 cGy (rad) to the specified site. The incorrect site received 10,000 cGy (rad). If the fractions would have been administered correctly, that site would have received 2,450 cGy (rad). The licensee believes that a typographical error occurred in entering the usable catheter length. The referring physician and patient were notified of the incident and the remaining treatment fractions were cancelled. Corrective actions included training and procedure revisions that require verification of treatment parameters. An NRC medical consultant determined that the patient will likely experience breast atrophy and fat necrosis in the overexposed region.

Event 060716 involved a patient prescribed to receive 18 Gy (1,800 rad) during a gamma knife treatment who actually received 28 Gy (2,800 rad), a 56% overdose. The gamma knife contained 267.7 TBq (7,236 Ci) of Co-60. The cause of the incident was determined to be human error. The prescribing physician, apparently in a hurry to leave for the day, had prescribed 18 Gy (1,800 rad). The physician then entered the prescribed value into the computer treatment plan rather than having the medical physicist do it as is the usual procedure. The physician erroneously entered 28 Gy (2,800 rad). The patient and referring physician were notified of the incident. Corrective actions taken by the licensee included a verification process to ensure the prescribed treatment value is transferred from the treatment planning computer to the gamma knife computer prior to patient therapy. A treatment plan signed by the treating oncologist, physicist, and neurosurgeon is now required. In addition, the treating oncologist and physicist will verify and initial the prescribed dose and isodose.

Event 060748 involved the incorrect placement of brachytherapy seeds during a prostate cancer treatment. On 10/25/2006, 104 I-125 seeds with a total activity of 1.57 GBq (42.4 mCi) were implanted into a patient. A post-implant CT scan performed on 12/8/2006 indicated that the seeds were misplaced approximately 1.5 cm inferior to the intended position. The patient and the prescribing physician were notified of the incident. Calculations showed the D90 value (the minimum dose received by 90% of the prostate volume) to be 6% of the prescribed dose or 800 cGy (rad) versus the prescribed dose of 14,500 cGy (rad). Also, an unintended tissue volume of 76.7 cc received 100% of the prescribed prostate dose.

The patient required further treatment of the prostate gland, which was performed using a linear accelerator. This event was caused by the failure to accurately identify the position of the prostate. Corrective actions include the requirement for a radiologist to review the volume study during implant procedure, filling the Foley catheter balloon with contrast to better identify the prostate base, and using fluoroscopy to confirm needle depth before depositing the seeds and fluoroscopic confirmation of seed position intermittently during the procedure. An NRC medical consultant concluded that no significant adverse effect was expected.

Event 070014 involved a patient who received an HDR treatment to the wrong site. The HDR unit contained a 370 GBq (10 Ci) Ir-192 source. A series of fractions were conducted on 11/29, 12/6, 12/13, and 12/20/2006. A portion of the patient's inner thighs were treated instead of the intended cancerous target. The delivered dose to the skin was 2,000 cGy (rad) and the dose to the intended site was zero. The medical physicist stated that the error had been identified as part of a chart audit that was conducted prior to performing the next similar treatment of a subsequent patient. Computerized dosimetry planning records showed that the prescribed treatment was to occur with an automated source travel distance of 120 cm. The actual data point used during treatment was a travel distance of only 100 cm. The authorized radiation oncologist confirmed reddening of the skin on both inner thighs of approximately 3 cm². HDR treatments have been rescheduled. The cause was determined to be human error, not equipment malfunction. An Illinois Department of Health investigation also determined that the hospital failed to ensure that both an authorized user and an authorized medical physicist were present for the treatments and that the treatment plan did not receive the routine review during any of the subsequent treatment fractions to ensure the prescribed dose was being administered. An NRC medical consultant found that personnel required additional operational training and that safety controls were missing. Corrective actions taken included procedural modifications to assure catheter lengths are verified prior to treatment, providing additional training to personnel, and generating new procedures.

Event 070015 involved a 51% overdose to a patient during the first of four HDR brachytherapy fractions. The HDR unit contained a 370 GBq (10 Ci) Ir-192 source. The patient was prescribed to receive four HDR brachytherapy fractions to a 7 cm length of the vaginal mucosa of 500 cGy (rad) each. About halfway through the first treatment fraction, it was determined that the inferior 3 cm of the treatment length received 756 cGy (rad). The medical physicist had entered 1,220 cGy (rad) into the HDR treatment planning computer instead of 500 cGy (rad). The physicist also entered 1,220 cGy (rad) on his HDR dosimetry check. He then completed the HDR dosimetry check, not realizing the incorrect dosage was entered on the checklist. Standard protocol is to check the treatment dose on the prescription plan, but that did not occur. The authorized user reviewed the treatment plan and isodose distribution curves and approved the plan for a dose of 1,220 cGy (rad) instead of 500 cGy (rad), which was stated on the written directive. As the patient was treated, the medical physicist gathered the pertinent medical documents for the patient file and noticed that the authorized user's checklist (physician's HDR dosimetry checklist) had 500 cGy (rad) for the prescribed dose. The medical physicist immediately terminated treatment. The patient received 756 cGy (rad) instead of the planned 500 cGy (rad), 51% over the prescribed dose. The patient received the prescribed total dose during the four fractions. The patient was notified of the incident. The Wisconsin Department of Health and Family Services dispatched a team to investigate. Corrective actions taken by the licensee included modifying existing procedures and writing new policies and procedures.

Event 070024 involved the incorrect placement of brachytherapy seeds during a prostate cancer treatment. The patient was prescribed a total dose of 12,000 cGy (rad) to the prostate using 41 I-125 seeds, with each seed containing 11.84 MBq (0.32 mCi). The patient moved after seven seeds had been implanted (two of the 14 treatment needles). The procedure was delayed to allow additional anesthesia to take effect. The lineup was checked using ultrasound and, once the urologist, radiation oncologist, and medical physicist were comfortable with the situation, the implant procedure was resumed. After the procedure was completed, radiographs revealed that 34 of the 41 seeds (needles 3 through 14) were inadvertently

deposited approximately 4 cm inferior to the prostate into the penile bulb. As a result, the prostate received a dose of 1,300 cGy (rad). In addition, the penile bulb received approximately 11,000 cGy (rad), and the patient's skin received approximately 240 cGy (rad), more than 50% greater than prescribed. The dose to the penile bulb could result in scarring, fibrosis, erectile dysfunction, and impotency. The patient was notified of the error. This event was caused by the failure to have adequate procedures and a lack of communication. The NRC contracted a medical consultant, who concurred with the licensee's evaluation. Corrective actions included procedure revision, including performing imaging during the treatment rather than only at the end of the treatment.

Event 070074 involved a patient who received 770 cGy (rad) to the cervix instead of the prescribed 3,000 cGy (rad). The patient also received doses to unintended locations. A tandem and ovoid applicator containing 6.29 GBq (170 mCi) of Cs-137 was loaded into the patient on 2/2/2007 for a treatment time of 48.5 hours. Upon removal of the device, it was observed that the tandem applicator had been loaded with a plastic radioactive source carrier insert (tandem insert) that was approximately 4 cm shorter than the required 24 cm. This caused the sources in the tandem applicator to be displaced from the intended position, resulting in a lower than intended dose to the treatment site and higher than intended doses to other locations. There were three areas of unintended dose. The rectum area was prescribed to receive 930 cGy (rad) and received 2,472 cGy (rad), the vaginal mucosa area was prescribed 411 cGy (rad) and received 1,484 cGy (rad), and a second vaginal mucosa area was prescribed 265 cGy (rad) and received 1,414 cGy (rad). The licensee administered external beam treatment to compensate for the underdose. An NRC medical consultant concluded that no significant adverse impact is expected. Corrective actions included additional training for applicable personnel and procedure modification.

Event 070215 involved a patient with a history of vaginal cancer who was prescribed 2,500 cGy (rad) via interstitial brachytherapy to the 50 cGy (rad) isodose line, but received 4,590 cGy (rad). The patient's anterior rectal dose was approximately 7,300 cGy (rad). The licensee used both Cs-137 and Ir-192 for the treatment. The medical physicist developed a treatment plan as directed by the authorized user/radiation oncologist using a commercial treatment planning software application. The licensee used 11 seed ribbons, each containing eight Ir-192 seeds, and each seed contained an activity of 1.855 mGyRaEq or 118 MBq (3.19 mCi). A template was used to place the Ir-192 ribbons, and the Cs-137 sources were loaded into a tandem applicator. The treatment was initiated on 3/6/2007. The medical physicist performed a manual check of the treatment plan calculations on 3/7/2007 and identified a significant discrepancy. It was noted that the hand calculations indicated a significantly higher dose rate than what was generated by the treatment planning software. After several hours of investigation, it was determined that the original treatment plan was in error. After 27 hours of the intended 50-hour treatment time, the sources were removed from the patient. The primary error was the use of an inappropriate dose rate factor in the treatment planning software. The value used corresponded to the dose rate factor for air Kerma; however, the source strength was entered in milligram radium equivalent. During the physics review, it was determined that acceptance testing of this treatment planning software did not include Ir-192; the acceptance testing covered only Cs-137 and I-125. There was no check of the preplan prior to obtaining the Ir-192 seeds, although there was sufficient time. Neither the physicist nor the radiation oncologist had prepared a treatment using Ir-192 in six years and the physicist had not used this particular treatment planning software for Ir-192. It would have been prudent to have an additional review or outside review. The double check was not performed until the day after the treatment began. Corrective actions taken by the licensee included changing the policy and procedures to require a check of calculations for any single fraction brachytherapy treatment. The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and, more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient was treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber. Department of Health staff performed a reactive inspection on 3/21/2007. Licensee staff was interviewed and radiation therapy quality assurance policies, procedures, and patient records were reviewed. The patient's record was sent for review by a radiation

oncologist and medical physicist. Their report identified several issues which the Department of Health will follow-up on.

Event 070263 involved a patient who received 1.25 GBq (33.9 mCi) of I-131 instead of the prescribed 1.11 MBq (30 uCi) for a diagnostic thyroid scan. A dose had been misdrawn and mislabeled at the pharmacy. Two different nuclear medicine technologists at the hospital measured the dosage in the dose calibrator; however, both failed to identify the error. The calibrator printed the results, which were attached to the dose without review. Additionally, the dosage was placed into a neck phantom for a third check, but those results were not evaluated. The dose was administered on 4/24/2007 and the error was discovered on 4/26/2007. The patient and physician were notified. The licensee is following up with the pharmacy. The physician indicated that the patient had a normally functioning thyroid prior to the administration, but is now expected to be on synthetic thyroid hormone for the remainder of her life. Investigations were performed by the North Carolina Radioactive Materials Branch and the North Carolina Board of Pharmacy on 5/8 and 5/9/2007. It was determined that both the licensee and the pharmacy were at fault. Corrective actions taken by the licensee included providing additional training to personnel.

Event 070276 involved a patient who received 146 MBq (3.94 mCi) of I-131 for a whole body scan instead of the prescribed 5.6 MBq (150 uCi) for a thyroid uptake scan on 1/16/2007. The event was discovered by a consulting physicist on 3/9/2007. The event occurred after a scheduling person (who does not have a background in nuclear medicine) ordered the wrong scan. The licensee calculated that the dose to the patient's thyroid was approximately 5,122 cGy (rad) and the whole body effective dose equivalent was approximately 15.37 cSv (rem). If the prescribed I-131 amount had been administered, the doses would have been 525 cGy (rad) and 0.24 cSv (rem), respectively. The State Radiation Control Program performed an onsite investigation on 5/24/2007. The cause of the event was human error. The licensee failed to verify the prescribed dosage and the written directive was not completed. Corrective actions taken by the licensee included revising procedures to improve communications with referring physicians and requiring the completion of written directives for I-131 administrations greater than 1.11 MBq (30 uCi). Personnel also received additional training.

Event 070547 involved a 400% overdose to a patient during a high dose rate afterloader procedure. The patient received 2,500 cGy (rad) during the first of five fractions instead of the prescribed dose of 500 cGy (rad). The afterloader contained a 260.6 GBq (7.043 Ci) Ir-192 source. Prior to the treatment, the patient had undergone a right upper lobectomy and the right upper bronchial stump received the dose. The incident was discovered following an independent physicist's review of the treatment plan. The incident occurred as a result of the incorrect isodose line being chosen and entered into the treatment planning system. The treatment planning system then normalized the calculations to the incorrect isodose line and the resulting treatment. The oncologist signed and approved the plan and the RSO performed a second calculation check on the plan. The calculation error was identified by an independent physicist prior to administration of the second fraction. Corrective actions included procedure modifications (requiring a second check by physics staff for prescription and treatment, retaining a check list in each treatment file that staff are required to review prior to treatment, adding a second calculation point to the plan, etc.) and personnel training.

Events of Interest

Event 070315 involved a patient with metastatic cancer and no thyroid who received a therapeutic dose of 0.99 GBq (26.8 mCi) of I-131, instead of the prescribed whole body scan. The doctor prescribed the whole body scan, but the technologist administered the therapy dosage. The doctor and patient were notified of the error. A Florida Department of Health investigation revealed that no violation occurred and that no corrective actions were required.

Embryo/Fetus or Nursing Child Dose Events

Doses to an embryo/fetus or nursing child are reportable per 10 CFR 35.3047. By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as an “Other” event. However, it is appropriate to also discuss these events in this section.

Event 070339 involved a thyroid cancer treatment to a patient that resulted in a dose to an embryo/fetus. On 5/22/2007, the licensee performed a pregnancy test on the patient with negative results. The patient was advised not to get pregnant prior to the treatment. On 5/29/2007, the patient was administered 4.64 GBq (125.5 mCi) of I-131. On 5/30/2007, the patient performed a home pregnancy test with positive results and notified the licensee. The licensee performed another test on 5/30/2007 with positive results indicating that the patient was four to five weeks pregnant at the time of the administration. This event was caused by a false negative pregnancy test result (due to the early stage of pregnancy) and the patient’s belief that she was not pregnant. The licensee estimated the dose to the embryo/fetus to be approximately 25 and 34 cSv (rem). The NRC contracted with medical consultant to review the medical significance of this event. The consultant concluded that the most likely outcome would be delivery of a normal infant with regard to thyroid function; however, there may be a slightly increased risk of childhood cancer. The licensee took no corrective actions because the cause of the event was beyond their control.

2.4 Radiation Overexposure

2.4.1 Ten-Year Data

Figure 4 displays the annual number of the 170 EXP events that occurred during the 10-year period. The trend analysis determined that the data do not represent a statistically significant trend 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.

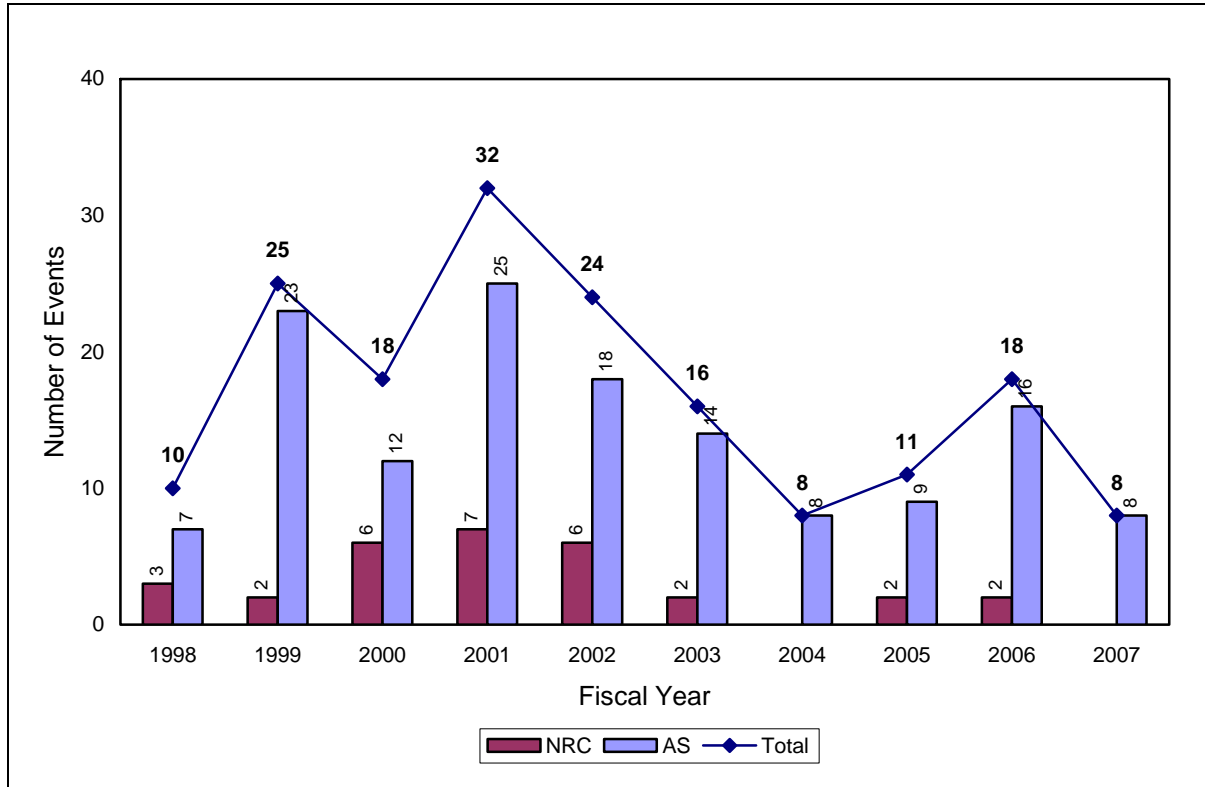


Figure 4. Radiation Overexposure Events (170 total)

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

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

Table 6. EXP Events Classified by CFR Reporting Requirement

CFR Reporting Req.	Fiscal Year										Total
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	
Immediate	0	2	1	2	1	2	1	0	1	1	11
24-Hour	5	11	1	1	0	1	1	1	3	0	24
30-Day	5	12	16	29	23	13	6	10	14	7	135
Total	10	25	18	32	24	16	8	11	18	8	170

2.4.2 FY07 Data

Eight EXP events occurred in FY07, one of which was classified as a significant event and resulted in a 5-10 rem whole body dose to a member of the public. Another event was classified as a potential AO and an event of interest. These events are described below.

Significant Events—Immediate Reports

None.

Significant Events—Within 24-Hour Reports

Event 070116 involved the loss of a 25.9 GBq (700 mCi) Cs-137 well logging source that caused personnel to receive radiation dose in excess of the limit for members of the public. The source dose rate was determined to be 264 R/hr skin dose at one inch. On 2/22/2007 at approximately 0600 CST, the well logging crew unknowingly dropped the source in the motor pool parking lot while loading it into a pig. At approximately 0900 CST, the source was picked up by a mechanic who placed it in his jacket pocket. The mechanic wore the jacket for about four hours. He visited several businesses and later hung the jacket on a bollard in an area where individuals were working. The jacket was later moved to a break room overnight. On 2/23/2007, the mechanic put the jacket back on. The well logging crew returned to the facility at approximately 0600 CST and discovered the source missing when they unpacked their equipment. The source was not discovered missing earlier because it was not needed in the field. The crew immediately started searching for the source. The mechanic produced the source when he heard it was missing. In total, the mechanic wore the jacket approximately 5.5 hours. The mechanic and a couple of co-workers were taken to a local hospital for examination. No abnormalities were noted. The mechanic was seen by a physician at the Oklahoma University Health Sciences Center (OUHSC). The physician believed that the mechanic would suffer from radiation burns on his abdomen and possibly on his finger tips. A blood sample was taken and shipped to RPA in London, England, for cytogenetic analysis. Their report cited damage that is slightly above normal background, perhaps indicating an exposure of 10 cGy (rad) averaged whole body dose. The report included uncertainties due to sampling statistics such that the upper and lower 95% confidence limits are 20 cGy (rad) and zero, respectively. The NRC and the Oklahoma Department of Environmental Quality calculated a dose of between 5 and 10 cSv (rem). It was stated that the only symptom displayed by the mechanic was some gastrointestinal upset, which could have been caused by emotional stress related to the incident. The mechanic denied any radiation burn symptoms. Regarding others who may have received dose in excess of limits due to this event, a co-worker who rode to lunch with the mechanic was identified as being most at-risk. This event was caused by the failure to conduct surveys during transfer of the source and the failure of the source handling tool and pig to positively secure the source. To prevent recurrence, the licensee removed similar sources from service pending upgrade of the source handling sticks, modified their procedures, retrained personnel. This event was classified as an EXP and LAS event.

Events of Interest

Event 060677 was classified as a potential AO event and involved the overexposure of four individuals. The individuals were involved in separating sources, lead pigs, and trash from drums. The total Am-241

activity from twelve drums was manifested at 6.8 GBq (184 mCi). However, only one drum was open at the time of the incident. The amount of Am-241 in that drum was manifested as 2.63 GBq (71 mCi). Work was being conducted in a ventilated room within a waste processing building. Two workers inside the room were wearing respirators and the supervisor, not wearing a respirator, was immediately outside the room directing the work. A contamination level of over 2,000,000 dpm/wipe was detected in the room and the building was evacuated. An air sample in the area revealed an alpha activity of 0.37 uBq/ml (0.001 pCi/ml). The three workers were taken to a survey area and found to be contaminated on the face. Contamination was also found on the respirators. The workers were decontaminated on site. Air sample analysis results for a particulate sample in the building exhaust stack was 340.4 Bq/ml (9.2 nCi/ml) gross alpha. Whole body counts the next day revealed that the supervisor received an intake of approximately 432.9 Bq (11.7 nCi) of Am-241 with an estimated lung dose of 97.5 cSv (rem) CDE. The supervisor also had an estimated dose to the endosteal (white bone matter) of 95 cSv (rem) CDE. The other two workers were given two lung counts with results of 248 and 188 Bq (6.7 and 3.2 nCi) for one and 56 and 19 Bq (1.5 and 0.5 nCi) for the other. A health physics technician working near the supervisor in the outer room was also counted with a result of less than 3.4 Bq (0.092 nCi). All four workers were given chelating treatments. Final doses were calculated by the Battelle internal dosimetry program, following extensive testing. The three individuals with greater intakes were estimated. One individual had an intake estimated at 1776 Bq (48 nCi) with a 50-year CDE to the whole body of 4.9 cSv (rem) and to the bone surface of 95 cSv (rem). The second individual had an intake estimated at 629 Bq (17 nCi) with a 50-year CDE to the whole body of 3.8 cSv (rem) and to the bone surface of 78 cSv (rem). The third individual had an intake estimated at 148 Bq (4 nCi) with a 50-year CDE to the whole body of 1.0 cSv (rem) and to the bone surface of 22 cSv (rem). The Department of Health's investigation into the incident determined that the root cause appeared to be failure to adhere to procedures and plans set forth for the project and inadequate training. The building was decontaminated and additional containment tents were installed around the contaminated room. Corrective actions taken by the licensee included a redistribution of the RSO's work to other onsite personnel and hiring additional personnel to ensure adequate coverage, management reorganization, increased training on procedures, increased management interaction and surveillance by the RSO, inclusion of engineering staff on all facility changes, hazard analysis on the ventilation systems, disciplinary action for culpable employees, and greater emphases to ensure orders and instructions to workers area clear and understood. This event was classified as an EXP and RLM event.

Event 070583 involved personnel overexposures during industrial radiography on 9/14/2007 on a 6.5-foot steel ladle at a steel mill east of Beaumont, Texas. The radiographers were using a QSA Global exposure device (model 943) and a Co-60 source (model A-424-14, serial #36391B) with an activity of 3.48 TBq (94 Ci). Two radiographers noticed that their pocket dosimeters read off-scale (>200 mR). The radiographers had just changed the film in the holder, which was located approximately seven inches from the source collimator. It was determined that the source was stuck approximately 1.5 feet from the exposure device due to a crimped guide tube. A ladder was used to enter the ladle from one side and the source collimator was positioned on the opposite side with a magnetic hold. The magnetic hold fell off the ladle during radiography and damaged the guide tube, restricting full retraction of the source during the last two shots. A survey taken on the last shot discovered that the source was unshielded. A specialist responded to the jobsite and successfully retracted the source. However, the source retrieval was difficult. During retrieval, the specialist's pocket dosimeter went off-scale (>5 R). The specialist switched to another pocket dosimeter with a range of 0 to 20 R. At the completion of the retrieval, the specialist had an indicated exposure of 13 cSv (rem). The licensee sent all three individuals' badges off for emergency processing. Results revealed 17.39 cSv (rem) to the radiographer, 7.4 cSv (rem) to the trainee, and 11.08 cSv (rem) to the specialist that retrieved the source. On 10/18/2007, the RSO provided a revised dose estimate with consideration given to the source being stuck at a height of approximately 15 inches off the ground. The estimates were 36.7 cSv (rem) to the radiographer and 13.47 cSv (rad) to the trainee, both at

the knees of the workers. The Texas Department of Health is investigating the incident. This event was classified as an EQP and EXP event.

2.5 Release of Licensed Material or Contamination

2.5.1 Ten-Year Data

Figure 6 displays the annual number and trend of the 172 RLM events that occurred during the 10-year period. The trend analysis determined that the data represent statistically significant decreasing trends in the number of events (indicated by the trend lines).

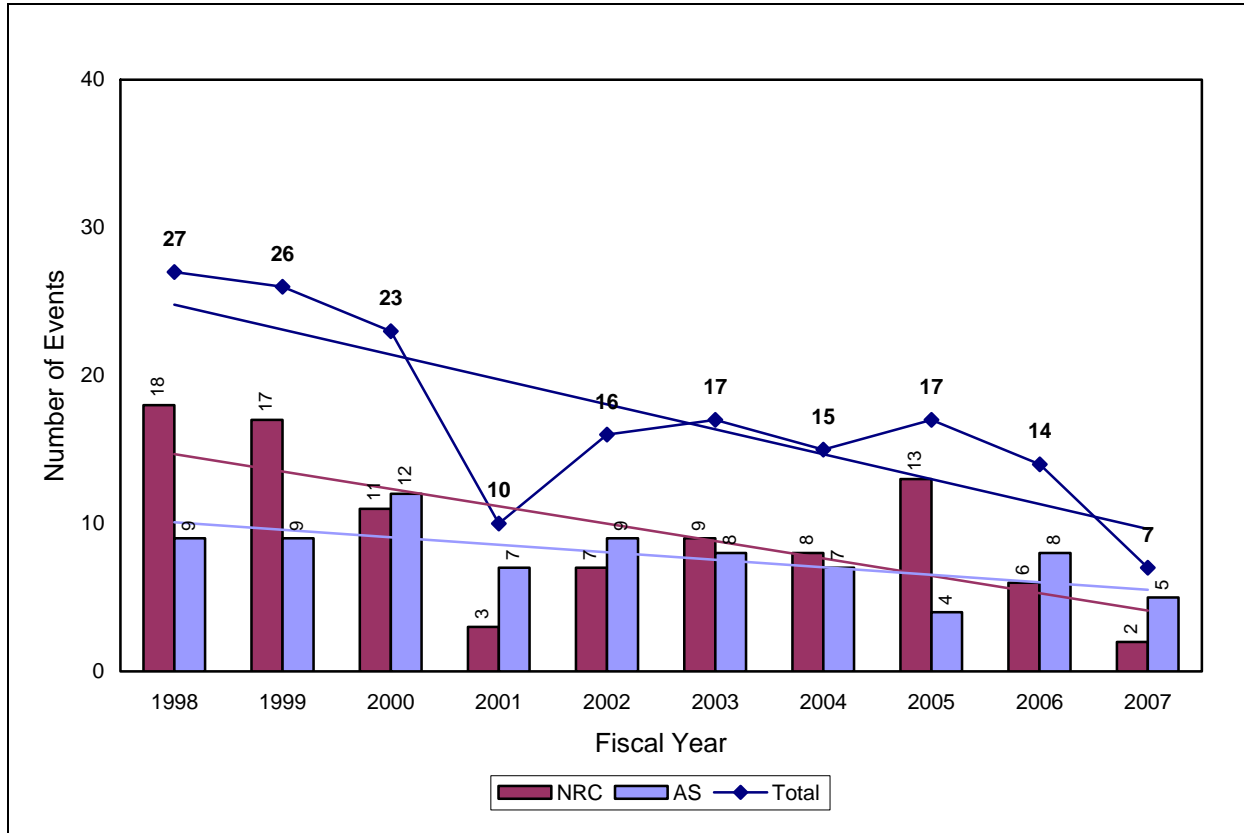


Figure 5. Release of Licensed Material or Contamination Events (172 total)

The significance of individual RLM events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, those events requiring immediate or 24-hour reporting, or reporting per 10CFR20.2203(a)(3)(ii) (an NRC metric) are considered safety significant.

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

Table 7. RLM Events Classified by CFR Reporting Requirement

CFR Reporting Req.	Fiscal Year										Total
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	
Immediate	0	1	1	0	0	0	2	0	0	0	4
24-Hour	26	25	19	9	13	16	13	17	12	7	157
30-Day	1	0	3	1	3	1	0	0	2	0	11
Total	27	26	23	10	16	17	15	17	14	7	172

2.5.2 FY07 Data

Seven RLM events occurred in FY07, one of which was classified as a potential AO. None of these events were significant enough to require immediate notification. All of the events required notification within 24 hours. The seven events are summarized below.

Significant Events—Immediate Reports

None.

Significant Events—Within 24-Hour Reports

Event 060630 involved two damaged shipping packages containing Cs-131 cancer therapy seeds. The shipping company discovered a flattened lead cap in their Spokane, Washington, terminal. A partial label on a lead container cap indicated it came from one of two packages containing 63 Cs-131 seeds with a total activity of 12.2 GBq (330 mCi). The second package was found crushed, but essentially intact; all seeds were present and undamaged. Scraps from the first package were found on the runway and on the floor of the tug; shipping personnel had placed the damaged packages on the floor on the passenger side of the tug cab. Licensee and Washington Department of Health (DOH) personnel responded to the scene. DOH personnel were able to recover three of the 63 seeds from the first package. Several areas of radioactive contamination were also found. Measurements on the floor of the tug's passenger side revealed 150 mR/hour with an Eberline RO2 ion chamber. Radiation measurements on the crushed pig lid were about 25 mR/hour. Using a GM instrument, contamination measurements of about 400 cpm were found on the crushed pig lid and 300 cpm on the crushed box. A spot on the tarmac was found reading about 12 mR/hour with an RO2. The undamaged stainless steel pig read about 5 mR/hour. Washington DOH requested that the shipping company revise their hazardous material transportation handling procedures and provide refresher training to staff. The shipping company found the bottom half of the missing lead container on 11/28/2006. It had been pushed by a snow-plow to the rear of their facility. The shipping company believes that the squashed container had been caught in the loader until it worked its way out. Licensee personnel went to the airport on 11/28/2006 and retrieved the squashed container. No radioactive contamination was discovered. There was no radioactive contamination on the outside of the container although it still contained a number of seeds. A dose rate measurement revealed 35 mR/hour at 3 cm and 0.5 mR/hour at 30 cm. The licensee will perform an autopsy on the container to determine its contents. This event was classified as an EQP, LAS, LKS, and RLM event.

Event 060633 involved a Cs-137 well logging source that was ruptured down hole. The well is located in Kern County, California, at Chevron USA, well number Amber 235 in the Midway-Sunset Field (Section 26, Township 31-S, Range 22-E). The licensee stated that a well logging tool with two sources had become stuck down hole on 10/4/2006. The two sources included an Am-Be source with an activity of 592 GBq (16 Ci) and a Cs-137 source with an activity of 63 GBq (1.7 Ci). Fishing attempts were successful in recovering the Am-Be source. During subsequent attempts to recover the Cs-137 source, licensee personnel monitoring the mud returns noticed a substantial increase on their radiation survey instrument. Readings went from 4 uSv/hour to 70 uSv/hour (0.4 mrem/hour to 7 mrem/hour). That increase indicated a potentially ruptured source and all operations and circulation were immediately

stopped. The licensee sent additional personnel to the site to conduct further radiation surveys and determine their future course of action. The source was indeed ruptured. They isolated the area and brought in a health physics consultant to assess potential exposures, develop a plan for decontamination of equipment, packaging and disposal of contaminated well mud, and development of a decontamination plan for the well area. The clean-up process is ongoing. There were no significant personnel exposures related to the incident. This event was classified as an EQP, LKS, and RLM event.

Event 060654 involved a contamination incident at a source handling facility. Two Cs-137 sources from fixed gauges (model 5178 and 5178A source holders) were breached during source disposal operations. One Cs-137 source containing an activity of 0.41 GBq (11 mCi) was breached when an individual cut into the source holder with a bandsaw. The other source contained an activity of 0.96 GBq (26 mCi) and was breached when the same individual drilled into the source holder. Radioactive contamination was detected on the individual conducting the source removal operations and throughout the source handling area. The contaminated areas were controlled access/restricted areas within the facility. Some contamination escaped from the room under two doors leading to the licensee's gauge manufacturing area, but not into any unrestricted areas. The contamination on the individual was estimated at 0.37 GBq (10 mCi) and was located on clothing, hair, arms, and hands. The individual was decontaminated onsite and sent to a local hospital as a precautionary measure. As of 10/23/2006, there was still some residual contamination on the individual's finger tips. However, further scrubbing to remove the contamination may have caused a breakdown of the skin. The individual put on gloves in an attempt to sweat out the residual contamination. Two urinalysis samples collected from the employee were negative. The source handling area was secured and closed to all personnel over the weekend. Preliminary surveys identified 14,000 to 500,000 dpm in large sample wipe tests of walkways in the manufacturing area. It was estimated that approximately 0.37 GBq (10 mCi) of contamination was involved in the source handling area. A decontamination contractor was retained by the licensee and arrived on site on 10/23/2006. An Ohio Bureau of Radiation Protection inspector visited the site on 10/25/2006 to assess the contractor's decontamination efforts and to further investigate the circumstances that caused the incident. The contaminated employee received a whole body count on 10/26/2006. The results revealed the presence of 133.57 Bq (3.61 nCi) in the lungs. A second whole body scan was performed after two weeks and revealed 125.4 Bq (3.39 nCi). Three calculations were performed by CHPs from Energy Solutions, resulting in a CEDE to the whole body ranging from 21.3 to 19.4 uSv (2.13 to 1.94 mrem). Corrective actions taken by the licensee included generating a new procedure for the removal of sources from holders. This event was classified as an EQP, LKS, and RLM event.

Event 060677 was classified as a potential AO event and involved the overexposure of four individuals. The individuals were involved in separating sources, lead pigs, and trash from drums. The total Am-241 activity from twelve drums was manifested at 6.8 GBq (184 mCi). However, only one drum was open at the time of the incident. The amount of Am-241 in that drum was manifested as 2.63 GBq (71 mCi). Work was being conducted in a ventilated room within a waste processing building. Two workers inside the room were wearing respirators and the supervisor, not wearing a respirator, was immediately outside the room directing the work. A contamination level of over 2,000,000 dpm/wipe was detected in the room and the building was evacuated. An air sample in the area revealed an alpha activity of 0.37 uBq/ml (0.001 pCi/ml). The three workers were taken to a survey area and found to be contaminated on the face. Contamination was also found on the respirators. The workers were decontaminated on site. Air sample analysis results for a particulate sample in the building exhaust stack was 340.4 Bq/ml (9.2 nCi/ml) gross alpha. Whole body counts the next day revealed that the supervisor received an intake of approximately 432.9 Bq (11.7 nCi) of Am-241 with an estimated lung dose of 97.5 cSv (rem) CDE. The supervisor also had an estimated dose to the endosteal (white bone matter) of 95 cSv (rem) CDE. The other two workers were given two lung counts with results of 248 and 188 Bq (6.7 and 3.2 nCi) for one and 56 and 19 Bq (1.5 and 0.5 nCi) for the other. A health physics technician working near the supervisor in the outer room was also counted with a result of less than 3.4 Bq (0.092 nCi). All four workers were given chelating treatments. Final doses were calculated by the Battelle internal dosimetry program, following extensive

testing. The three individuals with greater intakes were estimated. One individual had an intake estimated at 1776 Bq (48 nCi) with a 50-year CDE to the whole body of 4.9 cSv (rem) and to the bone surface of 95 cSv (rem). The second individual had an intake estimated at 629 Bq (17 nCi) with a 50-year CDE to the whole body of 3.8 cSv (rem) and to the bone surface of 78 cSv (rem). The third individual had an intake estimated at 148 Bq (4 nCi) with a 50-year CDE to the whole body of 1.0 cSv (rem) and to the bone surface of 22 cSv (rem). The Department of Health's investigation into the incident determined that the root cause appeared to be failure to adhere to procedures and plans set forth for the project and inadequate training. The building was decontaminated and additional containment tents were installed around the contaminated room. Corrective actions taken by the licensee included a redistribution of the RSO's work to other onsite personnel and hiring additional personnel to ensure adequate coverage, management reorganization, increased training on procedures, increased management interaction and surveillance by the RSO, inclusion of engineering staff on all facility changes, hazard analysis on the ventilation systems, disciplinary action for culpable employees, and greater emphases to ensure orders and instructions to workers area clear and understood. This event was classified as an EXP and RLM event.

Event 070204 involved a radioactively contaminated contractor who was transported from a commercial nuclear power plant to a hospital. The contractor sustained a back injury when he fell approximately 4 to 5 feet onto grating. The contractor was found unconscious in the containment drywell at the 630 foot elevation. The contractor regained consciousness when medical personnel arrived at the scene. Due to the injury, the worker's back was not completely surveyed prior to arrival at the hospital. Radiation Protection personnel accompanied the worker to aid in radiological assessment. The individual had fixed contamination on his protective clothing, safety belt, and tool belt. Contamination on his clothing revealed direct contact readings of between 100 and 150 cpm. Direct contact readings on the safety and tool belts were between 100 and 500 cpm. No contamination was detected in the ambulance or in the hospital.

Event 070376 involved I-131 contamination at a veterinary facility. A cat moved during an I-131 injection, resulting in radioactive material on the veterinarian's gloved hands, exam table, and floor; 37 MBq (1 mCi) of I-131 was spilled. The contaminated area was subsequently mopped, which spread the contamination. The contaminated area was covered with plastic and access was restricted for more than 24 hours. Inside the room, the highest radiation measurements were 12 mR/hour on one spot and 2 to 5 mR/hour on all other floor areas (measurements at 1 cm from contact using a Ludlum 44-88 GM). There was also one small spot of contamination on a technician's sweatshirt sleeve, which measured 15 mR/hour at 1 cm. There was no other personnel contamination and all thyroid measurements indicated no internal uptake. Corrective actions taken by the licensee included retraining staff on proper clean up of radioactive material spills and reporting requirements, in addition to hiring an RSO that is closer to their facility.

Event 070391 involved a radioactively contaminated employee that was transported from a uranium hexafluoride facility to a local hospital. The employee sustained multiple contusions and abrasions to his head, face, and body as a result of a fall from the permanently installed man-lift device. The individual was transported with measurable levels of uranium (U3O8) contamination of 5 kdpm/100 cm² on his clothing. Licensee health physics personnel accompanied the injured individual to the hospital, where they provided contamination control recommendations to the attending medical staff. No contamination was detected at hospital facilities, equipment, or staff following treatment of the individual. Following decontamination of the injured individual, survey results were less than 1 kdpm/100 cm². All contamination materials from the individual's decontamination and treatment were collected and returned to the licensee's facility.

Significant Events—Metric Events

None.

Events of Interest

None.

2.6 Leaking Sealed Sources

2.6.1 Ten-Year Data

Figure 7 displays the annual number and trend of the 346 LKS events that occurred during the 10-year period. An event reporting anomaly associated with a single ECD manufacturer occurred from Fiscal Year 2000 through early 2005, which notably increased the number of LKS events. The anomalous events were not significant and involved leaking ECD sources (Ni-63 foil sources) that had been returned to the manufacturer for refurbishment. The manufacturer discontinued refurbishing ECDs and now disposes of the returned sources without leak testing. To show this affect, Figure 7 displays the anomalous events as yellow shaded bars. The trend analysis determined that the Total and Agreement State-regulated events do not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data. However, the NRC-regulated events (excluding the anomalous data) represent a statistically significant decreasing trend (indicated by the trend line).

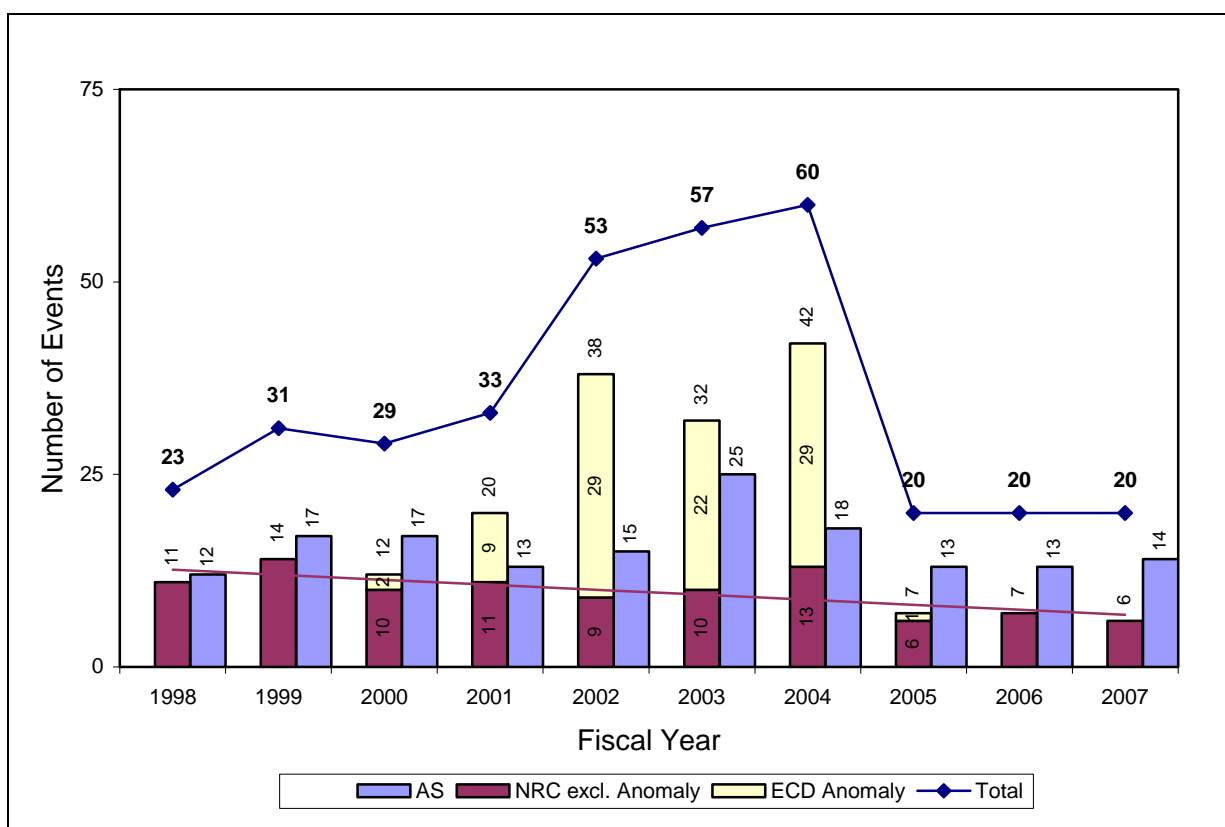


Figure 6. Leaking Sealed Source Events (346 total)

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

2.6.2 FY07 Data

Twenty LKS events occurred in FY07, none of which were classified as potential AOs or significant events.

Significant Events

None.

Events of Interest

Event 060654 involved a contamination incident at a source handling facility. Two Cs-137 sources from TN Technology fixed gauges (model 5178 and 5178A source holders) were breached during source disposal operations. One Cs-137 source containing an activity of 0.41 GBq (11 mCi) was breached when an individual cut into the source holder with a bandsaw. The other source contained an activity of 0.96 GBq (26 mCi) and was breached when the same individual drilled into the source holder. Radioactive contamination was detected on the individual conducting the source removal operations and throughout the source handling area. The contaminated areas were controlled access/restricted areas within the facility. Some contamination escaped from the room under two doors leading to the licensee's gauge manufacturing area, but not into any unrestricted areas. The contamination on the individual was estimated at 0.37 GBq (10 mCi) and was located on clothing, hair, arms, and hands. The individual was decontaminated onsite and sent to a local hospital as a precautionary measure. As of 10/23/2006, there was still some residual contamination on the individual's finger tips. However, further scrubbing to remove the contamination may have caused a breakdown of the skin. The individual put on gloves in an attempt to sweat out the residual contamination. Two urinalysis samples collected from the employee were negative. The source handling area was secured and closed to all personnel over the weekend. Preliminary surveys identified 14,000 to 500,000 dpm in large sample wipe tests of walkways in the manufacturing area. It was estimated that approximately 0.37 GBq (10 mCi) of contamination was involved in the source handling area. A decontamination contractor was retained by the licensee and arrived on site on 10/23/2006. An Ohio Bureau of Radiation Protection inspector visited the site on 10/25/2006 to assess the contractor's decontamination efforts and to further investigate the circumstances that caused the incident. The contaminated employee received a whole body count on 10/26/2006. The results revealed the presence of 133.57 Bq (3.61 nCi) in the lungs. A second whole body scan was performed after two weeks and revealed 125.4 Bq (3.39 nCi). Three calculations were performed by CHPs from Energy Solutions, resulting in a CEDE to the whole body ranging from 21.3 to 19.4 uSv (2.13 to 1.94 mrem). Corrective actions taken by the licensee included generating a new procedure for the removal of sources from holders. This event was classified as an EQP, LKS, and RLM event.

2.7 Equipment

2.7.1 Ten-Year Data

Figure 9 displays the annual number and trend of the 1,283 EQP events that occurred during the 10-year period. The trend analysis determined that the data represent a statistically significant decreasing trend in the number of Total and NRC-regulated events (indicated by the trend lines). However, the Agreement State-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line). Therefore, variations within the annual Agreement State values represent random fluctuation around the average of the data.

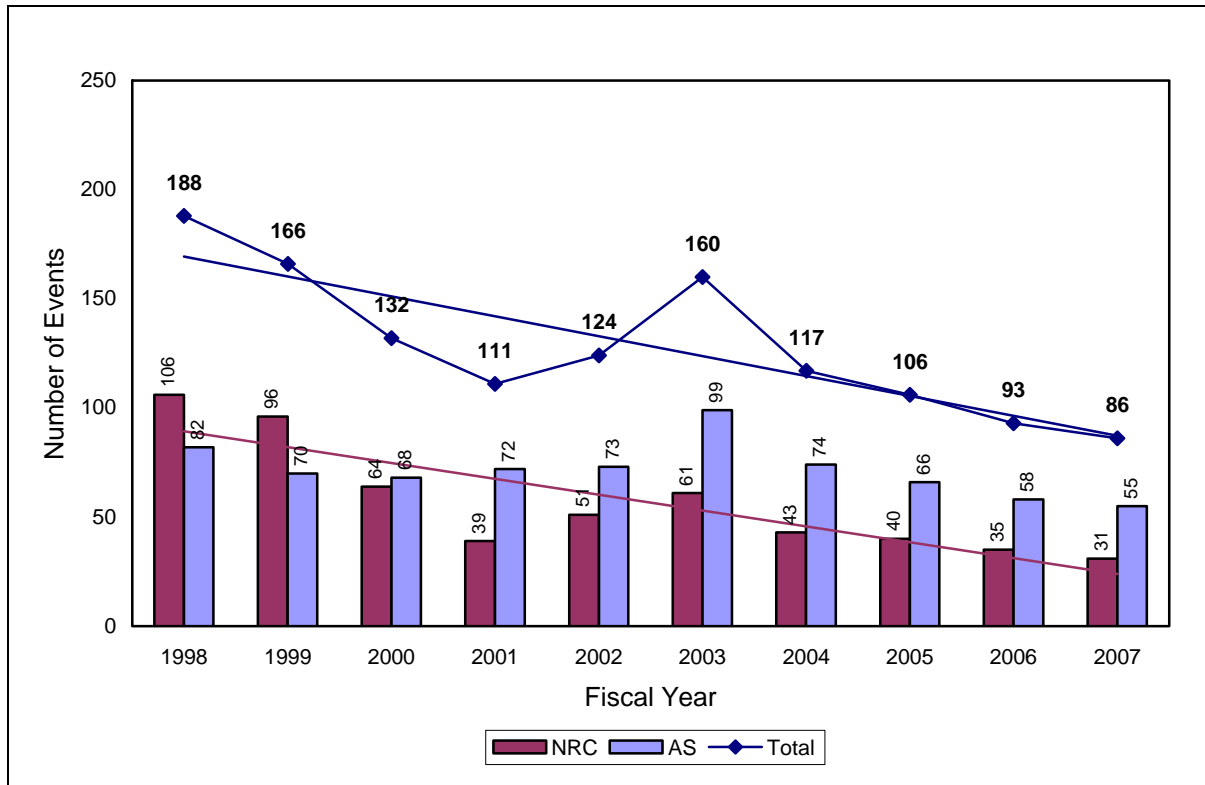


Figure 7. Equipment Events (1,283 total)

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

Starting 10/01/06 (Fiscal Quarter 07-1), NMED only marks EQP events as reportable if they meet all applicable reporting thresholds [(i), (ii), and (iii)]. If the report to NMED is not sufficient to clearly determine that all thresholds were met, the event reportability will be coded as Uncertain, and the event will be included in the normal request for additional information (RAI) process. If follow up information specifies that the event does not meet all thresholds, the reportability will be changed to Not Reportable.

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

It is not possible to discern significance strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5) because essentially all of the CFRs associated with EQP events require reporting within 24-hours.

2.7.2 FY07 Data

Eighty-six EQP events occurred in FY07, none of which were classified as potential AOs or significant events.

Significant Events

None.

Events of Interest

Event 070010 involved a 10 CFR 21 defect. A uranium enrichment facility identified a defect associated with a UF6 cylinder handling crane hoist drum hydraulic caliper brakes (Continental Brake Equipment Company, model 95400). The defect involved the mounting pin (part #3954022). The pin was intended to be held in place by a retaining ring set in a machined groove in the pin. The defect involved errors in the machining of the groove, which resulted in the ring not seating properly in the groove. Specifically, the grooves were too shallow and too narrow to properly accept and hold the retaining ring in place. During use, the retaining ring dislodged from the pin, allowing the pin to loosen. Loose mounting pins can result in the brake not performing its intended safety function as a hoist brake to prevent the uncontrolled lowering of a UF6 cylinder. The licensee inspected all of the subject mounting pins in-service and on-hand in the spare parts inventory. This inspection identified two additional cranes in service with mounting pin defects and four mounting pins in inventory with the same defect. These pins came from the same purchase of sixteen pins. All sixteen pins were located, removed from service, and replaced with new pins machined to the proper dimensions. To prevent occurrence, the receipt inspection criteria were revised to include inspection of the groove dimensions.

Event 070026 involved the malfunction of an MDS Nordion teletherapy unit (model Theratron-80, serial #2640986) that contained a Neutron Products Co-60 source (model NPTT, serial #T-1444) with an activity of 62.53 TBq (1,690 Ci). The Co-60 source did not return to the shielded position after completing a patient's treatment. The therapist immediately entered the room and retracted the source to a safe configuration. The patient was exposed for less than 30 seconds following the completion of the prescribed treatment and it was determined that no medical event occurred. The teletherapy unit was repaired by Neutron Products on 12/8/2006. The problem was identified as an old air cylinder and detent pin, which were replaced, returning the unit to normal operation.

Events 070161 and 070387 both involved the loss of 0.3 GBq (8 mCi) Cs-37 sources from Troxler moisture/density gauges. Both gauges had faulty welds on the source rod, which allowed the Cs-37 source to separate from the gauge, unknown to the operator. In one case, an assistant observed the source drop off and recovered the source. In the other event, the gauge user unknowingly left the source at the jobsite.

Event 070202 involved a moisture/density gauge (model 3440) that was damaged by a fire at a construction site in Charlotte, North Carolina. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.296 GBq (8 mCi) Cs-137 source. The licensee stated that a truck carrying the gauge was parked in a field covered with mulch. The truck bogged down and its muffler set the mulch on fire. The fire spread to the truck and fully engulfed the truck in flames. The Charlotte Fire Department responded to the scene and extinguished the fire, but not before the truck and gauge were heavily damaged by the fire. The gauge was virtually completely destroyed. The Am-Be source was outside the gauge housing and the Cs-137 source was still attached to the source rod. The stainless steel encased sources were not breached. The sources were packaged with the inspector's assistance and returned to the licensee's facility. Radiation levels on contact with the package were 15 mR/hr. The licensee was operating in North Carolina without reciprocity approval.

Event 070227 involved the failure of a high pressure fire water (HPFW) sprinkler system riser at a gaseous diffusion plant, resulting in 500,000 gallons of water on the ground floor of a process building. The leak was quickly located under the concrete floor inside the process building on an underground eight inch header under the alarm and actuation controls. The water intruded into the stage motor breaker housings for three cells in Unit 3, shorting out the breaker housing switches and causing the stage motor breakers to open. Operators tripped the three affected cells. The cells were evacuated, a leak-rate was performed, and the cells were re-started without incident. During this event, the HPFW system for all process buildings was inoperable. The leak was isolated, the HPFW pumps were restarted, and the elevated tank refilled. Those actions restored HPFW operability to the other areas in the plant. This event was caused by the improper installation of the HPFW system in 1958, resulting in leakage that compromised carbon steel retaining rods. An investigation identified other HPFW systems with severed restraint rods. All affected systems were repaired and returned to service.

Event 070441 involved a 10 CFR 21 defect. A medical center reported that an error message was received while performing a monthly calibration and position verification test on an HDR unit on 7/15/2007. A dummy source wire was used for the test. The doctor entered the room with a survey meter and no elevated radiation readings were noted. The emergency source retract hand wheel was used to retract the dummy source wire. After about 12 turns, the room radiation alarms initiated, causing the doctor to leave the room and close the door. Troubleshooting discovered that the 192 GBq (5.2 Ci) Ir-192 source became exposed. The estimated exposure to the doctor was 0.75 mSv (75 mrem). The medical center modified their calibration procedures and provided training to HDR staff. The manufacturer was contacted concerning the incident and ultimately issued a 10 CFR 21 report (see event 070579). The manufacturer determined that the active source wire can become dislodged from the internal tungsten safe if the emergency source retract hand crank is used when the active source is safely parked in the internal shield. A new warning label was developed to restate the proper use of the hand wheel and a formal revision was made to user training to emphasize this event.

Event 070579 involved a 10 CFR 21 defect. An HDR manufacturer reported a 10 CFR 21.21 violation that involved an HDR afterloader. The active source can become dislodged from the internal tungsten safe if the emergency source retract hand crank is used when the active source is safely parked in the internal shield (see NMED events 070441 and 060372). This event can only occur if the operator turns the emergency hand crank while the source is safely parked. A Customer Technical Bulletin CTB-VS-366A, "Clarification on the use of the emergency retract hand wheel to prevent accidental exposure" was issued to all users of these HDR units on 4/27/2004. The CTB will be reissued to all domestic customers. A warning label addressing the proper use of the emergency hand crank was attached to all of these HDR units in 2004. A new warning label was developed that restates the proper use of the hand crank. Also, a formal revision was made to user training to emphasize that this event is possible if the user makes an error by operating the emergency hand crank when the active source is safely parked in the tungsten shield. There are 191 of these HDR units in the United States.

2.8 Transportation

2.8.1 Ten-Year Data

Figure 9 displays the annual number and trend of the 280 TRS events that occurred during the 10-year period. The trend analysis determined that the data do not represent statistically significant trends in the number of events (indicated by the absence of trend lines). Therefore, variations within those annual values represent random fluctuation around the average of the data.

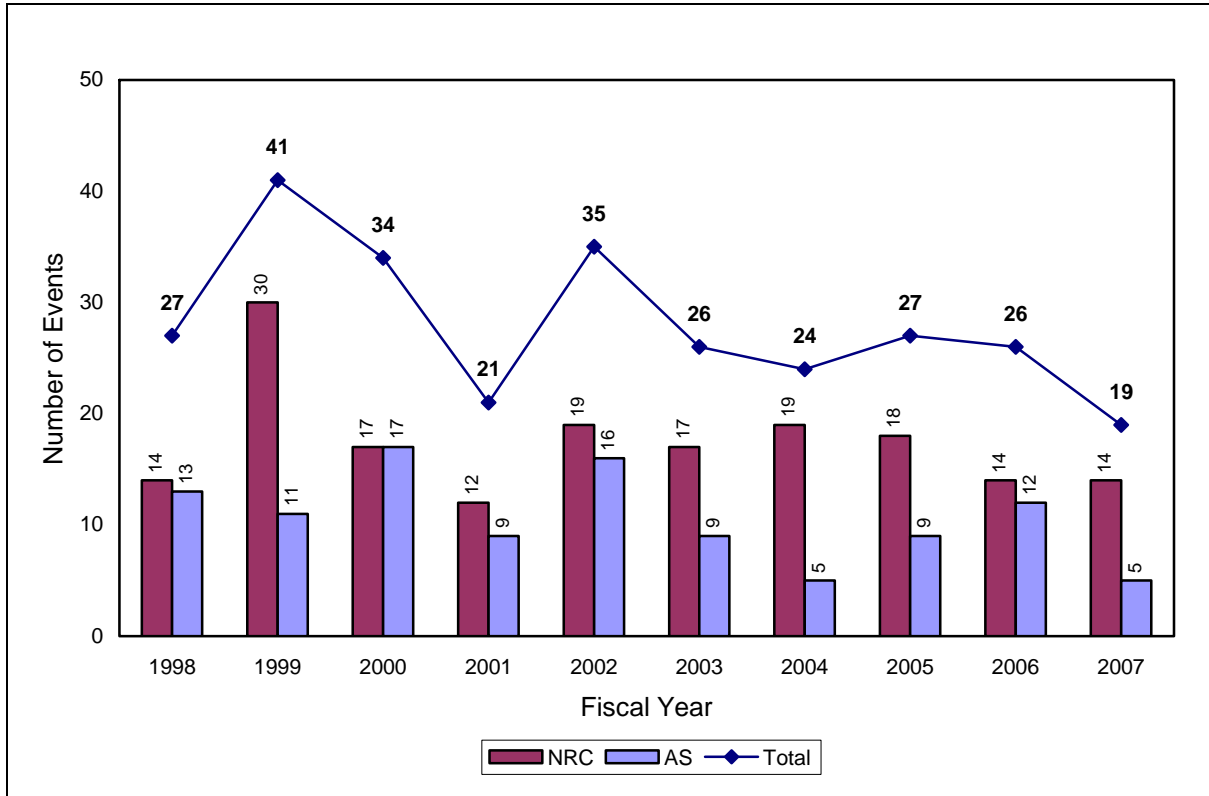


Figure 8. Transportation Events (280 total)

2.8.2 FY07 Data

Nineteen TRS events occurred in FY07, none of which were classified as potential AOs or significant events.

Significant Events

None.

Events of Interest

None.

2.9 Other

2.9.1 Ten-Year Data

Figure 10 displays the annual number of the 69 OTH events that occurred during the 10-year period. Because OTH events do not fit a defined criterion that ensures consistency within the data, trending analysis is not performed on this data.

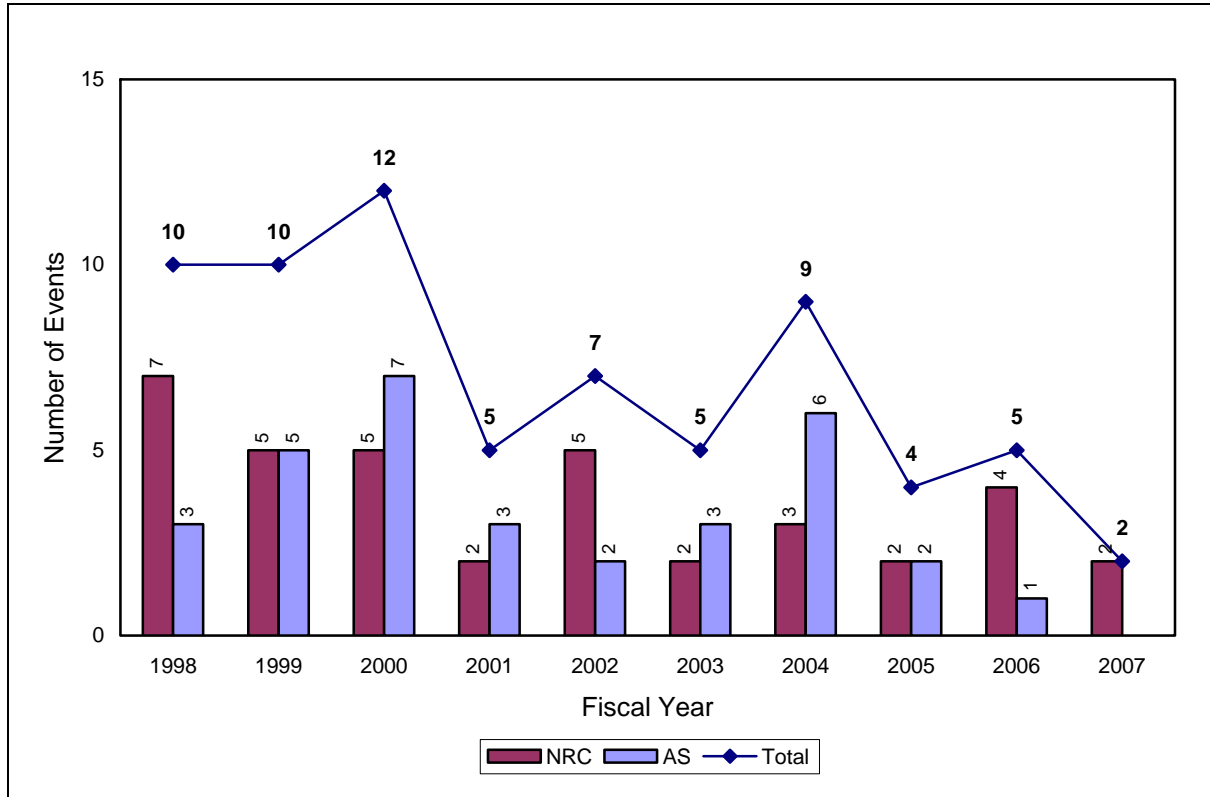


Figure 9. Other Events (69 total)

2.9.2 FY07 Data

Two OTH events occurred in FY07. One of these events was coded as a potential AO and is summarized below as an event of interest.

Significant Events

None.

Events of Interest

Event 070339 involved a thyroid cancer treatment to a patient that resulted in a dose to an embryo/fetus. On 5/22/2007, the licensee performed a pregnancy test on the patient with negative results. The patient was advised not to get pregnant prior to the treatment. On 5/29/2007, the patient was administered 4.64 GBq (125.5 mCi) of I-131. On 5/30/2007, the patient performed a home pregnancy test with positive results and notified the licensee. The licensee performed another test on 5/30/2007 with positive results indicating that the patient was four to five weeks pregnant at the time of the administration. This event was caused by a false negative pregnancy test result (due to the early stage of pregnancy) and the patient's belief that she was not pregnant. The licensee estimated the dose to the embryo/fetus to be approximately 25 and 34 cSv (rem). The NRC contracted with medical consultant to review the medical significance of this event. The consultant concluded that the most likely outcome would be delivery of a normal infant with regard to thyroid function; however, there may be a slightly increased risk of childhood cancer. The licensee took no corrective actions because the cause of the event was beyond their control.

Appendix A

Event Type Descriptions and Criteria

Appendix A

Event Type Descriptions and Criteria

The NMED events covered by this report are divided into the following categories based on the event reporting requirements defined in 10 CFR.

Lost/Abandoned/Stolen Material (LAS)

The LAS event category includes those events where licensed radioactive material is lost or found, abandoned or discovered, and stolen or recovered. The radioactive material involved can be sealed or unsealed material, specifically or generally licensed, exempt or non-exempt quantities, involve a licensee or a non-licensee, and can be found anywhere. Abandoned well logging sources are included in this category. LAS events are categorized as follows:

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

Medical (MED)

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

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

- an administration of a wrong radioactive drug containing byproduct material;
 - an administration of a radioactive drug containing byproduct material by the wrong route of administration;
 - an administration of a dose or dosage to the wrong individual or human research subject;
 - an administration of a dose or dosage delivered by the wrong mode of treatment; or
 - a leaking sealed source.
- c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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

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

- c) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
 - d) When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose.
6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:
- a) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
 - b) When the dose to the individual exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

Events are not considered MED events if they involve:

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

Events are considered MED events if they involve:

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

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

Radiation Overexposure (EXP)

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

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

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

Release of Licensed Material or Contamination (RLM)

The RLM event category includes two types of events. The first type is a radioactive release to air or water exceeding the old 10 CFR Part 20 appendix governing maximum permissible concentrations (MPCs) or the new 10 CFR Part 20 appendix containing annual limit on intakes (ALIs). The second type of RLM event involves contamination events such as a radioactive spill outside of work areas, removable contamination found on equipment, or material tracked around a laboratory such that additional radiological control measures had to be implemented. This category does not include spills inside of laboratory hoods, radiopharmaceutical dose preparation areas, or hot cells where radioactive work routinely requires cleanup or changing of absorbent paper after the performance of a task. Should there be multiple release types (e.g., surface, or air, or water) or areas of contamination associated with the release, this information is classified individually into the NMED Event Table. RLM events are categorized as follows:

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

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

Leaking Sealed Source (LKS)

The LKS event category includes events involving leaking sealed sources. The NRC requires that most sealed sources be periodically leak tested to verify that the material is still sealed and that the source is still considered safe to use without contamination controls, including protective clothing or gloves. A source is considered leaking if a leak test can detect greater than 0.005 μCi of removable radioactive material. The leaking source is then removed from service, disposed of or returned to the manufacturer for repair, and a report is sent to the NRC or Agreement State with the details of the leaking source. For regulatory reporting purposes, a leaking source is generally considered a failed device under 10 CFR 30. Some specific reporting criteria are also listed in 10 CFR 31 (generally licensed material), 10 CFR 34 (radiography), and 10 CFR 35 (medical use of byproduct material).

Equipment (EQP)

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

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

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

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

Transportation (TRS)

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

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

Other (OTH)

The OTH event category includes the following types of events:

1. Doses to an embryo/fetus or nursing child. According to 10 CFR 35.2, these are not medical events.
2. Exposure rates in an unrestricted area in excess of 2 mR/hr, but no individual received a dose in excess of limits (if a dose in excess of limits is received, the event is an EXP event).
3. Reportable events that do not specifically fit into one of the previous categories.
4. Events not reportable to the NRC but included in the NMED program for informational purposes.

Appendix B

Statistical Trending Methodology

Appendix B Statistical Trending Methodology

General

The following is a general discussion of statistical trending techniques.

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

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

Fitting a Straight Line to Data

Consider a linear function

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

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

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

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

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

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

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

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

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

and an estimate of σ is

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

Testing for Trend

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

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

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

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

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

One can show by algebra that

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

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

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

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

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

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

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

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

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

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

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

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

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

Applying the Model to the NMED Data

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

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

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

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

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

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

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

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

Appendix C

IAEA Radionuclide Categorization

Appendix C

IAEA Radionuclide Categorization

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

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

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

- Category 5: Most unlikely to be dangerous.** Exposures to these sources would not cause permanent injury, although delayed health effects are possible.

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

Radionuclide	Category 1		Category 2		Category 3		Category 4		Category 5	
	TBq	Ci ¹	TBq	Ci ¹	TBq	Ci ¹	TBq	Ci ¹	TBq	Ci ¹
Am-241	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Am-241/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Cf-252	20	541	0.2	5.4	0.02	0.54	0.0002	0.0054	1.0e-08	2.7e-07
Cm-244	50	1,352	0.5	13.5	0.05	1.35	0.0005	0.0135	1.0e-08	2.7e-07
Co-60	30	811	0.3	8.1	0.03	0.81	0.0003	0.0081	1.0e-07	2.7e-06
Cs-137	100	2,703	1.0	27.0	0.10	2.70	0.001	0.0270	1.0e-08	2.7e-07
Gd-153	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-05	2.7e-04
Ir-192	80	2,162	0.8	21.6	0.08	2.16	0.0008	0.0216	1.0e-08	2.7e-07
Pm-147	40,000	1,081,200	400.0	10,812.0	40.00	1,081.20	0.4	10.8120	1.0e-05	2.7e-04
Pu-238	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Pu-239/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Ra-226 2	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.
2. Discrete sources of Radium-226. Although this radionuclide is included in this table, events involving these sources are not included in this report (because they do not meet the current definition of byproduct material and are therefore not reportable per 10CFR).

Appendix D
Revision of Data

Appendix D Revision of Data

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

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

In future versions of this report, this appendix will include figures that show the net numerical differences to the 10-year data previously published. A positive value will indicate that the net value has increased from that published in a previous report, while a negative value will indicate that the net value decreased from the previous report.

Update of Nuclear Fuel Services, Inc.

1. SITE IDENTIFICATION

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

2. SITE STATUS SUMMARY

Nuclear Fuel Services (NFS) did not meet the criteria established in SECY-02-0216 for discussion at this year's AARM. However, NFS was discussed at last year's AARM meeting, and Region II and NMSS recommend that the status of the NFS improvement actions be discussed this year due to the unique aspects of NRC oversight at the facility. In particular the establishment of a Safety Culture and Configuration Management Improvement Oversight Panel (Panel) that is evaluating NFS implementation of the February 21, 2007, Confirmatory Order (Order).

3. MAJOR TECHNICAL OR REGULATORY ISSUES

NFS Safety Culture and Configuration Management Improvement Oversight Panel

The panel was formed after the February 2007 Order was issued to provide specific oversight of NFS implementation of the order. The Panel has already begun reviewing the licensee's implementation of the Order. The qualifications, plan, and schedule of the independent third party performing the initial safety culture assessment has already been completed. The Panel's review prompted the licensee to augment their initial assessment strategy, which resulted in NRC granting a 90 day extension for its implementation. The Panel will then review the initial assessment report and assess NFS plans to address the safety culture issues identified in the assessment.

The Panel will also review the corrective actions for the escalated enforcement issues outlined in the Order as well as the licensee's amendment to upgrade the configuration management program.

NFS Repetitive Significant Program Issues

NFS' current performance, as indicated by the number of violations identified since mid-2007, has not significantly improved since the last licensee performance review (LPR). The violations continue to indicate that NFS needs to improve its management oversight to ensure adherence to operational, radiological protection, and engineering procedures. This area for improvement is longstanding as indicated by two of the previous three LPRs.