POLICY ISSUE
INFORMATION

April 17, 2006 SECY-06-0087

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 2005

PURPOSE:

This paper provides the fourth annual report on significant nuclear materials issues, as well as adverse licensee performance trends in the Materials and Waste Programs pursuant to Staff Requirements Memorandum (SRM) SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated February 25, 2003 (ML030560328). This report covers Fiscal Year (FY) 2005.

SUMMARY:

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 includes 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 indicating adverse licensee performance. The staff identified no nuclear materials licensees that met the criteria as described in Table 1 of SECY-02-0216 (ML022410435) for discussion in this paper, as well as for discussion at the Agency Action Review Meeting (AARM). A discussion on performance trends will also be presented at the AARM. This paper does not address any new commitments or resource implications.

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BACKGROUND:

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

In response, on December 11, 2002, the staff issued SECY-02-0216, providing criteria for determining nuclear materials licensees that will be discussed at the AARM. 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.

This paper is the fourth annual report developed to keep the Commission informed of the overall performance trends, as well as significant issues among NRC and Agreement State licensees in the Materials and Waste Programs.

DISCUSSION:

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

The aggregated information used to evaluate significant adverse performance issues and performance trends was obtained through existing processes and systems and includes the following: (1) Abnormal Occurrence (AO) data; (2) strategic, goal and performance goal data; (3) data derived through escalated enforcement actions; (4) generic and special event study results; (5) quarterly report data based on assessment of events reported to the Nuclear Material Events Database (NMED); 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) AO Data:

The staff determined that nine of the events reported to NRC in FY 2005, involving the Materials and Waste Programs, met the criteria for AOs. The FY 2005 AO Report is scheduled to be published around April 2006. The AO events include seven therapeutic medical events/misadministrations (including one involving a dose to an embryo/fetus) and two diagnostic medical events/misadministrations (including one involving an infant). Although the nine AO events for FY 2005 represent a decrease from the 17 events reported for FY 2004, there is no discernable trend in the number of AO events when data from 1999-2005 are compared (Enclosure 1).

The staff's analysis and evaluation of these events resulted in the common finding that human error was the primary contributor to the root cause for all the events reported as FY 2005 AOs. In addition, four of the nine events reported involved incorrect input to computer software. These input errors, combined with other errors, such as failure to verify that the sources were in the correct position, resulted in medical events/misadministrations. However, given the small number of events reported versus the very large number of total medical treatments and diagnostic procedures performed by all licensees per year, the staff does not believe that this represents a generic issue for all treatments and procedures. Other examples of human errors that contributed to the root cause included: 1) failure to verify correct dosages (activity); (2) use of sources incompatible with the applicator; and 3) improper positioning of equipment and sources and failure to verify correct placement.

No significant performance trends or generic concerns were identified when FYs 1999-2005 data was analyzed.

(2) Strategic Goal and Performance Goal Data:

NRC staff focused on verification and validation of data generated by NRC, as well as by the industry and other external sources, to determine the impact on performance measures. Performance measure data highlighted in this report are those with values exceeding a performance goal or likely to exceed a performance goal within 80 percent of the maximum value, as described in SECY-02-0216, Table 1 (ML022410435). For FY 2005, all Strategic Goals were met. The metrics for the strategic goals are zero, and there were no events reported during FY 2005 that met any of the strategic measures. All performance and precursor goals were met in FY 2005. No measured values for the performance or precursor goals exceeded 80 percent of the metric.

The number of medical events and misadministrations reported in FY 2005 has decreased from the number of events reported for previous years. Thirty-one medical events and misadministrations occurred during FY 2005 (versus 40 in FY 2004 and 39 in FY 2003). However, based on the "Fourth Quarter FY 2004 NMED Quarterly Report," a statistical trend analysis performed on data from 1995 through 2005 determined that the data do not indicate a statistically significant trend. No generic issues were identified after an evaluation of these events was conducted.

NRC met its strategic, performance, and precursor goals in the Materials and Waste Programs for FY 2005.

(3) Data Derived Through Escalated Enforcement Actions:

During FY 2005, NRC issued 40 escalated enforcement actions involving NRC materials licensees. Escalated enforcement in the Materials and Waste Programs includes civil penalties, orders, and Notices of Violation for Severity Levels I, II, and III violations. In FY 2005, there were four enforcement actions that resulted in Severity Level I or II violations. In the past 4 years, the average for Severity Level I or II violations is about four per year. There were three in FY 2002, five in FY 2003, five in FY 2004, and four in FY 2005. Summaries of Severity Level I or II violations for FYs 2002, 2003, 2004, and 2005 are described in Enclosure 2. The Office of Enforcement's (OE) "Enforcement Program Annual Report" describes the agency's enforcement activities during a given fiscal year, and includes various tables and figures. OE's "Enforcement Program Annual Report - FY 2004" does not identify any significant trends.

(4) Generic and Special Event Study Results:

This annual report presents studies in two areas: high-risk lost and stolen sources, and overexposure events.

High-risk Lost and Stolen Sources:

Given the continued level of focus on high-risk lost and stolen sources, an update to last year's analysis was performed on the number of lost and stolen radioactive sources exceeding the threshold for quantities of concern, which is found in Enclosure 3. This special review of lost and stolen radioactive sources of greatest concern uses a risk-informed approach to data analysis. The radioactive sources of greatest concern are those sources that may pose a significant risk to individuals, society, and the environment. The threshold quantities used for this analysis are the Category 2 quantities in Table I of International Atomic Energy Agency's "Code of Conduct on the Safety and Security of Radioactive Sources." Staff reviewed the number of events involving lost and stolen sources of greatest concern from calendar years 1994 - 2005 (Enclosure 3).

Between 1994 and 2005, there were 60 events involving loss or theft of risk-significant sources (70 percent were lost sources and 30 percent were stolen). This is an average of about 5 per year. In approximately 80 percent of the events for the 12-year period, the sources were recovered. This results in an average of about one unrecovered source per year. In FY 2005, a new Performance Goal, Goal 2: Security-Performance Measure #1, was established under the Security Area to monitor the number of unrecovered, risk-significant sources that pose a safety or security threat (NSIR determination).

In FY 2005, one source was lost and not recovered. The event involved the loss of a radiography source in about 27 meters (90 feet) of water in the Gulf of Mexico, as it was being transferred from an offshore platform to a transport boat. This event does not meet the criteria of Goal 2: Security-Performance Measure #1, based on a determination, by NRC's Office of Nuclear Security and Incident Response (NSIR), that the risk-significance of this source is low, based on the location (i.e., water depth) of the source.

The analysis provided this year represents no significant change to the averages from the period from calendar years 1994 - 2004. The data analysis does not reveal a discernable trend in the number of lost and stolen events for radioactive material exceeding the threshold quantities. There is no evidence of theft for malevolent use.

Although the number of high-risk lost and stolen sources is very low, NRC takes each of these events very seriously. The NRC, in partnership with Agreement State regulators, have enhanced the security and control measures for these sources, as a means of further reducing the number of lost and stolen sources. These measures have been put in place for all licensees throughout the U.S. The NRC and the Agreement States are inspecting those licensees to verify compliance with these requirements.

Overexposure Events:

Given the significant potential consequences of overexposures, staff performed a special study of the overexposure events that have occurred in the 4-year period from FYs 2002-2005. Details are found in Enclosure 4.

Analysis of the data showed that only a small percentage of the total events each year are overexposures. There were 56 overexposure events in the 4-year period analyzed. This is only about 3 percent of the total 2038 events for the 4-year period. In addition, few of these overexposure events meet AO criteria (i.e., significant events). There were 6 overexposures that were AOs in the 4-year period. This is less than 0.3 percent of total events, or less than 10 percent of the overexposure events. There were zero AO overexposures in FY 2005.

To put this in perspective, it must be compared to the total number of opportunities for an overexposure to occur. Per NUREG-0713, vol. 26, it is estimated that there are over 13,000 monitored occupational workers at over 120 materials licensees. Also, per NUREG-1350, vol. 17, there are over 21,000 materials licensees. In addition, some types of activities involving radioactive sources are conducted in environments where members of the public are nearby, such as in hospitals, in radiography or portable gauge field work, or during transportation. This is a normal part of the nature of these activities. Although the material and areas are controlled, the proximity of the public presents the possibility of inadvertent pportunities for members of the public to be in close proximity to sources (e.g., medical, radiography, well logging, portable gauges, transportation). Given the large number of individuals either working with sources, or in the area where sources might be used, there are a large number of opportunities each day for an inadvertent overexposure to occur. Considering this, it is significant that the number of overexposures recorded each year is so low.

The analysis also showed that overexposure events primarily involved three type of licensees. Approximately 88 percent involved radiography, well logging, and radiopharmaceuticals (49 out of 56). The remaining 12 percent involved a brachytherapy source, two fixed gauges, and three events involving unsealed material (7 out of 56). In evaluating the specific events, we found certain patterns within the three primary types of licensees involved.

Radiography overexposure events typically involve whole body doses less than 10 rem to occupational workers and only involve one person. Of the 6 events where doses exceeded 10 rem, the highest was 152 rem, and the next highest was 31.4 rem. One event involved a dose to the public (doses to 2 FedEx package handlers from handling a damaged shipping package containing Ir-192 wafers for radiography sources).

Well logging overexposure events typically involve non-radiation rig workers in the area and involve more than one person.

Events involving radiopharmaceuticals typically involve extremity doses to occupational workers. The exception to this was 2 events that involved whole body doses to family caring for or visiting patients that were receiving therapeutic radiopharmaceutical doses, and where the family member did not adhere to directions/controls provided by the hospital to minimize dose received (e.g., moved lead shield out of the way to be closer to the patient).

These patterns are not unexpected given the types of work being performed in these areas, and the typical environments in which they are conducted.

Lastly, the analysis showed that human error was the cause in approximately 80 percent of the events (45 out of 56). Awareness of workers regarding the need for attention to procedures and detail is important in reducing the potential for overexposures.

In summary, no regulatory changes are recommended. The NRC is already engaged in raising awareness of the potential for overexposure. Some examples are: issuance of Information Notices to make licensees aware of potential problems or weaknesses; sharing of examples of overexposures in the NMSS Quarterly Newsletter (which goes to all licensees); communicating the importance that NRC places on avoiding overexposure by issuing enforcement (which also provides incentive for other licensees to avoid actions which could cause them to receive enforcement); and conducting inspections (to allow NRC to identify pre-cursor issues that may lead to overexposures). In addition, human reliability studies have been started with RES to explore whether there are ways to further reduce potential for human errors.

(5) Assessment of Data Reported to NMED:

NMED contains records of events involving nuclear material reported to NRC by its licensees, Agreement States, and non-licensees. These reported events are classified based on 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 a quarterly report, in which 16 quarters of historical data are aggregated for evaluation of potential trends. The NMED Quarterly Report is posted on the NMED web site at **https://NMED.inl.gov** and is directly available to NRC and Agreement State staffs. Using event analysis and reviews published in the NMED Quarterly Report, performance trends can be identified. Fourth-quarter reports include an annual summary of data.

Enclosure 5 is a copy of the "Fourth Quarter FY 2005 NMED Quarterly Report." For the 16-quarter period covering October 1, 2001, through September 30, 2005, a total of 2038 events associated with materials licensees were reported to NRC, versus a total of 2060 that were reported for the previous 16-quarter period, covering October 1, 2000, through September 30, 2004.

For the 16-quarter period ending September 30, 2005, 47 percent of the events were classified as "Lost/Abandoned/Stolen Material." The remaining 53 percent were divided among "Equipment" (24 percent); "Leaking Sealed Source" (8 percent); "Transportation" (7 percent); "Medical Events (or Misadministrations)" (7 percent); "Radiation Overexposure" (3 percent); "Release of Material or Contamination" (3 percent); and "Other" (1 percent). This represents no significant change from the percentages for the previous 16-quarter period.

Although some of the graphs in the Quarterly Report indicate slight increasing or decreasing patterns, ongoing routine assessment of events did not reveal any significant adverse performance trends.

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

There are no nuclear materials licensees that met the significant issues criteria as described in SECY-02-0216. This indicates that there were no critical failures in licensee performance, and that there were no issues that were not able to be addressed in the normal inspection and enforcement processes.

SECY 02-0216 defines the criteria to identify those issues and licensees that rise to the level of needing the highest level management attention and awareness. These 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. In FY 2005, there were no licensees identified for discussion according to these criteria. NMSS, STP and the Regions used this as an opportunity to review the threshold criteria to ensure that it was still appropriate. It was determined that the criteria continue to appropriately identify those issues that need to be raised for discussion at the

AARM. This does not imply that events, issues, and licensee performance below these criteria are not of importance. The staff determined however, that those items were being appropriately dealt with at lower levels or in other venues, and did not warrant discussion at the AARM. We are confident that our processes would allow us to identify licensees or candidates meeting the SECY-02-0216 criteria.

<u>OVERALL PERFORMANCE CONCLUSIONS</u>:

Based on review of numerical 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 nuclear materials licensees that were identified through event evaluations, or other follow-up reviews, as having significant performance issues, during FY 2005. Moreover, it is important to recognize that the degree of NRC oversight applied to different licensees, or regarding NRC followup of trends or issues, is not driven solely by the AARM process. Heightened oversite of licensees, or followup and action taken relative to trends seen in events, may be in effect even if that licensee's performance does not rise to the level of the AARM criteria in a given year.

<u>COORDINATION</u>:

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

/RA by William F. Kane Acting For/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Annual Trend in AO Events from FYs 1999-2005
2. Summary of Severity Level I and II Enforcement Actions for FYs 2002-2005
3. Annual Trend in Lost and Stolen Source Events Exceeding the Threshold Quantities for Radioactive Sources of Concern
4. Review of Overexposure Events
5. Fourth Quarter FY 2005 NMED Quarterly Report (ML060310600)

ANNUAL TREND IN AO EVENTS FROM FYS 1999 - 2005

Table 1 shows the number of events reported annually that were determined to meet the Abnormal Occurrence (AO) criteria. A total of 72 events was found to meet the AO Criteria for the 7 year period 1999 - 2005. Seventy-eight percent of the AO events were 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. The numerical dose criteria applied to medical events also appear to be a factor in medical events meeting the AO criteria. For example, the criteria for medical events are: (1) the total dose delivered differs from the prescribed dose by greater than 20 percent; and (2) the dose to an organ is greater than 0.05 Sv (5 rem). Therefore a broad range of dose deviations can result in a medical event AO.

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 one loss/theft event in 7 years has been found to meet the AO criteria. The average over the 7 years is 10.3 AOs/year.

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

Year	Lost/Stolen	Medical	Personnel Overexposure	Fuel Cycle Facility	Totals
1999	0	10	2	1	13
2000	0	7	1	0	8
2001	0	0	2	0	2
2002	1	4	4	0	9
2003	0	12*	2	0	14
2004	0	14*	1	2	17
2005	0	9	0	0	9
Totals	1	56	12	3	72

*Fiscal Years 2003 and 2004 include events involving a dose to embryo/fetus (one each year).

SUMMARY OF LEVEL I AND II ENFORCEMENT ACTIONS FOR FYS 2002 - 2005

FY 2002:

Bristol-Myers Squibb Radiopharmaceuticals, Inc. **Severity Level II**
Rio Piedras, Puerto Rico
EA 02-160
Docket No. 030-34187

On August 22, 2002, a Notice of Violation was issued for a Severity Level II problem involving the failure to control occupational dose (two operators received extremity overexposures) and the failure to perform adequate surveys to evaluate radiation exposure to the extremities.

Eastern Isotopes, Inc. **Severity Level II**
Charlotte, North Carolina
EA 02-097
Docket No. 030-32974

On July 30, 2002, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $4800 was issued for a Severity Level II violation involving an overexposure to a pharmacist in excess of U.S. Nuclear Regulatory Commission (NRC) requirements. Although the civil penalty would have been fully mitigated based on the normal civil penalty assessment process, NRC exercised enforcement discretion in accordance with Section VII.A.1 of the Enforcement Policy and proposed a base civil penalty because the violation resulted in an actual overexposure.

J. L. Shepherd and Associates **Severity Level II**
San Fernando, California
EA 02-043
Docket Nos. 71-0122, 71-6280

On August 13, 2002, an Order Imposing Civil Monetary Penalty in the amount of $19,200 was issued. The action was based on a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $19,200 that was issued on June 11, 2002, for a Severity Level II problem involving the willful failure to comply with a Certificate of Compliance with regard to fabrication and shipment of packages. The licensee’s July 10, 2002, response did not deny that the violations occurred as stated in the Notice, but requested mitigation of the penalty. After considering the licensee’s response, NRC concluded that the violations occurred as stated and that there was not an adequate basis for mitigating the civil penalty.

FY 2003:

Advanced Medical Imaging and Nuclear Services **Severity Level II**
Easton, Pennsylvania
EA 02-072
Docket No. 030-35594

On October 22, 2002, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $43,200 was issued for a Severity Level II problem involving willfully using byproduct material without an Authorized User, failing to appoint a Radiation Safety Officer, and creating incomplete and inaccurate records. Although the normal civil penalty assessment process would have resulted in a base civil penalty, NRC exercised discretion in accordance with Section VIIA.3 of the Enforcement Policy and assessed a base civil penalty for each day the violation continued after the licensee's consultant raised the issue. Discretion was warranted base on the egregiousness of the violations, the level of management involved, the economic benefit of being in noncompliance, and the failure to take corrective action after the consultant's finding.

Pacific Radiopharmacy, Ltd. **Severity Level I**
Honolulu, Hawaii
EA-02-172
EA-02-246
Docket: 030-12031

On March 27, 2003, a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $9000 was issued for a Severity Level I problem. The Severity Level I problem (assessed a $6000 civil penalty) involved the failure to limit the occupational dose to an individual adult to the shallow-dose equivalent of 500 mSv (50 rem) to any extremity, and the failure to make surveys that are necessary to comply with regulations.

St. Joseph Mercy Hospital **Severity Level I**
Ann Arbor, Michigan
EA-02-248
Docket: 030-01997

On May 7, 2003, Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $6000 was issued for a Severity Level I problem involving: (1) the failure to conduct operations so that the total effective dose equivalent to individual members of the public from licensed operations does not exceed 1 mSv (0.1 rem) in a year; and (2) the failure of the radiation safety officer to investigate overexposures and other deviations from approved radiation safety practice, and implement corrective actions as necessary.

Structural Testing and Inspection **Severity Level II**
Pocatello, Idaho
EA-03-006
Docket: 999-90004

On July 1, 2003, a Notice of Violation was issued for a Severity Level II violation involving the willful failure to obtain a specific license from NRC or an Agreement State, before acquiring and using byproduct material. Although a civil penalty would normally be considered for this type of case, NRC exercised discretion in accordance with Section VII.B.6 of the Enforcement Policy and refrained from assessing a civil penalty based on the fact that the gauges were returned to an authorized NRC licensee and the company withdrew its application for an NRC license.

Testing Technologies, Inc. **Severity Level II**
Woodbridge, Virginia
EA-02-166
Docket: 030-30657

On January 22, 2003, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $9600 was issued for a Severity Level II problem involving the willful:
(1) performance of radiographic operations at temporary job sites by radiographers' assistants and helpers who were not accompanied by at least one qualified radiographer; (2) performance of radiographic operations by individuals who had not met training requirements; (3) failure to wear a combination of a direct reading pocket dosimeter, an alarming ratemeter, and either a film badge or TLD and (4) failure of the corporate and site Radiation Safety Officer to oversee the radiation safety program.

FY 2004:

State of Alaska Department of Transportation **Severity Level II**
& Public Facilities
Anchorage, Alaska
EA-03-126, EA-03-190, EA-04-061
Docket No. 030-07710

On March 15, 2004, a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $21,000 was issued: for (1) a willful Severity Level II problem ($15,000), involving radiation exposures in excess of NRC 's annual public exposure limit and failure to perform surveys appropriate to demonstrate compliance with NRC dose limits for individual members of the public; and (2) a willful Severity Level III violation ($6000) involving the failure to provide copies of two exposure reports to six affected individuals. A Notice of Violation was also issued for a Severity Level II violation based on the licensee discriminating against one of its employees for raising safety concerns regarding radiation exposures to other employees. In addition, a Confirmatory Order was also issued in conjunction with this action.

U.S. Inspection Services **Severity Level II**
Dayton, Ohio
EA-03-204
Docket No.

On June 15, 2004, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $19,200 was issued for a Severity Level II problem involving multiple violations related to an overexposure of radiographer, including issues such as failure to survey, failure to calibrate and inspect equipment, and failure to follow procedures.

Westinghouse Electric Company **Severity Level II**
Columbia Nuclear Fuel Plant
Columbia, South Carolina
EA-04-096
Docket No. 70-1151

On July 28, 2004, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $24,000 was issued for a Severity Level II problem involving multiple violations related to the discovery of ash deposits in the incinerator off-gas system at concentrations that exceeded the bounding assumptions of the approved safety basis.

Shannon Kokkeler **Severity Level II**
IA-03-005

On October 14, 2003, a Notice of Violation was issued for a Severity Level II violation based on the individual’s deliberate activities while employed at Schlumberger Technology Corporation. As a field engineer in training on a well-logging crew, the individual knowingly failed to perform any required radiation surveys of the source storage container to ensure the source was present in the container before loading the container back onto the vehicle and departure from the wellsite, and falsified a log certifying that she had "personally checked each logging source shield with a survey meter to ensure that the source is contained within," despite her knowledge that this information was not accurate.

Shane Moran **Severity Level II**
IA-03-006

On October 14, 2003, a Notice of Violation was issued for a Severity Level II violation based on the individual’s deliberate activities while employed at Schlumberger Technology Corporation. As a senior operator on a well-logging crew, the individual knowingly failed to perform any required radiation surveys of the source storage container to ensure the source was present in the container before loading the container back onto the vehicle and departure from the wellsite, and falsified a log certifying that he had "personally checked each logging source shield with a survey meter to ensure that the source is contained within," despite his knowledge that this information was not accurate.

FY 2005:

Saint Joseph Regional Medical Center **Severity Level II**
South Bend, IN
EA-05-128
Docket No. 030-13685

On September 23, 2005, a Notice of Violation and Proposed Imposition of Civil Penalties in the cumulative amount of $19,200, was issued for three Severity Level II problems, one Severity Level II violation, and two Severity Level IV violations, associated with brachytherapy treatments that resulted in unintended radiation doses to five patients. Because these violations directly contributed to significant health consequences for Patients Nos. 3, 4, and 5, each of those three events is categorized as a separate Severity Level II problem in accordance with the NRC Enforcement Policy. In addition, the licensee became aware that three medical events had occurred and did not notify the NRC of the events until more than one day after the medical events were discovered, contrary to 10 CFR 35.3045(c) that requires licensees to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of such events. The events associated with Patients Nos. 1 and 2 are categorized as separate examples of a Severity Level IV problem in accordance with the NRC Enforcement Policy due to the more limited health consequences associated with these medical events.

Baxter Healthcare Corp. **Severity Level II (2 actions)**
Aibonito, PR
EA-04-118 and EA-04-208
Docket No. 03019882

On October 25, 2004, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $44,400 was issued for two willful Severity Level II violations (assessed $28,800 for three occurrences of failure to adhere to emergency procedures and $9600 for failure to perform an adequate survey) and a willful Severity Level III violation ($6000 for failure to provide an individual radiation monitoring device) related to an event involving personnel entering an irradiator when the source was stuck in an unshielded position.

Soil Consultants, Inc. **Severity Level II**
Manasas, VA
EA-04-103
Docket No. 030-33635

On April 27, 2005, an immediately effective Confirmatory Order was issued to confirm commitments made as part of a settlement agreement concerning an Order Imposing Civil Monetary Penalty in the amount of $9000 issued on February 1, 2005. The action was based on a Severity Level II violation for discrimination against an employee for engaging in certain protected activities (reporting safety concerns to his employer or to the NRC). In response to the Order, the licensee requested the use of the NRC's alternative dispute resolution (ADR) process to resolve differences it had with the NRC concerning the violation. As part of the settlement agreement that was reached through the ADR process, the licensee agreed to pay a civil penalty in the amount of $1200 and to take additional corrective actions to emphasize the importance of a Safety Conscious Work Environment at their facility.

ANNUAL TREND IN LOST AND STOLEN SOURCE EVENTS EXCEEDING THE THRESHOLD QUANTITIES FOR RADIOACTIVE SOURCES OF CONCERN

An analysis of lost and stolen radioactive sources of concern data from the U.S. Nuclear Regulatory Commission’s (NRC’s) Nuclear Material Events Database (NMED) for calendar years 1994 - 2005 was performed. Table 1 describes the number of lost and stolen events involving material exceeding the threshold quantities for radioactive sources of concern. The threshold quantities are those for Category 2 sources from the International Atomic Energy Agency’s (IAEA’s) “Code of Conduct on the Safety and Security of Radioactive Sources” (2004).

Table 1 - Number of Lost and Stolen Source Events Involving Material Exceeding the Threshold Quantities for Radioactive Sources of Concern from Calendar Years 1994 - 2005[1]

Radionuclide[2]	Threshold, TBq (Ci)	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Am-241	0.6 (20)												
Cf-252	0.2 (5)												
Cm-244	0.5 (10)												
Co-60	0.3 (8)			2(0)[3]									
Cs-137	1 (30)			1(0)									
Ir-192	0.8 (20)	5(3)	4(1)	8(3)	4(0)	7(1)	5(1)	2(0)	7(1)	4(0)	7(1)	3(0)	2(1)[4]
Pu-238	0.6 (20)												
Pu-239	0.6 (20)												
Sr-90/ Y-90	10 (300)												
Total Sources		5	4	11	4	7	5	2	7	4	7	3	2
Total Sources Not Recovered		3	1	3	0	1	1	0	1	0	1	0	1

Note 1: For isotopes in use in the U.S.
Note 2: Am-241 - americium-241; Cf-252 - californium-252; Cm-244 - curium-244; Co-60 - cobalt-60; Cs-137 - cesium-137; Ir-192 - iridium-192; Pu-238 - plutonium-238; Pu-239 - plutonium-239; Sr-90/Y-90 - strontium-90/yttrium-90
Note 3: Total number of events, followed in parentheses ( ) by number of events where at least one source was not recovered
Note 4: One event involved the loss of a radiography source in about 27 meters (90 feet) of water in the Gulf of Mexico, as it was being transferred from an offshore platform to a transport boat. This event does not meet the criteria of Goal 2: Security-Performance Measure #1, based on a determination, by NRC’s Office of Nuclear Security and Incident Response (NSIR), that the risk-significance of this source is low, based on the location (i.e., water depth) of the source.

Analysis of the data shows that in 80 percent of the events involving lost and stolen radioactive sources, the radioactive sources of concern were recovered. Seventy percent of these events were caused by losses of radioactive sources and 30 percent caused by theft. This represents no significant change to the averages from the period from calendar years 1994 - 2004. The data analysis does not reveal a discernable trend in the number of lost and stolen events for radioactive material exceeding the threshold quantities.

For the 12 sources not recovered, after decay correction, the total activity remaining is less than 3 Ci (Category 3). All ten of the unrecovered sources lost or stolen prior to CY 2003 have now decayed below exempt quantity levels (10 microcuries). The one source stolen in CY 2003 has decayed to a Category 5 source. The source lost in CY 2005 has decayed to a Category 3 source, and will be a Category 4 source by the end of April 2006. The source will be a Category 5 source by August 2006. The current risk posed by the source is limited.

REVIEW OF OVEREXPOSURE EVENTS

Given the significant potential consequences of overexposures, staff performed a special study of the overexposure events that have occurred in the 4-year period from FYs 2002-2005.

Frequency of Occurrence:

Only a small percentage of events per year are overexposures.

- Only 3% of total events (56 overexposure events out of a total 2038 events reported for a 4-year period from FYs 2002-2005).

Few overexposure events per year meet AO criteria (i.e., significant events).

- Zero AO overexposures in FY 2005.
- Only 6 out of 56 total overexposure events for FYs 2002-2005 were AOs (an average of 1.5 per year).
- Less than 0.3% of total events are AO overexposures.
- About 10% of the overexposure events are AOs.

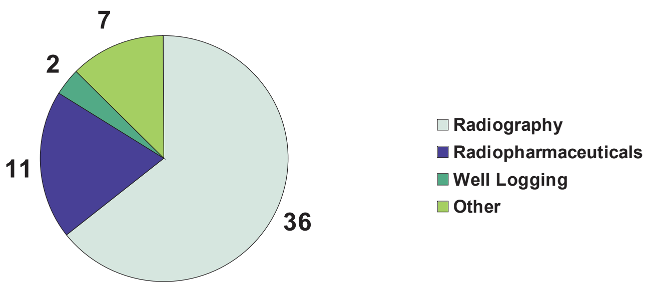
Few overexposures per number of individuals involved in work with radioactive materials.

- Perspective: compare to the total number of opportunities for an overexposure to occur.
- Per NUREG-0713, vol. 26, it is estimated that there are over 13,000 monitored occupational workers at over 120 materials licensees.
- Per NUREG-1350, vol. 17, there are over 21,000 materials licensees.
- Some types of activities involving radioactive sources are conducted in environments where members of the public are nearby, such as in hospitals, in radiography or portable gauge field work, or during transportation. This is a normal part of the nature of these activities. Although the material and areas are controlled, the proximity of the public presents the possibility of inadvertent opportunities for members of the public to be in close proximity to sources (e.g., medical, radiography, well logging, portable gauges, transportation).
- Given these high numbers, it is significant that there are so few overexposures per number of individuals involved in work with radioactive materials, or that could possibly come in proximity to work involving these materials.

Type of Licensee:

Overexposure events primarily involved three type of licensees.

- 88% involved radiography, well logging, and radiopharmaceuticals (49 out of 56).
- Remaining 12% involved a brachytherapy source, two fixed gauges, and three events involving unsealed material (7 out of 56).



There are certain patterns within the three primary types of licensees involved.

- Radiography overexposure events typically involve whole body doses less than 10 rem to occupational workers and only involve one person.
  - 92%, 33 of the 36 radiography events, only 3 of these involved more than one person.
  - 82% did not exceed 10 rem (27 out of 33). Of the 6 exceeding 10 rem, the highest was 152 rem, and the next highest was 31.4 rem.
  - Only one event involved a dose to the public (doses to 2 FedEx package handlers from handling a damaged shipping package containing Ir-192 wafers for radiography sources).

- Well logging overexposure events typically involve non-radiation rig workers in the area and involve more than one person.
  - 2 events out of the 56 total overexposure events for FYs 2002-2005.

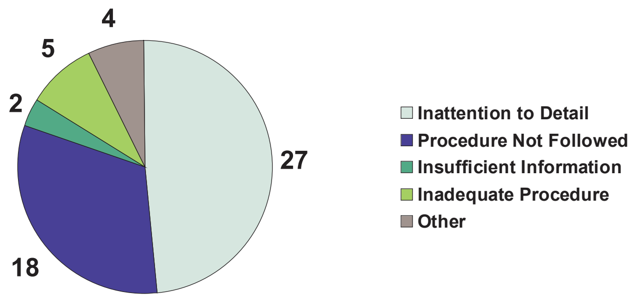
- Overexposure events involving radiopharmaceuticals typically involve extremity doses to occupational workers and involve only one person.
  - 11 events out of the 56 total overexposure events for FYs 2002-2005 involved radiopharmaceuticals.
    - 9 of these 11 events involved extremity doses to workers. Only 1 event of the 9 involved more than one person.
    - 2 events involved whole body doses to family caring for or visiting patients that were receiving therapeutic radiopharmaceutical doses, and where the family member did not adhere to directions/controls provided by hospital to minimize dose received (e.g., moved lead shield to be closer to the patient).

- The patterns seen are not unexpected given the types of work being performed in these areas, and the typical environments in which they are conducted.
  - Radiography: field work, fast moving, temporary setups, coordination with other types of non-rad work, large sources increasing the potential to (and more likely than users of small sources to) exceed the annual whole body doses by small amounts), handling source connections by hand (increasing potential for extremity doses to fingers in cases where sources are mishandled)

- Well logging: field work, fast moving, temporary setups, doses to public possible if source is left behind
- Radiopharmaceuticals: handling doses with hands increasing the potential for doses to extremities, unsealed material increasing the potential for contamination events, most handling done in restricted area increasing likelyhood that any doses would be to only rad workers (and not to non-rad workers). Doses to family members not unexpected given family members more focused on comforting patient than in abiding by restrictions placed to minimize dose.

<u>Cause:</u>

Human error was the primary cause (80% of the events, 45 out of 56).



<u>Summary:</u>

Awareness of workers regarding the need for attention to procedures and detail is important in reducing the potential for overexposures.

No regulatory changes are recommended.

- There is a very low rate already and most of the errors could not easily have been foreseen (e.g., the equipment was well-designed, the procedure was adequate, the training was adequate, but the worker just did not follow the procedure or was inattentive).
- NRC is already engaged in raising awareness.
    - Issuing Information Notices to make licensees aware of potential problems or weaknesses
    - Sharing of examples of overexposures in NMSS Quarterly Newsletter (which goes to all licensees)
    - Communicating the importance that NRC places on avoiding overexposure by issuing enforcement (which also provides incentive for other licensees to avoid actions which could cause them to receive enforcement)
    - Conducting inspections (to allow NRC to identify pre-cursor issues that may lead to overexposures)
    - Starting human reliability studies with RES to explore whether there are ways to further reduce potential for human errors.

INL/EXT-05-00099 (FY 2005 QTR 4)

January 2006

Nuclear Material Events Database (NMED) Quarterly Report

Fourth Quarter Fiscal Year 2005

Michele L. Burgess, NRC

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Published January 2006
https://nmed.inl.gov

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Prepared for the
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Under U.S. Department of Energy-Idaho Operations Office
Contract DE-AC07-99ID13727

ABSTRACT

This quarterly 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. The event categories are: (1) Medical, (2) Radiation Overexposure, (3) Release of Licensed Material or Contamination, (4) Lost/Abandoned/Stolen Material, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, (8) Fuel Cycle Facility, (9) Non-Power Reactor, and (10) Other. The scope of the NMED quarterly report is limited to a discussion and evaluation of the reportable events in categories (1) through (7) and (10). The Fuel Cycle Facility and Non-Power Reactor event categories are excluded from this report due to the significant difference in operation of these facilities compared to the operation of other facilities licensed by NRC and Agreement States to use by-product, source, and special nuclear material. Events involving abandoned well-logging sources are also excluded from this report. Event data are presented for a 16-quarter period covering October 1, 2001, through September, 30, 2005. Data on events tracked by the NRC as performance measures are presented on page *ix*.

Copies of this report are available on the Internet at https://nmed.inl.gov.

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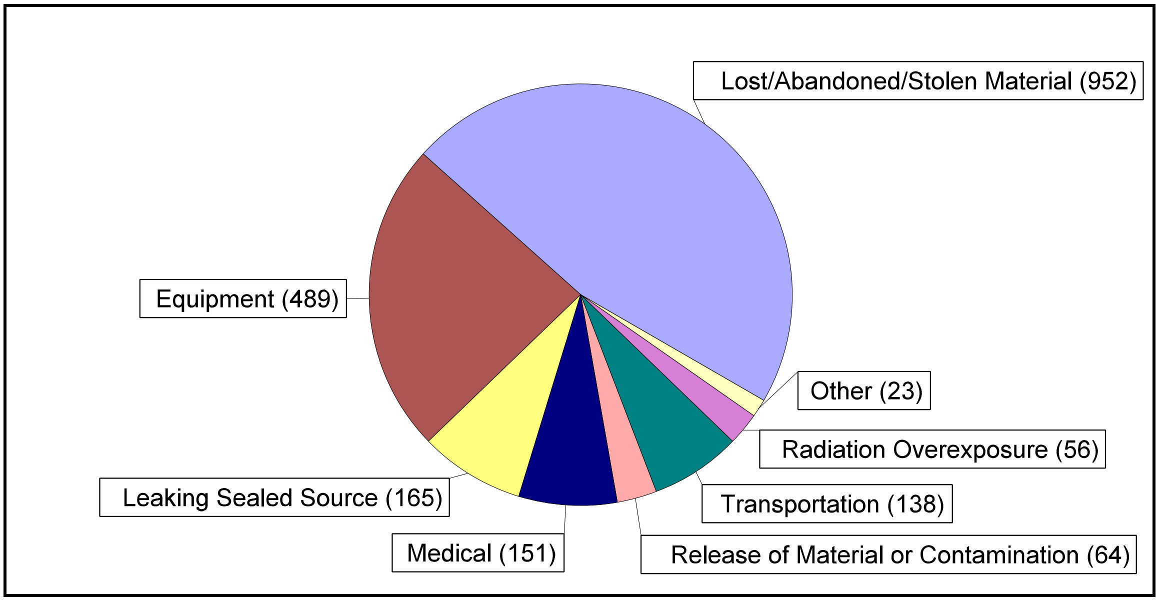
FIGURES

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 event reporting requirements defined by Title 10 of the Code of Federal Regulations. The event reports are evaluated to identify safety-significant events or concerns and their causes. The reported information aids understanding of why the events occurred and in identifying any actions necessary to improve the effectiveness of the nuclear material regulatory program.



Two thousand thirty-eight events occurred during the 16-quarter period (October 1, 2001 through September 30, 2005). One hundred six of these events occurred during the current quarter. Forty-seven percent of the 16-quarter events were classified as lost/abandoned/stolen material events.

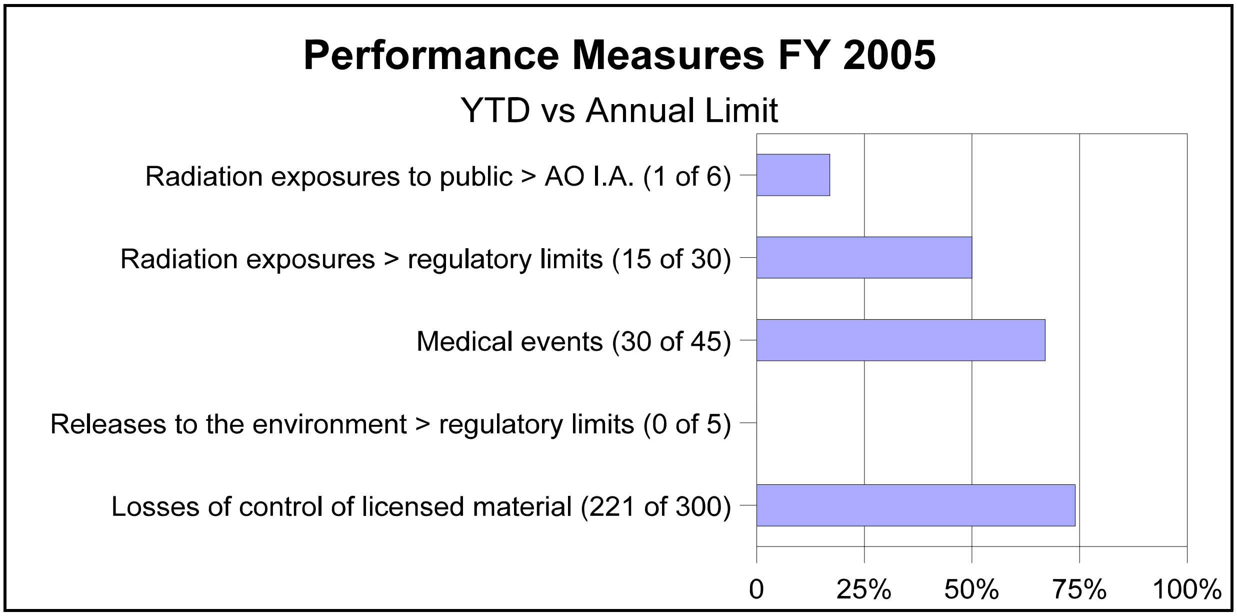
During the 16-quarter period, the event reporting rate was about 2.5 events per 100 licensees annually for all events, and about 0.5 events per 100 licensees annually for medical events. This was based on an estimate of about 21,809 material licensees (about 4,511 NRC licensees and 17,298 Agreement State licensees) that averaged 510 events per year. Of the 21,809 material licensees, about 8,775 were medical licensees that averaged about 38 medical events per year. This indicates that, annually, only 2.5% of all licensees report any type of incident/accident involving licensed material. For incidents involving medical events, less than 1% of medical licensees report an event annually.

PERFORMANCE MEASURES

Certain NMED reportable events are tracked by the NRC as performance measures. Those events involve:

1. Radiation exposures from licensed material that exceed the Abnormal Occurrence Criteria I.A (as published in the Federal Register on December 19, 1996 (61 FR 67072) and as revised and published on April 17, 1997 (62 FR 18820)),
2. Radiation exposures from licensed material that exceed applicable regulatory limits,
3. Medical events,
4. Releases to the environment of licensed material from operating facilities that exceed regulatory limits, or
5. Losses of control of licensed material.

The following chart displays Fiscal Year 2005 performance measures as a percentage of the annual limits. Data for the performance measure charts may be more or less current than the data presented in the body of this report.



Nuclear Material Events Database (NMED) Quarterly Report: Fourth Quarter Fiscal Year 2005

1. INTRODUCTION

1.1 Overview and Objectives

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

A database for tracking nuclear material events was developed by the Nuclear Regulatory Commission (NRC) in 1981. In 1993, using existing material events databases, the NRC developed a new and more comprehensive database for tracking material events. This database, designated the Nuclear Material Events Database (NMED), contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by the Idaho National Laboratory (INL) and contains almost 17,000 records of material events submitted to the NRC from approximately January 1990 through November 2005.

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

1. Medical (MED),
2. Radiation Overexposure (EXP),
3. Release of Licensed Material or Contamination (RLM),
4. Lost/Abandoned/Stolen Material (LAS),
5. Leaking Sealed Source (LKS),
6. Equipment (EQP),
7. Transportation (TRS),
8. Fuel Cycle Facility (FCP),
9. Non-Power Reactor (NPR), and
10. Other (OTH).

The scope of the NMED quarterly report is limited to a discussion and evaluation of reportable events in categories 1 through 7 and 10. The Fuel Cycle Facility and Non-Power Reactor event categories are excluded from this report due to the significant difference in operation of these facilities compared to the operation of other facilities licensed by NRC and Agreement States to use by-product, source, and special nuclear material. Events involving abandoned well-logging sources are also excluded from this report. A description of categories addressed in this report and associated screening criteria is 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). Within this report, the term “event” is used to describe an individual event category; multiple “events” can result from a single occurrence report.

Data presented in this report were downloaded from the NMED on December 1, 2005. Because the NMED is a dynamic database that is updated daily, variations in quarterly data may be encountered over time. Furthermore, even though many events were reported and entered in the database for record keeping purposes, only those events required to be reported by 10 CFR are addressed in this report.

This report displays short-term data for each of the event categories by quarter for a 16-quarter period. A statistical 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 16-quarter display indicates the direction and approximate rate of change with a sloped line. If no statistically significant trend exists, the 16-quarter display indicates the statistical mean (arithmetic average) of the data for the period with a horizontal line. For comparison purposes, long-term annual trend data are also presented to contrast with the short-term results. For the purposes of this report, a statistically significance trend exists if the analysis indicated that the computed fit and slope of a least squares linear model was valid at a 95% confidence level. A primer on the statistical methods employed in the trend analysis is presented in Appendix B.

In summary, this report focuses on reportable events that occurred between October 1, 2001, and September 30, 2005, that were entered into NMED prior to the data download on December 1, 2005. This report includes a depiction of selected NMED 16-quarter trend data and a breakdown of event causes, reporting categories, and event type data. Performance measures data are presented on page *ix*.

Reporting guidance for Agreement States is presented in the *Handbook on Nuclear Material Event Reporting in the Agreement States*. The handbook is an appendix to the NRC Office of State and Tribal 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. Sixteen-quarter (short-term) and annual (long-term) trend charts were developed to show general data trends. For this report, 16-quarter event data through Fiscal Quarter 05-4 were evaluated and compared with annual data starting with Fiscal Year 1995.

Some event reports did not contain sufficient information to determine the event causes. Such events were categorized as "Insufficient Information" with respect to the event causes.

2.1 All NMED Events

Figure 1 displays the annual counts and trend of the 5841 NMED events that occurred from Fiscal Year 1995 through 2005. The statistical trend analysis determined that the data do not indicate a statistically significant trend in the number of events at the 95% confidence level. Therefore, variations between the annual values represent random fluctuation around the average of the data (indicated by the horizontal line). The decrease in events during Fiscal Year 2004 and Fiscal Year 2005 is not insignificant, however. In fact, an overall decreasing trend would be indicated if the confidence level were reduced to 93%. This recent decrease becomes more apparent in the 16-quarter trend graph shown in Figure 2.

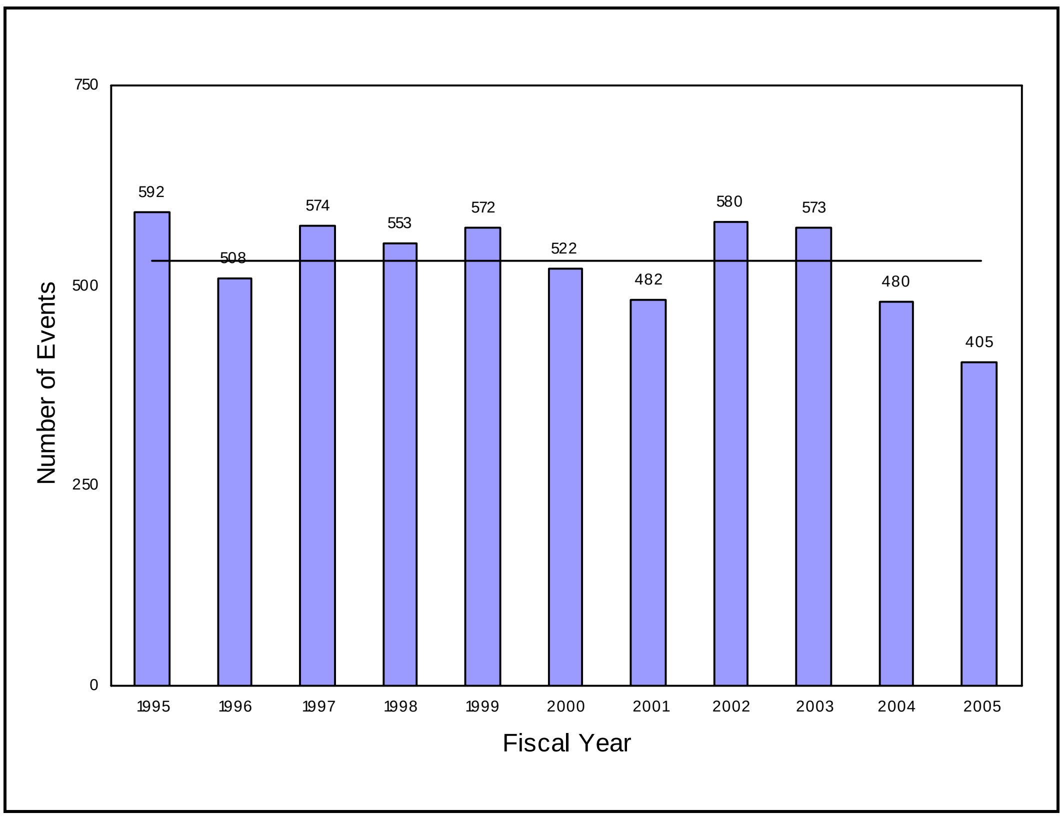


Figure 1. Long-Term Trend of All NMED Events (5841 total)

Figure 2 displays the quarterly counts and trend of the 2038 NMED events that occurred during the 16-quarter period. Utilizing a smaller time period for each data point, which results in a smaller data population size, typically has the effect of increasing the proportional (to the average) degree of random fluctuation between the data points. Over the 16-quarter period, the total number of reportable NMED events has shown a noticeable decrease in the later quarters. The result of this decrease is a statistically significant decreasing trend and the addition of the latest quarter (Fiscal Quarter 05-4) has continued this trend.

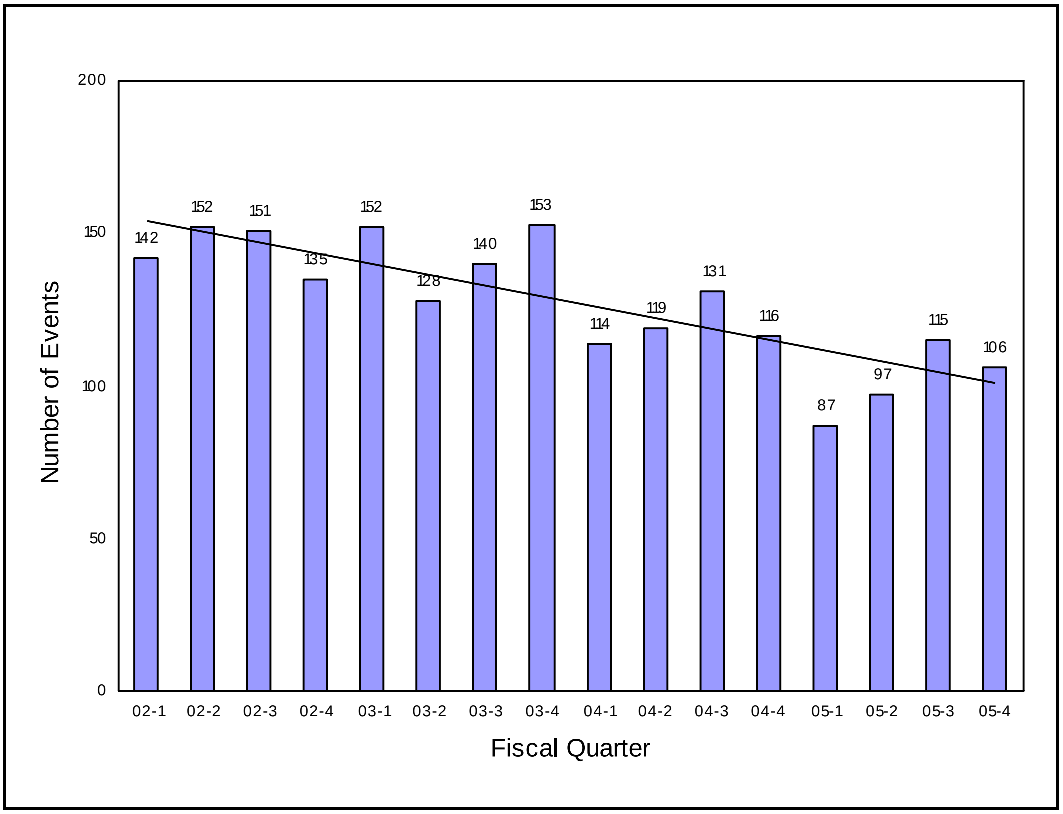


Figure 2. Short-Term Trend of All NMED Events (2038 total)

The following observations are made regarding the short-term decreasing trend.

1. The most recent four quarter's data are typically 20 records less (10 in the most recent quarter) than their final value when subsequent updates and late reports are received (see Appendix C and Figure C-1). This effect exaggerates the slope of the decreasing trend, but even with the addition of these events, the decreasing trend would remain statistically significant.

2. The NRC's Sensitive Information Screening Process (SISP) reduced the number of public documents available in ADAMS for input into NMED since Fiscal Quarter 05-1, but did not necessarily reduce the number of NMED event records. Because the SISP occurred late in the trending period, it is too early to assess the full effect on NMED.

3. The revised 10 CFR 35 became effective October 2002. This revision relaxed previous reporting requirements and could have resulted in a decreased number of reportable medical events. However, a review of Figures 3 and 4 in section 2.2, *Medical* indicates that the revision has not reduced the number of reportable medical events. Note that Agreement State agencies had until April 2005 to adopt compatible regulations.

4. The short-term decreasing trend in NMED events cannot be attributed solely to a decreasing trend in a single event category. Rather, it resulted from a compilation of event categories. During this report's short-term trend period, LKS and TRS events experienced statistically significant,

decreasing trends while no event categories experienced statistically significant, increasing trends.

2.2 Medical

Figure 3 displays the annual counts and trend of the 419 Medical (MED) events that occurred from Fiscal Year 1995 through 2005. The statistical trend analysis determined that the data do not indicate a statistically significant trend in the number of events. Therefore, variations within the annual values represent random fluctuation around the average of the data (indicated by the horizontal line).

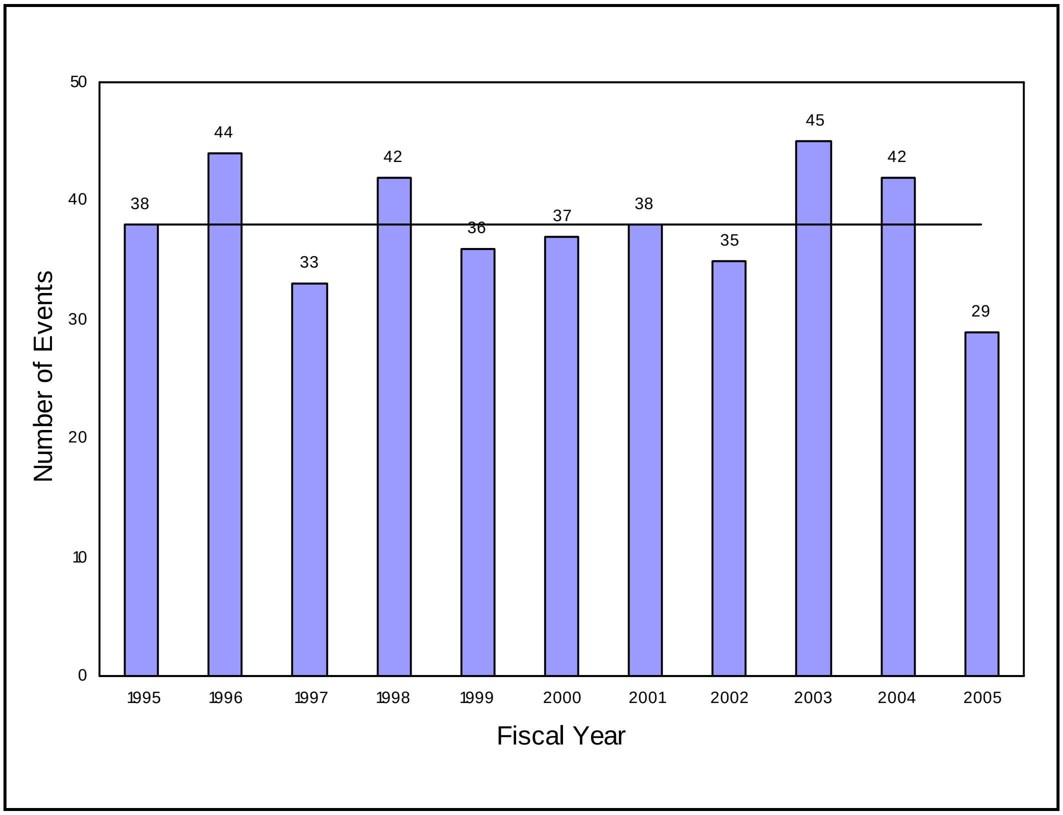


Figure 3. Long-Term Trend of Medical Events (419 total)

Figure 4 displays the quarterly counts and trend of 151 MED events that occurred during the 16-quarter period. Utilizing a shorter time period for each data point results in an increased degree of random fluctuation proportional to the average. This increased fluctuation reduces the likelihood of the data representing a trend. The degree of fluctuation causes the statistical trend analysis to determine that the data do not indicate a statistically significant trend in the number of events. Therefore, variations within the quarterly values represent random fluctuation around the average of the data (indicated by the horizontal line).

The 151 MED events involved 230 procedures performed on 228 patients. Event 040229 involved a single patient that received three separate brachytherapy procedures. Figures 5 through 7 display the distributions of event causes, types of problems (based on reporting requirements), and types of medical procedures involved. It should be noted that although each individual event has only one cause (Figure 5), the event may involve more than one type of problem or procedure (Figures 6 and 7).

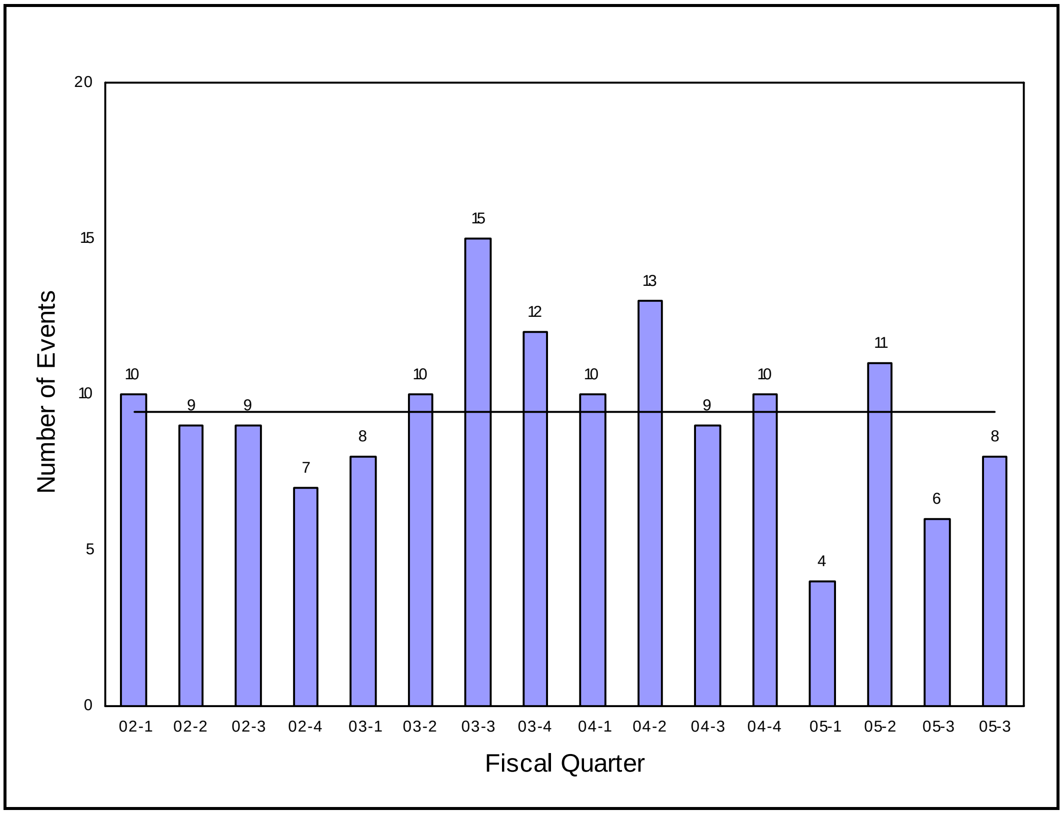


Figure 4. Short-Term Trend of Medical Events (151 total)

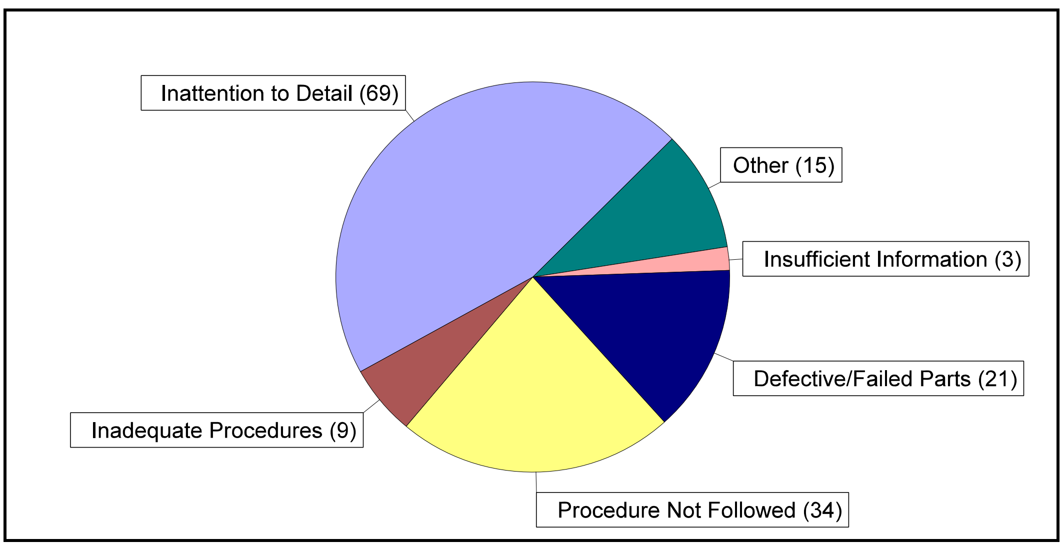


Figure 5. Medical Event Causes (16 quarters)

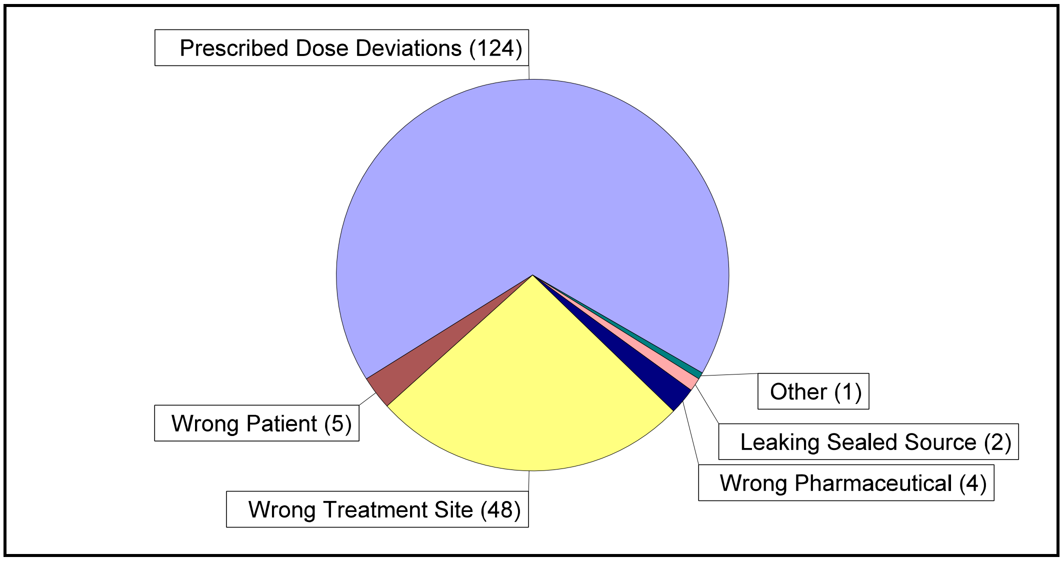


Figure 6. Medical Event Problems (based on reporting requirements - 16 quarters)

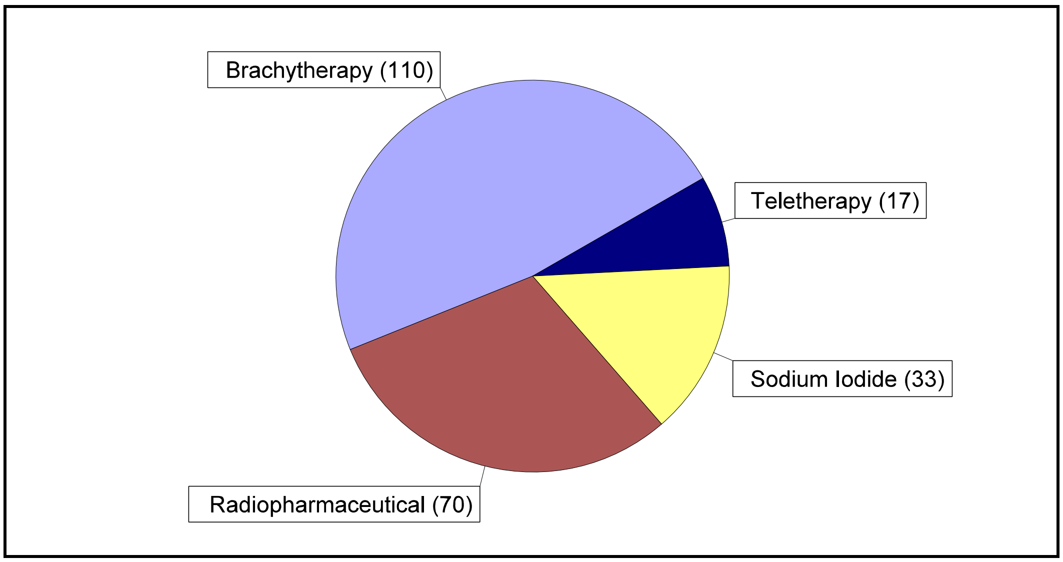


Figure 7. Medical Procedures Performed (16 quarters)

A single event (011158) substantially influenced the Figure 7 “radiopharmaceutical” data. This event involved a pharmacy that dispensed Sm-153 doses containing 21-29% less material than identified on the label to nine hospitals. The licensee’s calibration procedures for Sm-153 did not properly account for the different shielding properties of plastic syringes and glass vials. Before discovering the error, doses were administered to 61 patients.

A single event (021005) substantially influenced the Figure 7 “teletherapy” data. Ten patients received radiation doses of at least 60% more than prescribed during gamma knife treatments. The prescribed radiation doses ranged from 1,200 to 2,400 cGy (rad) to the brain. When the manufacturer’s employee changed the unit's printer, he inadvertently reset the calibration parameters to an older date, indicating that the sources had 60% less activity than actual. The error was discovered during a later re-calibration of the instrument.

Eight MED events occurred in Fiscal Quarter 05-4, two of which were classified as potential Abnormal Occurrences (AOs) (050550 and 050560). The event causes, problem types, and procedure types reflected distributions similar to those shown in the pie-charts above for the 16-quarter period. Inattention to detail was the cause of most of the Fiscal Quarter 05-4 events, most of which involved prescribed dose deviations. The majority of events involved brachytherapy procedures. The eight MED events are summarized below, beginning with the potential two AO events.

Event 050550 was classified as a potential AO. This event involved a patient who received an overdose to an unintended site and an underdose to the intended site during a palliative treatment for metastatic disease. The treatment used a Nucletron Corporation HDR brachytherapy unit (model 105.999, serial #31062) with an Ir-192 source (model 105.002, serial #D36A-7277) containing an activity of 252 GBq (6.81 Ci). The patient was prescribed to receive three palliative fractions to the left bronchus using a special catheter separately placed, imaged, and digitized for each fraction occurring approximately a week apart. The intended dose for each fraction was 700 cGy (rad). The first fraction was delivered as prescribed. During the second fraction, the catheter was in a slightly different location within the left bronchus than in the first fraction. A reference distance of 995 mm was specified at the first digitized treatment position. The reference distance should have been 965 mm at the first digitized treatment position. A 3 cm length of the left bronchus received 640 to 1,860 cGy (rad) more at 0.5 cm depth than would have been received from planned proximity to the source. That same 3 cm length received 254 to 662 cGy (rad) more at 1 cm depth than would have been received from the planned proximity. A 3 cm length of the 4 cm region intended for treatment received up to 600 cGy (rad) less than the intended dose. The physician decided not to alter the patient’s treatment plan for the third fraction or attempt to compensate for the lack of dose at the proximal end of the intended region. The cause of the event was determined to be insufficient time to insure adequate preparation and verification for a non-typical HDR treatment. Corrective actions taken by the licensee included adding a question addressing the reference distance to the second check of the procedure.

Event 050560 was classified as a potential AO. This event involved a patient who received 1,451 cGy (rad) instead of the intended 550 cGy (rad) during the first of two fractions for vaginal cancer treatment. The patient was scheduled to receive 1,100 cGy (rad) in two fractions during remote high dose rate afterloader treatment. The licensee used a Varian HDR remote afterloader (model VariSource) and an Ir-192 source (Omnitron, model SL-777V, serial #02-01-0695-0054-063005-10374-05) with an activity of 249.8 GBq (6.75 Ci). The first fraction was oriented interior 4.5 cm, resulting in a dose 164% greater than intended. The medical physicist discovered the error in the brachytherapy vision software. When digitizing the calculation point of the coronal plane, the sagittal plane viewing plane was in an incorrect position that resulted in the calculation point being entered incorrectly. There was no other medical physicist to second check the plan at the time due to personnel shortage issues. The second fraction was not administered and the patient is not returning for further treatment. Corrective actions taken by the licensee included implementing a policy that requires the medical physicist to have the plan second checked by another HDR trained physicist.

Event 050451 involved a patient who received a dose to an unintended site during a bile duct carcinoma brachytherapy procedure using 22 Ir-192 sources totaling 1.99 GBq (53.9 mCi) in a seed ribbon. The ribbon was routed through the nasal gastric system to the treatment site. A radiograph was taken of the source placement in the bile duct before releasing the patient to a hospital room. The bile duct procedure prescribed a dose of 2000 cGy (rad) at 1 cm during a 35 hour treatment. A radiograph verified that the sources were in the prescribed location. On the following day, a verification image was taken and revealed that the sources had moved approximately 5 cm toward the gastrointestinal tract. The location of the sources was outside of the intended site and some of the sources were located in the duodenum of the small intestine. The authorized user decided to terminate treatment after 25 hours. Dose estimates revealed 490 cGy (rad) to the the liver/unintended site. The Wisconsin DHFS investigated the incident.

The licensee failed to obtain the correct catheter (more flexible) with a lead marker, the nursing staff was not specifically trained on the procedure, the follow-up radiograph was placed in the wrong day's request tray, the authorized user's orders for the follow-up radiograph was not interpreted by the radiologist as to be read STAT, and there was no procedure/policy requiring the radiologist to take action to immediately notify the ordering physician of findings. Additionally, the bedside radiograph taken was of poor quality and a second radiograph should have been ordered to better image the sources. Corrective actions taken by the licensee included revising procedures, changing the written directive form, and refining staff education.

Event 050492 involved a patient who received 2.44 GBq (66 mCi) of Sm-153 instead of the intended 3.96 GBq (107 mCi) dose for bone pain therapy. The patient received a calculated exposure of 26.4 cSv (rem) to the whole body, 16,498 cGy (rad) to the bony surfaces, and 3,753 cGy (rad) to the bone marrow (assuming a quality factor of 10). The event was discovered when the medical technologist questioned the dose and raised a question with the supervisor. The technologist checked the calibration setting of the instrument used to measure the dose and discovered that it was incorrect. Corrective actions taken by the licensee included retraining personnel and adding a check on their administration sheet that requires the technologist to check the instrument calibration setting.

Event 050503 involved a patient who received 46% less dose than prescribed during a SIR-sphere treatment for liver cancer. SIR-sphere treatments utilize radioactive microspheres that contain Y-90. The first of two scheduled treatments prescribed 0.46 GBq (12.4 mCi) of Y-90. Due to difficulty in determining how much of the Y-90 remained in the vial and the injection catheter, the licensee determined that only 0.25 GBq (6.8 mCi) was administered in the first treatment. The patient will be given a second treatment.

Event 050529 involved a patient who received 50% less dose than prescribed to two of seven lesions during a gamma knife treatment. The Elekta gamma knife unit (model 24001) contained several Co-60 sources (Eleckta model 43047) with a combined activity of 259 TBq (7,000 Ci). The patient was prescribed 1,500 cGy (rad) per lesion, but only received 750 cGy (rad) to two lesions. The event was discovered about two weeks later during an internal audit of treatments. The cause of the event was determined to be personnel lack of knowledge concerning the treatment planning software and communication difficulties between the physicist and neurologist. Correction actions taken by the licensee included additional education in treatment planning and reinforcement of the necessity of communications between personnel.

Event 050551 involved a patient who received only two of five scheduled gamma knife treatments to a glioblastoma lesion. This resulted in the patient receiving 900 cGy (rad) instead of the prescribed 1,200 cGy (rad). Prior to the third treatment, the shielding jaws on the Leksell gamma knife (manufactured by Elekta Instrument AB, model Leksell 23005 type B) were unable to open completely and the gamma knife was removed from service. The patient had inadvertently knocked off the metal clip that holds a microphone to the patient couch and it fell into the unit's shielding jaws. Because of this, the microswitches inside the unit would not allow the shielding jaws to open completely. Consequently, the patient did not receive the final three prescribed treatments at that time. The licensee requested repairs on the gamma knife unit from an authorized service representative. The configuration of the microphone was changed so that there is no metal clip involved (now a Velcro strip is used). The remainder of the treatment dose was subsequently administered. This treatment interruption was not expected to have any deleterious effect on the projected outcome of the treatment. This event was also classified as an EQP event.

Event 050676 involved a patient who received only one of two prescribed capsules during I-131 therapy. Consequently, only 3.44 GBq (93 mCi) of an ordered 5.55 GBq (150 mCi) was delivered to the patient.

The referring endocrinologist was notified and determined that the patient had received an adequate amount for the therapy. The patient will be monitored closely and, if necessary, will receive additional therapy after six months. The technologist involved in the event was also responsible for a previous medical event and resigned immediately following the discovery of the second event. The licensee provided in-service training to the remaining staff on the importance of dose verification. The capsule that was not administered was found in the lead container while preparing for a subsequent procedure for another patient.

Doses to an embryo/fetus or nursing child are reportable per 10 CFR 35.3047. By definition, these events are not medical events (i.e., reportable per 10 CFR 35.3045) and are captured in NMED as “Other”. However, it is appropriate to also discuss these events in this section. No fetal dose events occurred in Fiscal Quarter 05-4.

2.3 Radiation Overexposure

Figure 8 displays the annual counts and trend of the 201 Radiation Overexposure (EXP) events that occurred from Fiscal Year 1995 through 2005. The statistical trend analysis determined that the data do not indicate a statistically significant trend in the number of events. Therefore, variations within the annual values represent random fluctuation around the average of the data (indicated by the horizontal line).

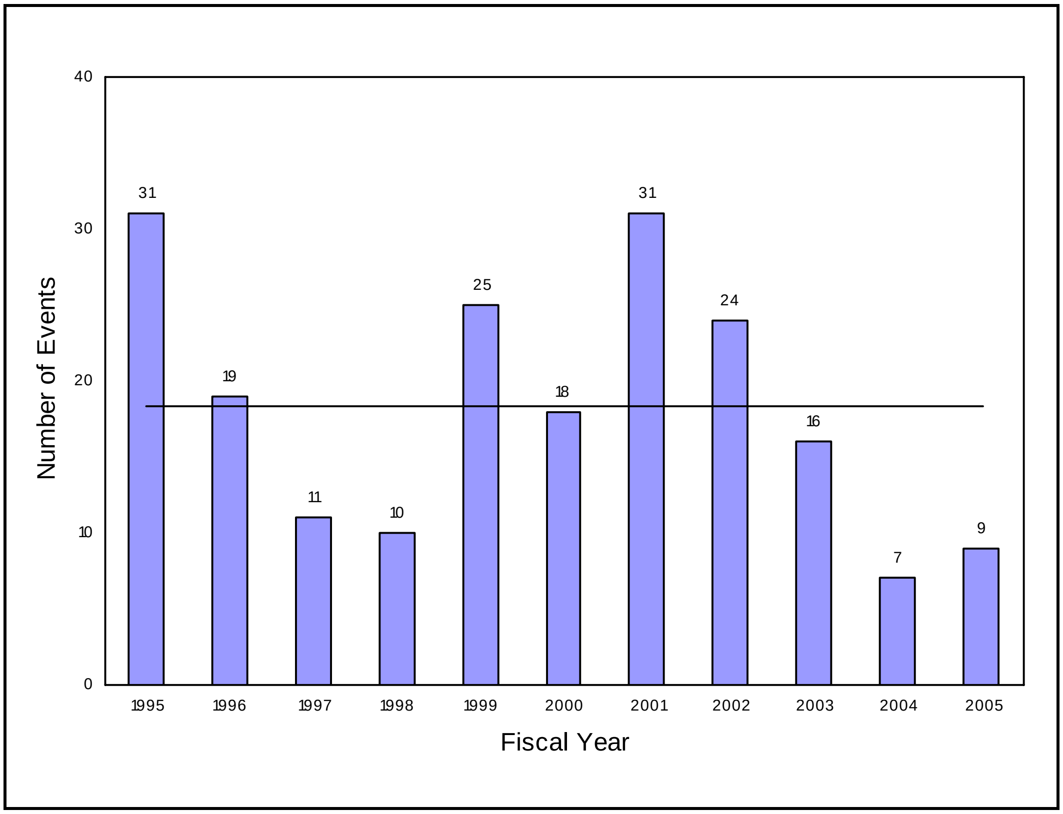


Figure 8. Long-Term Trend of Radiation Overexposure Events (201 total)

Figure 9 displays the quarterly counts and trend of the 56 EXP events that occurred during the 16-quarter period. As can be seen, the number of EXP events per quarter can fluctuate substantially. This fluctuation is influenced by the nature of annual exposure limits, which may result in a data spike in the first fiscal quarters. Specifically, individuals typically exceed annual occupational exposure limits in the last quarter of the calendar year (first fiscal quarter of the next year). The presence of this known data influence results in a cyclical fluctuation in the data. Because of this known cyclic, non-random pattern in the data, the quarterly data display of Figure 9 does not lend itself to standard statistical trending techniques. Special methodology would be required to account statistically for the non-random pattern. If standard trending methodologies identical to those used in the other sections of this report were applied to Figure 9, a statistically significant decreasing trend would not be indicated because of the high degree of random fluctuation in the data.

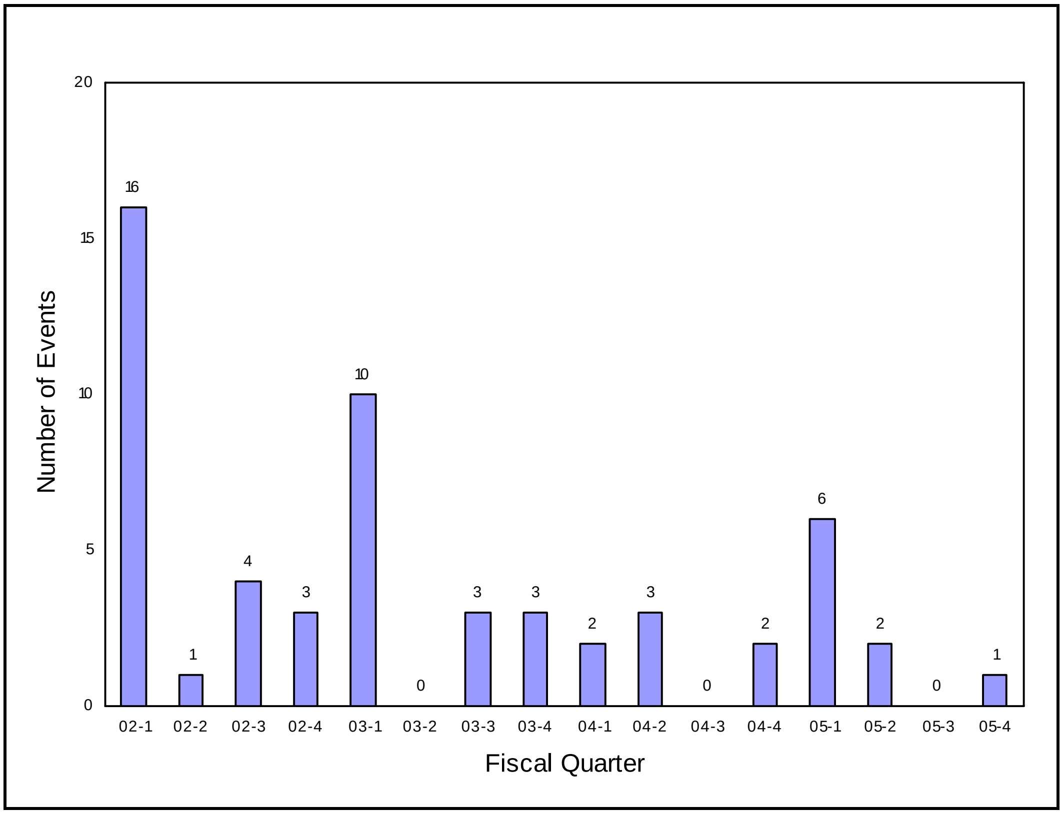


Figure 9. Short-Term Trend of Radiation Overexposure Events (56 total)

The 56 EXP events involved 134 overexposure doses to 129 people. One event involved extremity doses to an individual in two different years (020313), two events involved extremity and whole body doses to a single individual (030565 and 040517), and one event involved extremity, organ, and whole body doses to a single individual (030726). Figures 10 and 11 display the causes and work activities associated with the 56 EXP events. The pharmaceutical category displayed in Figure 11 refers to overexposure doses to people other than medical patients; patients overexposed during medical procedures are captured as MED events. Figure 12 displays a distribution of the 143 doses by type (occupational or public) and range.

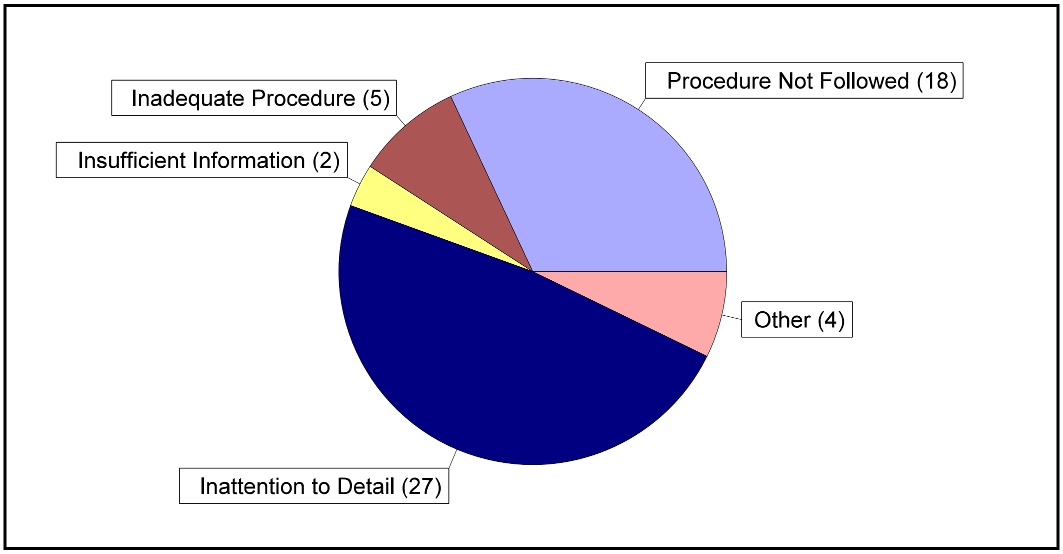


Figure 10. Radiation Overexposure Event Causes (16 quarters)

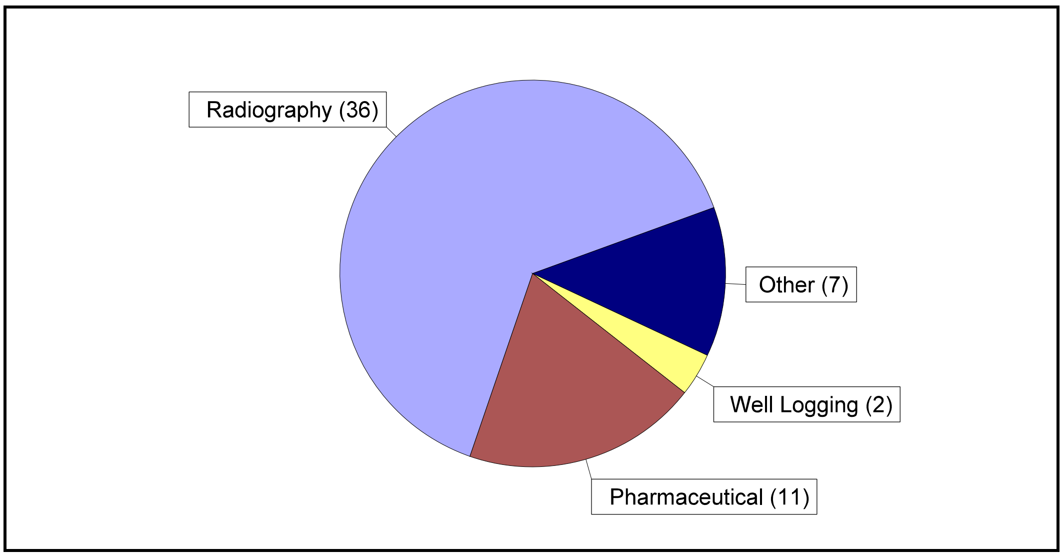


Figure 11. Radiation Overexposure Event Work Activities (16 quarters)

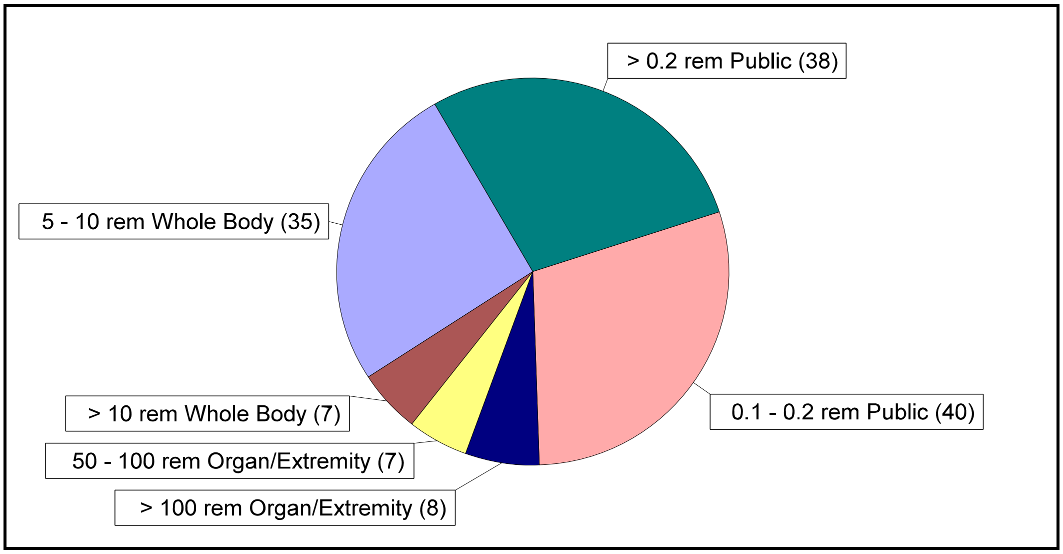


Figure 12. Radiation Overexposure Dose Types (Occupational or Public) and Ranges (16 quarters)

Although Figure 11 shows that only two overexposure events resulted from well logging activities (020536 and 040517), these events resulted in overexposures to 17 members of the public. In event 020536, while transferring a Cs-137 source from a well logging tool to its shielded transportation container, the sealed source fell unnoticed onto the rig floor next to the shielded transportation container. The source remained unshielded on the drill rig floor until recovered by the licensee approximately 56 hours later. Thirteen rig workers received doses ranging from 0.2 to 0.4 cSv (rem). In event 040517, a well logging source was left unshielded for up to 36 hours at a previous rig location when the well rig was moved to a new site. A person on the drilling crew picked up the source by hand and received an estimated dose of 49 cSv (rem) to his hand and 1.21 cSv (rem) to his whole body. Three other members of the drilling crew received calculated doses of 2.9, 2.7 and 1.5 mSv (291, 270 and 148 mrem).

Figure 12 shows that 78 overexposure doses were received by members of the public during the 16-quarter period. Three events accounted for 66 of these doses (020536, 020923, and 030565). Event 020536 is described in the preceding paragraph.

Event 020923 resulted in overexposure doses to 11 members of the public. The exposures occurred to family members who were in prolonged, close contact with a patient who had received a therapeutic dose of I-131. Radiation levels were 4 mSv/hr (400 mrem/hr) at the bedside and 0.4 mSv/hr (40 mrem/hr) at one meter. The licensee had placed shielding around the patient to reduce the radiation levels and counseled the individuals on the need to minimize their time and proximity to the patient. However, many of the individuals did not adhere to the directions and controls. NRC inspectors estimated that the highest dose received was between 3 and 15 cSv (rem).

Event 030565 resulted in overexposure doses to 42 members of the public. This event involved a loss of control of a 37 GBq (1 Ci) Cs-137 source that came out of a damaged level gauge. Employee A picked up the broken gauge pieces, which included the Cs-137 source, and placed them on employee B’s desk. The source remained on the desk for approximately 2 weeks. During this time, employee B occupied the desk for approximately 50 to 60 hours and received a whole body dose of approximately 40 cSv (rem). Employee A received an extremity dose of approximately 1,800 cSv (rem) to the hand. Re-enactments were performed to estimate the exposures to 100 individuals employed at the plant. The two highest exposures were estimated to be 74 and 18 cSv (rem). Altogether, 42 non-radiation workers exceeded the

0.1 cSv (rem) exposure limit to members of the public. This event was also classified as an LAS and EQP event. The NRC classified this event as an AO.

One EXP event occurred in Fiscal Quarter 05-4. Event 050537 involved a small amount of I-131 contamination under a nuclear medicine technician's right thumbnail. A patient was treated with 5.48 GBq (148 mCi) of I-131 (liquid) for a hyperthyroid problem. Later that day, the technologist identified contamination on her right thumb. The assistant RSO estimated an activity of 0.19 MBq (5 uCi) on the technologist's thumb. Decontamination techniques removed 0.11 MBq (3 uCi) of I-131 activity. The technician underwent a thyroid count (per procedure), which identified an uptake of 3.74 kBq (101 nCi) in the technologist's thyroid. The technologist was prescribed a thyroid blocking agent. Initial dose estimates for the localized extremity dose revealed 800 cGy (rad). Follow-up estimates indicated an extremity dose of approximately 130 cGy (rad) and a thyroid dose of 0.556 cSv (rem). There was no other radioactive contamination found on the technologist, other personnel, equipment, or room surfaces. The licensee stated that the most likely cause was a loss of integrity of the protective glove the technologist was wearing while handling the I-131.

2.4 Release of Licensed Material or Contamination

Figure 13 displays the annual counts and trend of the 264 Release of Licensed Material or Contamination (RLM) events that occurred from Fiscal Year 1995 through 2005. The statistical trend analysis indicates that the annual RLM numbers represent a statistically significant decreasing trend, which is shown in the figure by the sloped line.

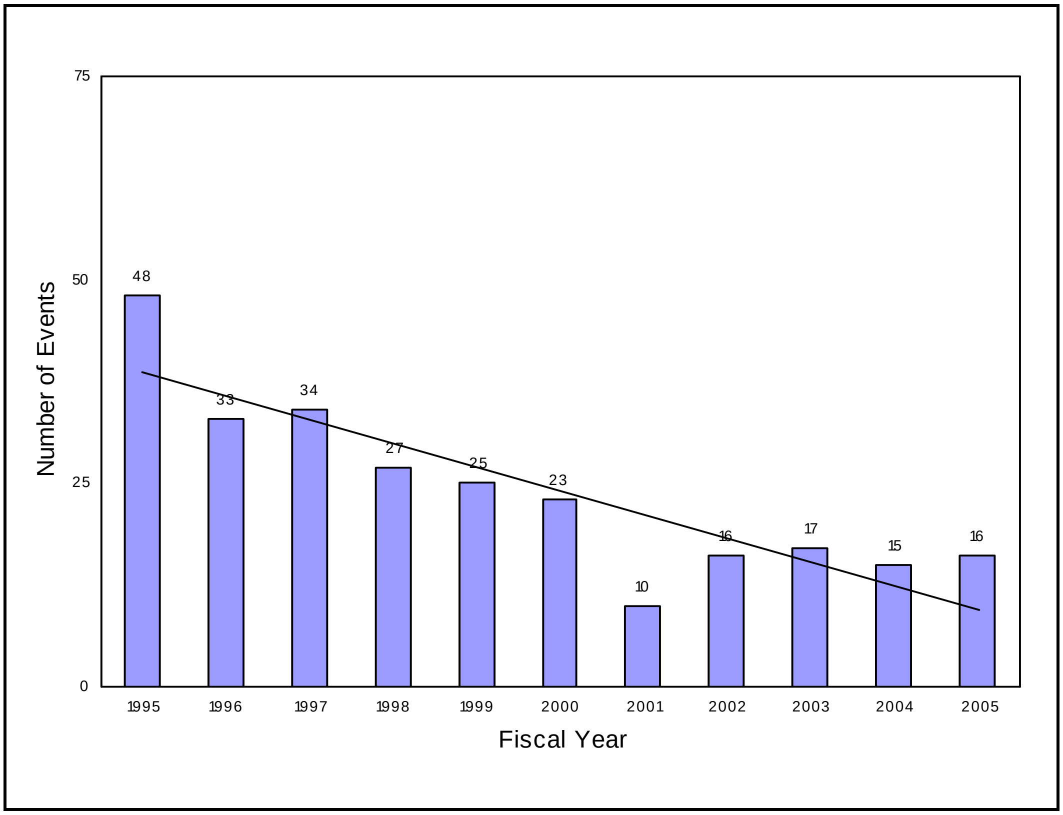


Figure 13. Long-Term Trend of Release of Licensed Material or Contamination Events (264 total)

A review of the types of contamination involved over the 11-year period indicates that a decrease in surface contamination events accounted for the majority of the overall decrease in RLM events. The other types of contamination involved in RLM events (air, water, and personnel) did not contribute notably to the decrease shown in Figure 13. This is understandable as 78 percent of RLM events between Fiscal Years 1995 and 2005 involved surface contamination. The other three contamination types (water, air, and personnel) were collectively involved in only 36 percent of the RLM events during the same period (an RLM event can involve more than one release type).

Figure 14 displays the quarterly counts and trend of the 64 RLM events that occurred during the 16-quarter period. The statistical trend analysis determined that no statistically significant trend in the number of events is indicated due to the degree of random fluctuation. Therefore, any changes in RLM numbers over the 16-quarter period represent random fluctuation around the average of the data (shown by the horizontal line).

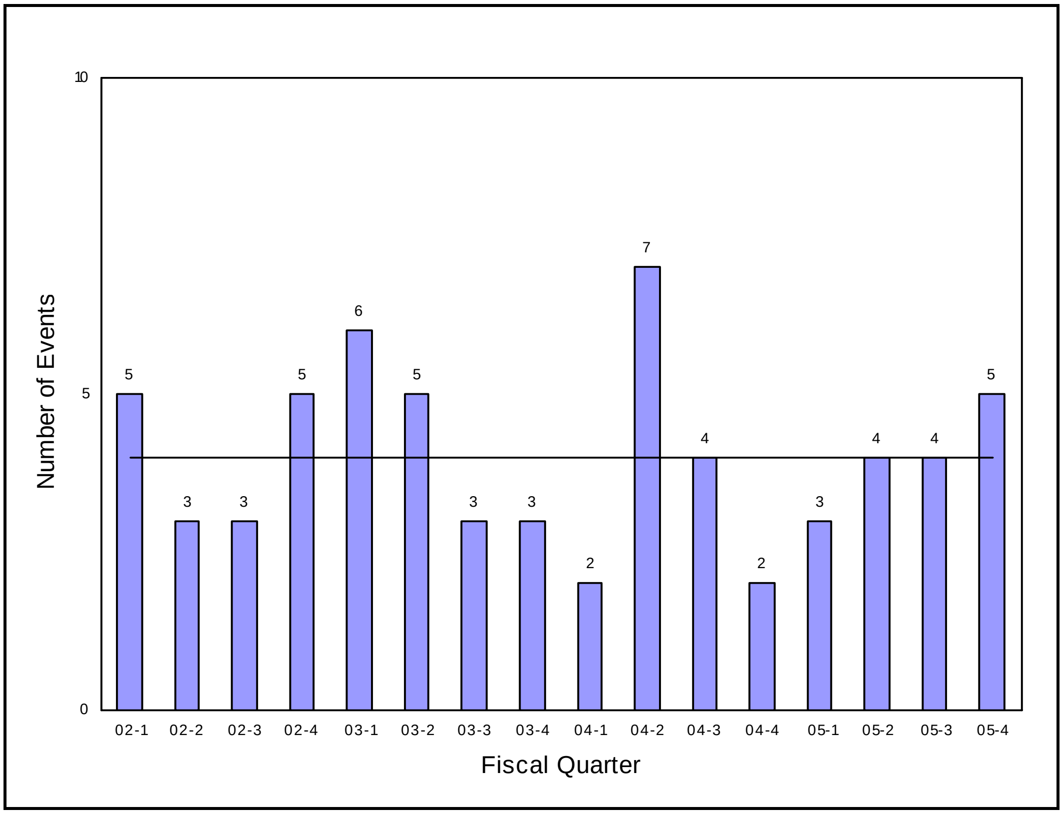


Figure 14. Short-Term Trend of Release of Licensed Material or Contamination Events (64 total)

Figures 15 and 16 display the distributions of event causes and release/contamination media for the 64 RLM events. It should be noted that although each individual event has only one cause (Figure 15), the event may involve more than one type of release/contamination media (Figure 16).

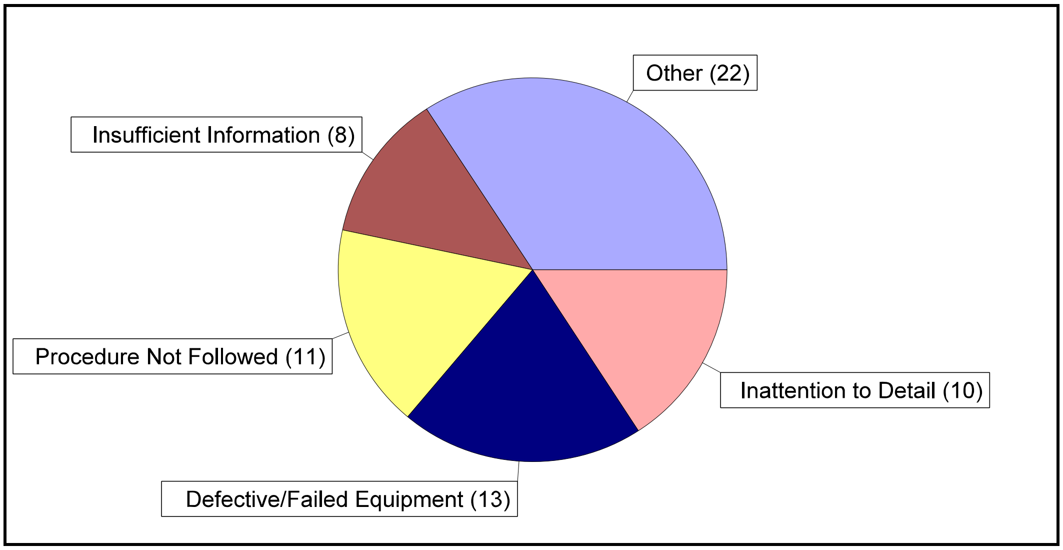


Figure 15. Release of Licensed Material or Contamination Event Causes (16 quarters)

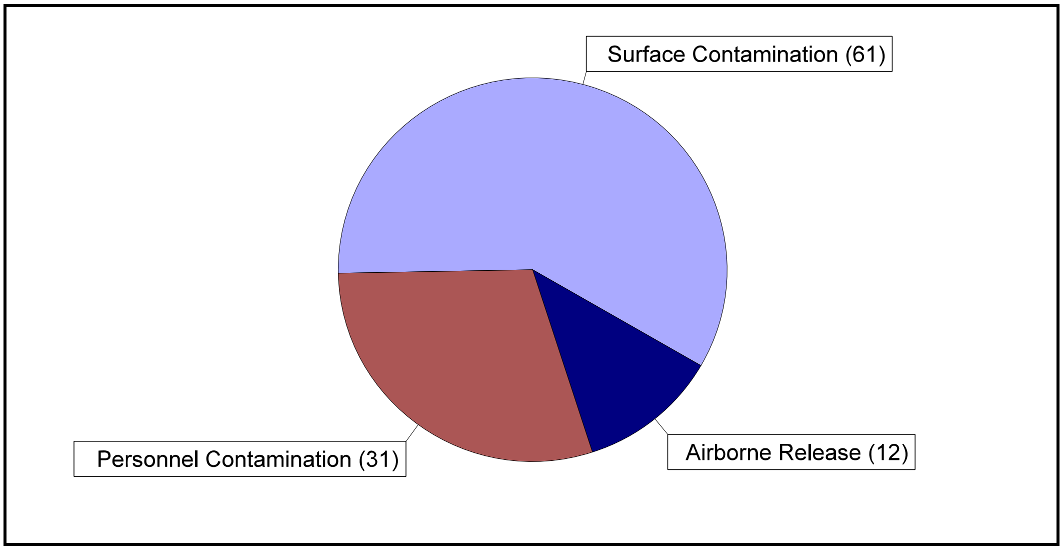


Figure 16. Release and Contamination Media (16 quarters)

Five RLM events occurred in Fiscal Quarter 05-4 and are summarized below.

Event 050499 involved an unplanned contamination event due to a filter failure in the Feed Materials Building at the Honeywell International, Inc., uranium hexaflouride production facility. The Ash Vacuum Cleaner filters failed, which allowed spar and dust filter fines containing uranium to exit the discharge of the vacuum. Due to the proximity of the vacuum discharge and the inlet to the building ventilation, some of the material was picked up by the ventilation system and distributed throughout the Feed Materials Building. A dust plume was noted coming from the discharge line of the vacuum. At approximately the same time, personnel in the building noted dust being emitted from building ventilation system registers. The vacuum was secured. Personnel recognized the potential for airborne radioactivity and immediately required respiratory protection for all personnel in the building. Special bioassay samples were required for 19 people who were present in the building during the release. Results of the bioassay samples indicated no uptake of radioactivity. Fixed air samplers analyzed after the event on all floors indicated air activity in the range of 1.85E-6 Bq/ml (5E-11 uCi/ml) to greater than 6.29E-6 Bq/ml (17E-11 uCi/ml). Air samples and contamination surveys performed downwind were at background levels. Cleanup of the granular material in the Feed Materials Building commenced immediately. The isotope released was U-238, the chemical form was UF_4, and the physical form was granular. The Feed Materials Building was cleaned of contamination and the licensee put a hold on use of the vacuum cleaner pending an investigation. This event was also classified as an EQP event.

Event 050575 involved a well logging vehicle that was involved in a single-vehicle, roll-over accident in a remote area on State Highway 550, south of Ouray, Colorado. The accident resulted in the spill of a small quantity of Sc-46. A shipping container was ejected that contained a total of 7.4 GBq (200 mCi) of Ir-192, 4.4 GBq (120 mCi) of Sc-46, and 4.1 GBq (110 mCi) of Sb-124, all in the form of ProTechnics "Zero Wash" non-soluble tracer beads. The force of the impact broke the valves off two of the reservoirs used for tracer injection and the broken containers landed in the middle of the Highway. The police HAZMAT responders moved the broken containers to the side of the road to allow traffic to pass, without checking for radioactive contamination (they did not have a survey meter). Emergency response personnel were checked for contamination when licensee personnel arrived at the scene and none was detected. All spilled material was cleaned including one spot that was reading 0.15 mSv/hour (15 mrem/hour) on contact. The contaminated dirt was returned to the licensee's office for disposal. Spectral analysis of the dirt identified a total activity of less than 37 MBq (1 mCi) of Sc-46, Ir-192, and Sb-124. The Colorado Department of Health initiated an investigation of the incident and performed a confirmatory survey of the area. No additional radioactive contamination was found at the scene. Corrective actions taken by the licensee included providing additional training, generating a new procedure, and obtaining new equipment. This event was also classified as a TRS event.

Event 050598 involved an airborne contamination event on the second floor of the Feed Materials Building at the Honeywell International, Inc. uranium hexaflouride production facility. Air samples from the second floor were analyzed and the airborne radioactivity averaged approximately 2.4E-5 Bq/ml (6.5E-11 uCi/ml). The airborne contaminant was natural uranium ore concentrate (U3O8) and the physical form was a light microscopic dust. Additional radioactive controls imposed wearing air purifying respirators on the second floor of the Feed Materials Building. The processes in the area of the elevated levels of airborne radioactivity were secured and potential leakage paths were investigated. The investigation identified two specific pieces of equipment with visual leakage paths. The Ore Blender had a leak in the shaft packing and the shafts on the #2 Prepared Feed Mill were emitting airborne uranium due to insufficient vacuum on the system. Repairs were made to both pieces of equipment. Bioassay sampling of personnel affected by the event indicated no uptake of radioactivity in excess of normally expected levels. This event was also classified as an EQP event.

Event 050610 involved a pipe crack in the waste water system allowed contaminated water to drip onto a laboratory's air handling equipment at Virginia Commonwealth University. The leak occurred in the receiving area for waste disposal. The waste water penetrated the air handler and contaminated the unit; however, no contamination was found in the ducts leading out of the air handler or on surfaces in the building outside the confined mechanical area. The air handling unit was shutdown, access to the area was restricted, and the leakage was contained. Contamination levels were measured up to 20,000 dpm, but no personnel were contaminated. Most of the beta activity was from P-32, C-14, and S-35. Area decontamination activities were initiated.

Event 050618 involved a release of contaminated liquid to a small area of asphalt (less than 100 square feet) located directly adjacent to the outside west wall of the Uranium Dioxide (OU2) Building laboratory addition at the Framatome ANP, Inc., uranium fuel fabrication facility. The OU2 Building is located within the central portion of the site's restricted area. While conducting annual preventive maintenance testing of smoke detectors, a craftsman mistakenly removed and tripped a heat detector. This activated the water fog deluge system protecting the HEPA filters and discharged an estimated 5 to 8 gallons of deluge water into the contaminated ductwork and then out the associated system drain onto the asphalt. Access to the area was restricted and water samples were collected. The water samples were found to contain 113 ppm uranium. GM measurements of the wetted area revealed no detectable radioactivity; however, subsequent readings after the area dried indicated 4,000 cpm on contact. The dried area was covered with impermeable plastic sheeting until cleanup actions were completed. The impacted area was painted to seal the fixed contamination. Corrective actions included personnel training and procedure modification.

2.5 Lost/Abandoned/Stolen Material

Figure 17 displays the annual counts and trend of the 2486 Lost/Abandoned/Stolen Material (LAS) events that occurred from Fiscal Year 1995 through 2005, excluding abandoned well-logging sources. The statistical trend analysis determined that the data do not indicate a statistically significant trend in the number of events. Therefore, variations within the annual values represent random fluctuation around the average of the data (indicated by the horizontal line).

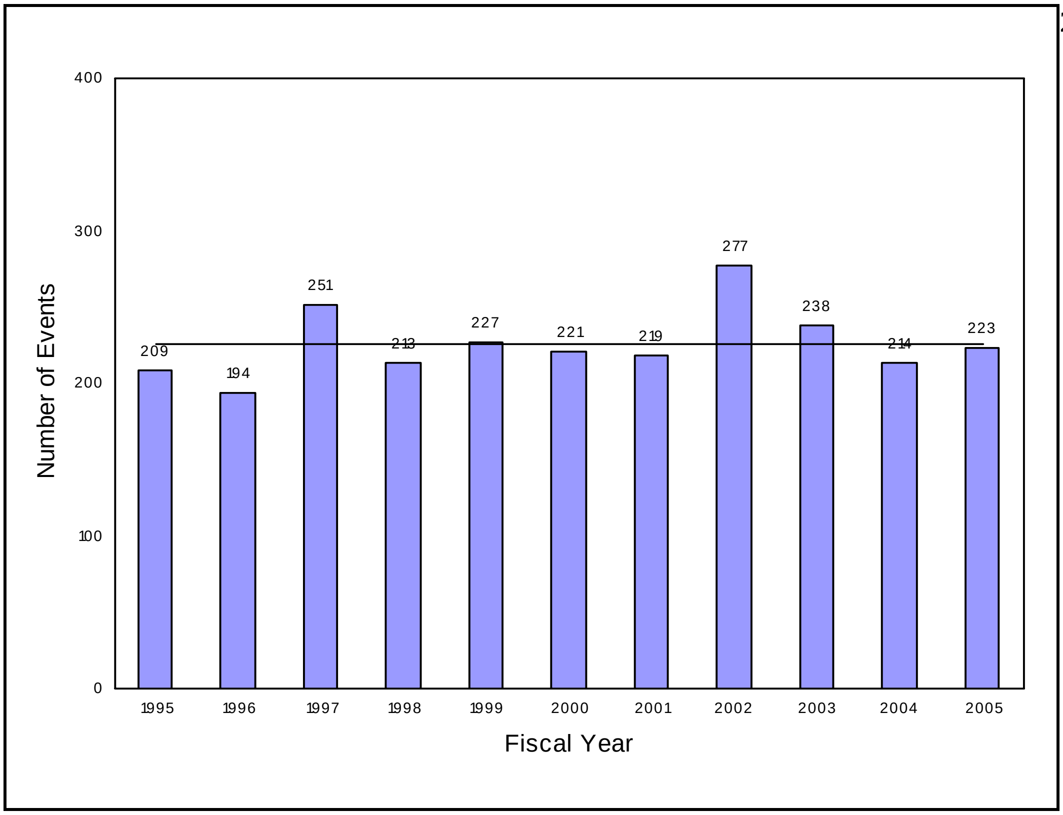


Figure 17. Long-Term Trend of Lost/Abandoned/Stolen Material Events (2486 total)

Figure 18 displays the quarterly counts and trend of the 952 LAS events that occurred during the 16-quarter period. The statistical analysis indicates that the data do not statistically significant trend. Therefore, variations within the 16-quarter values represent random fluctuation around the average of the data (indicated by the horizontal line).

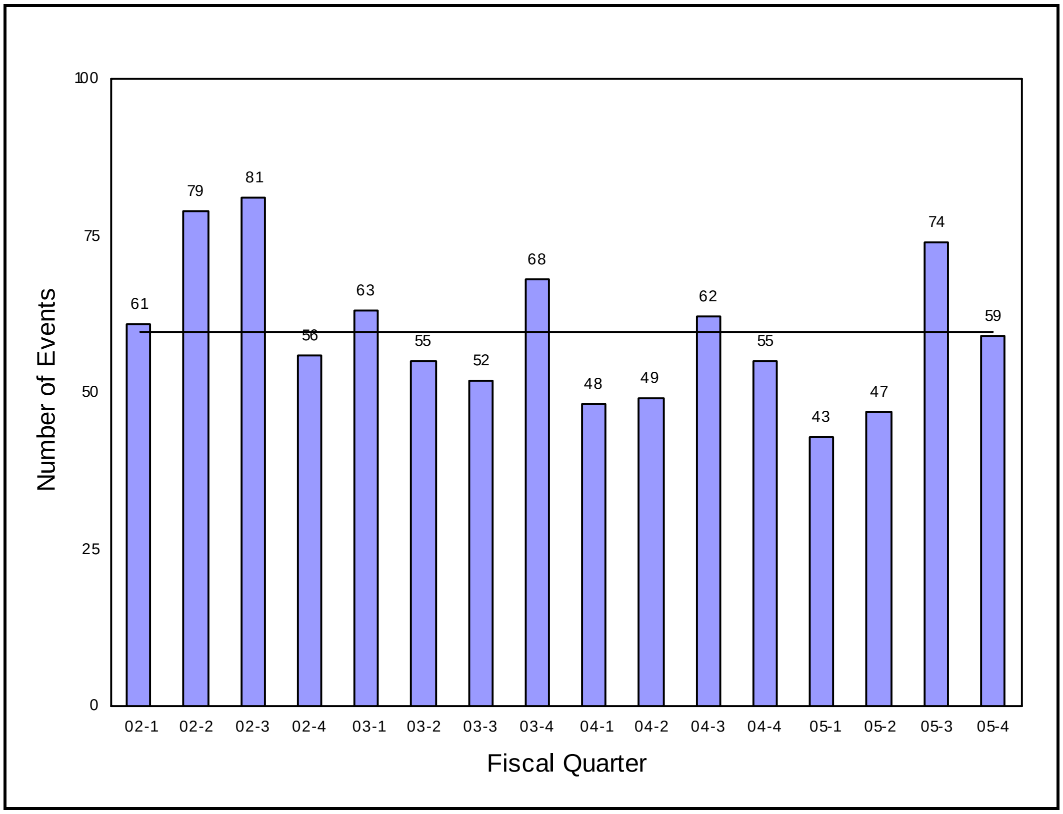


Figure 18. Short-Term Trend of Lost/Abandoned/Stolen Material Events (952 total)

Figures 19 through 21 display the distributions of event causes, type of material lost (based on reporting requirements), and nature of the losses. Figure 21's "found" category represents material found for which the owner is not known (e.g., material discovered at a landfill). "Partially found" or "partially recovered" is used for events involving multiple lost/stolen sources, where some (but not all) sources were found/recovered.

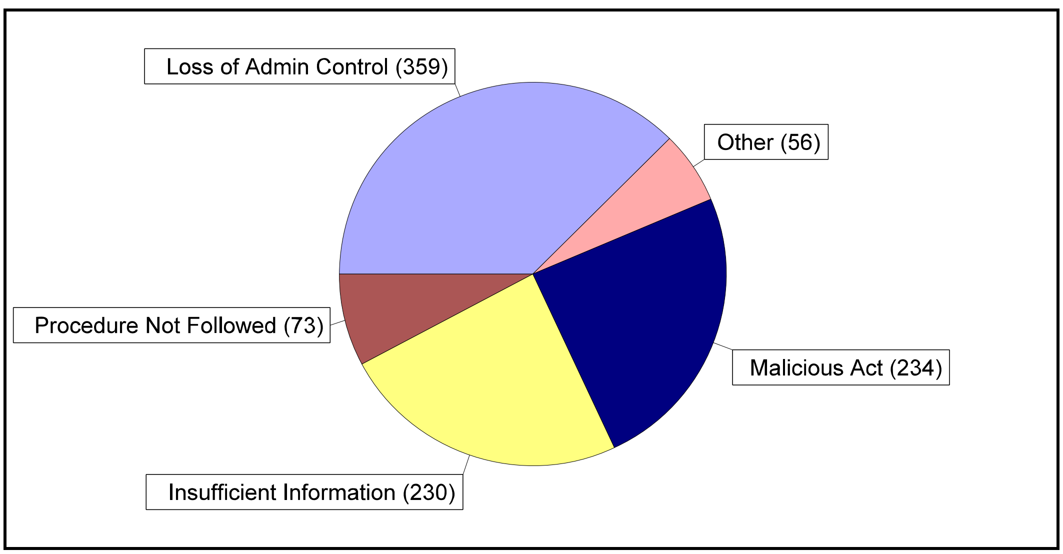


Figure 19. Lost/Abandoned/Stolen Material Event Causes (16 quarters)

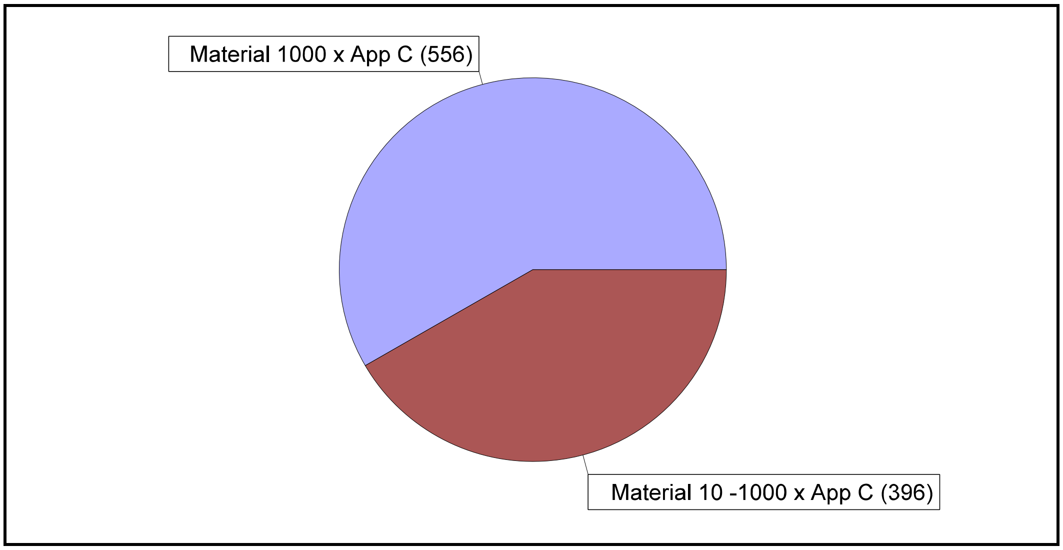


Figure 20. Lost/Abandoned/Stolen Material Event Material Types (based on reporting requirements - 16 quarters)

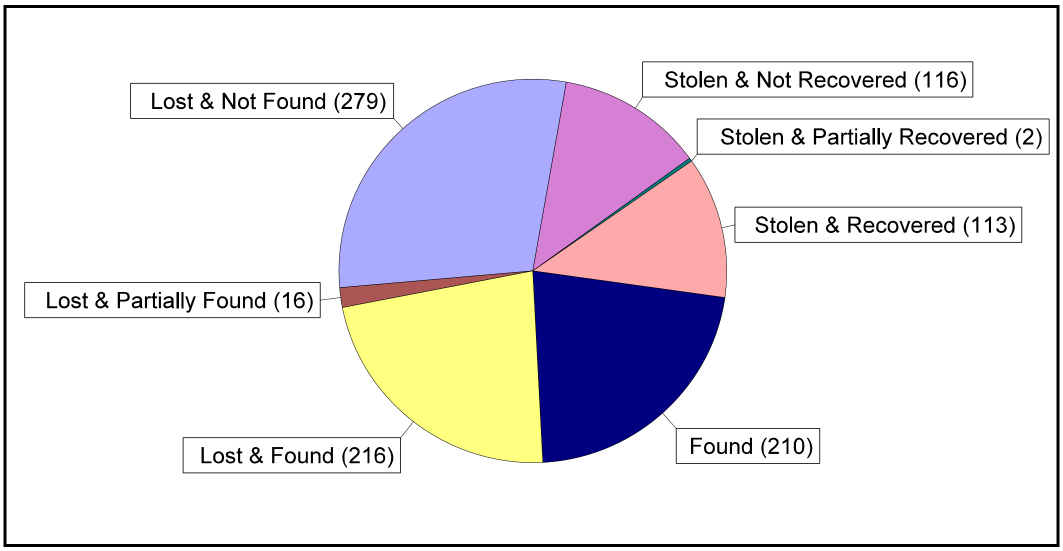


Figure 21. Nature of Loss Associated with Lost/Abandoned/Stolen Material Events (16 quarters)

Fifty-nine LAS events occurred in Fiscal Quarter 05-4, none of which were classified as a potential AOs. The event causes, types of material lost, and nature of the losses reflected distributions similar to those shown in the pie-charts above for the 16-quarter period. Loss of administrative control and malicious act were the primary causes of the Fiscal Quarter 05-4 events. Almost two-thirds of the events involved lost material greater than or equal to 1000 times the 10 CFR 20 Appendix C limits. In almost one-half of the events, the missing material was not found/recovered.

Two Fiscal Quarter 05-4 events involved orphan sources and are summarized below.

In event 050484, the U.S. Customs Service, Port of Oakland reported that a load of scrap metal bound for China set off radiation monitor alarms. The California Department of Health Services responded. Radiation measurements were conducted of the trailer using a Bicron FieldSPEC-N. Results revealed 260 uR/hour on the surface, 38 uR/hour one foot from the surface, 35 uR/hour one foot to the left side, 45 uR/hour one foot to the right side, and 19 uR/hour one foot above the surface. The isotope was Am-Be and the scrap originated from the Pleasant Hill Recycling Center. The Recycling Center was visited and stated that the load was lead scrap, which had been accumulating for several years. The Recycling Center contacted a health physics consultant to dispose of the Am-Be sources. The area where the lead was stored was surveyed with negative results. Based on measurements and calculations, the activity of the Am-Be source was determined to be between 1.85 and 5.55 GBq (50 and 150 mCi). The California Radiation Control Program personnel, with the assistance of U.S. Customs, inspected the scrap metal and found nine Am-Be sources. They took custody of the sources and conducted analysis to identify and determine where the sources originated. It was determined that CPN International, Incorporated, had mistakenly disposed of the sources/source holders through Pleasant Hill Recycling Center. The source holders were manufactured by Seaman Nuclear Corporation and the sources were used in moisture/density gauges. CPN reviewed their records to try to determine the date the sources were transferred. They believe that they were transferred sometime in 2002. Each source contained an activity of 1.48 GBq (40 mCi). The cause was determined to be inadequate inspection and surveys. No corrective actions were taken because corrective actions taken due to a 2003 violation will prevent future unauthorized disposals.

In event 050574, Cascade Asset Management Company reported finding several H-3 exit signs in a shipment of recyclable material. The Wisconsin Radiation Protection Section was dispatched to investigate. Six intact signs and pieces of other signs were found in a trash barrel. Wipes were taken of the signs and barrel and are being analyzed for radioactive contamination. The signs were placed in bags, sealed, and stored in a remote part of the building. An investigation into the origin of the signs is being conducted. The State of Wisconsin is tracking the event as report number WI050030.

2.6 Leaking Sealed Source

Figure 22 displays the annual counts and trend of the 356 Leaking Sealed Source (LKS) events that occurred from Fiscal Year 1995 through 2005. Previous quarterly reports showed an increasing trend for the annual data through Fiscal Year 2004, although Fiscal Year 2004 data itself appeared to represent a reversal or termination of this increase. The addition of Fiscal 2005 data clearly negated the increasing trend. The statistical trend analysis now indicates that the data do not represent a statistically significant increasing trend over the 11 year period. Therefore, variations within the annual values represent random fluctuation around the average of the data (indicated by the horizontal line).

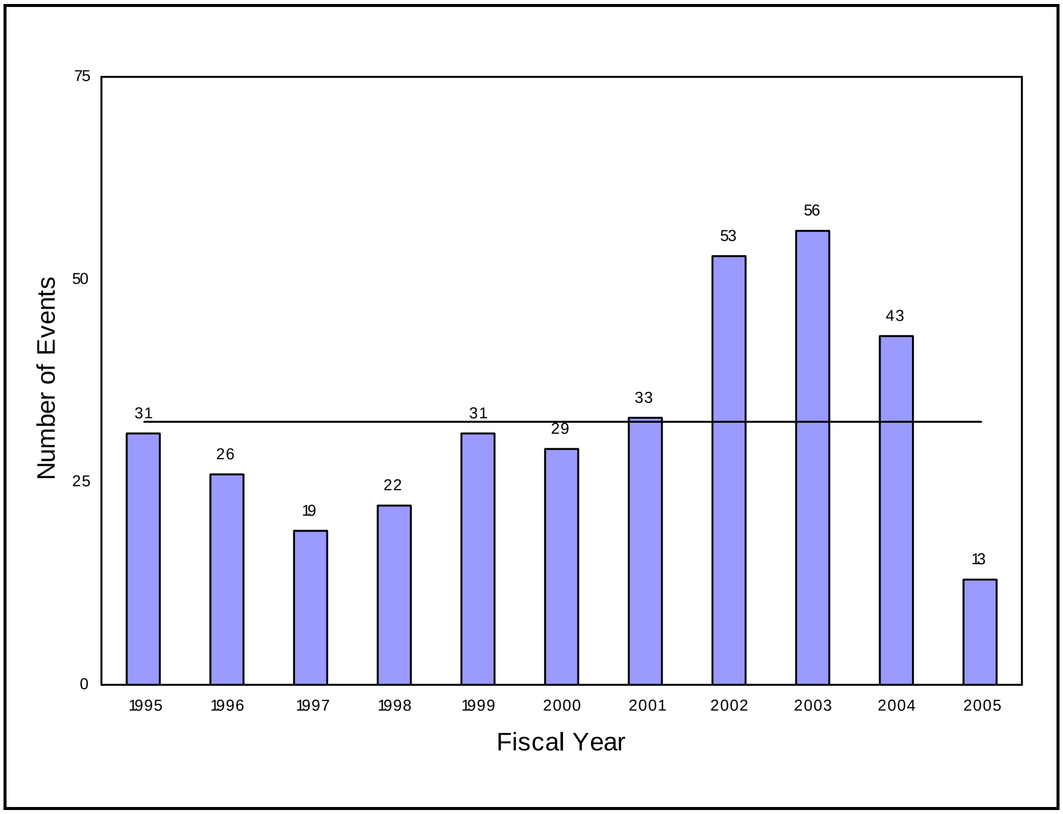


Figure 22. Long-Term Trend of Leaking Sealed Source Events (356 total)

Figure 23 displays the quarterly counts and trend of the 165 LKS events that occurred during the 16-quarter period. The statistical trend analysis indicates that the data represent a statistically significant decreasing trend. As noted in previous reports, a reporting anomaly by Agilent Technologies occurred from 2000 through early 2004, which notably increased the number of LKS events during this period.

Figures 24 through 26 display the distributions of event causes, device types (based on reporting requirements), and types of sealed sources for the reportable LKS events in the 16-quarter period. It should be noted that although each individual event has only one cause (Figure 24), the event may involve devices associated with more than one reporting requirement or sealed source (Figures 25 and 26).

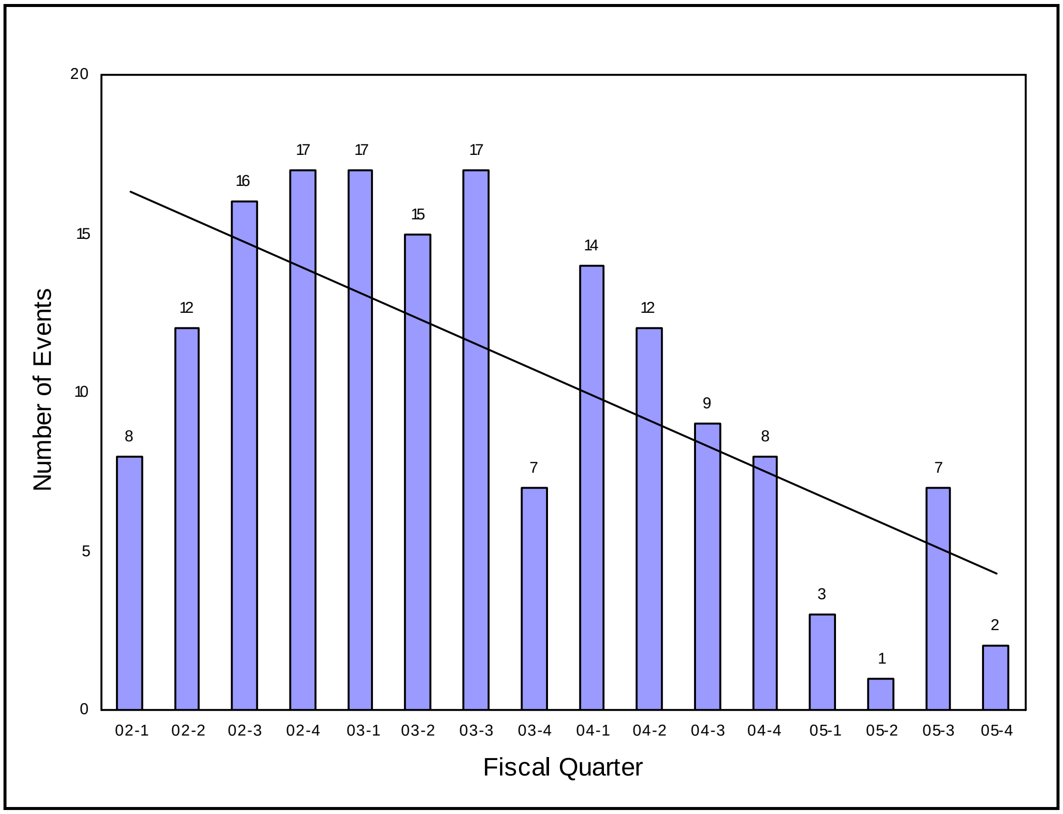


Figure 23. Short-Term Trend of Leaking Sealed Source Events (165 total)

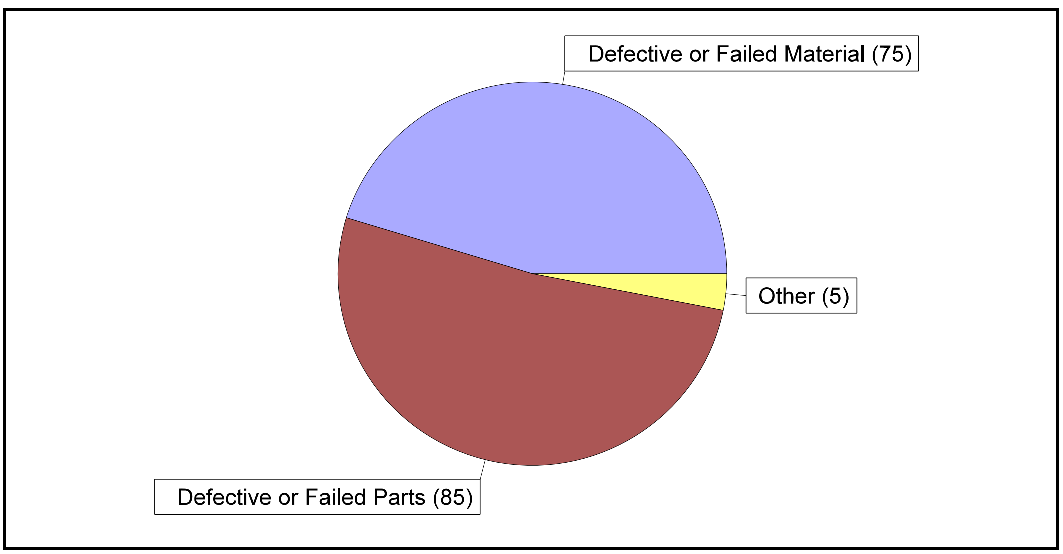


Figure 24. Leaking Sealed Source Event Causes (16 quarters)

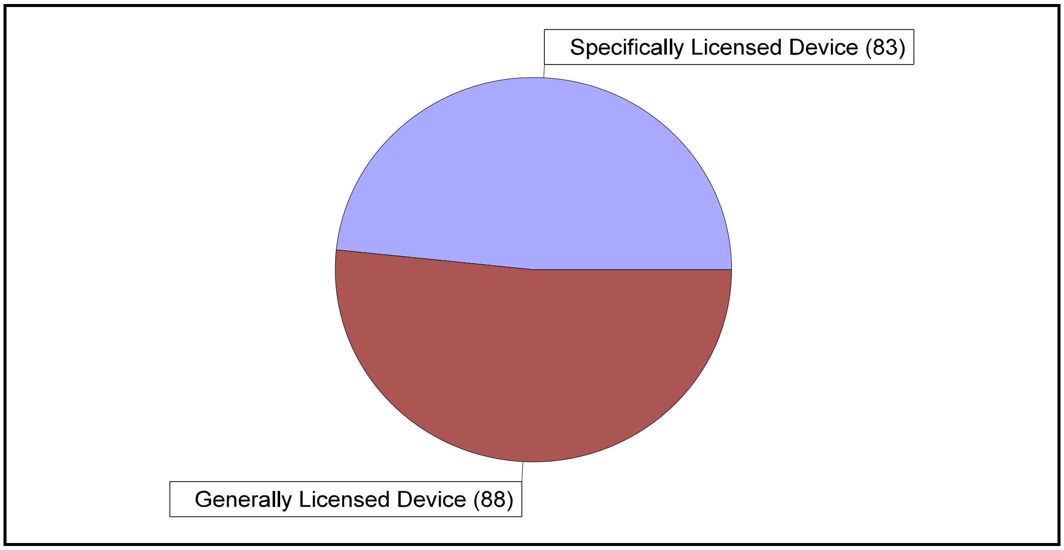


Figure 25. Leaking Sealed Source Device Types (based on reporting requirement - 16 quarters)

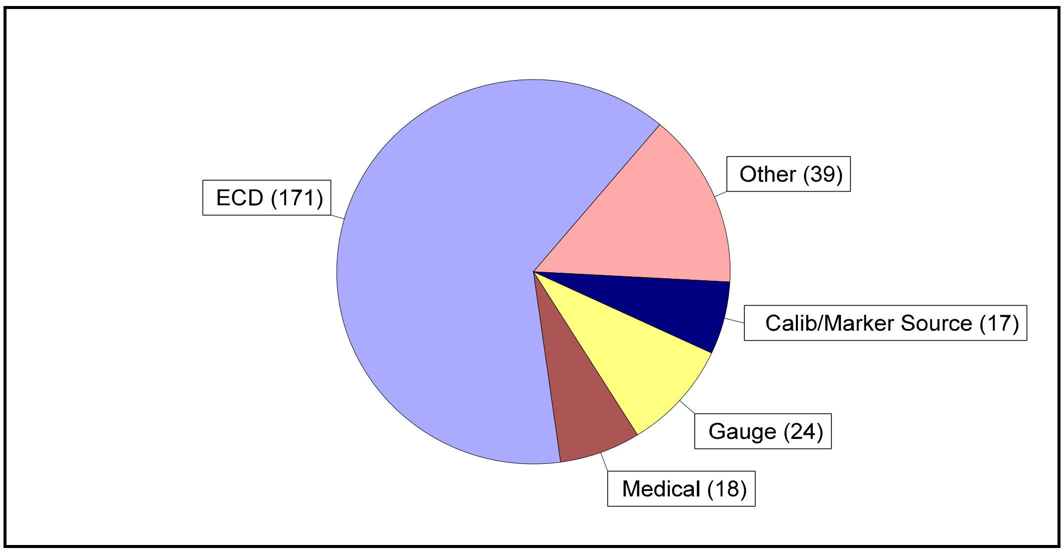


Figure 26. Leaking Sealed Source Types (16 quarters)

Two LKS events occurred in Fiscal Quarter 05-4 and are summarized below.

Event 050572 involved a leaking Tl-204 source (Isotope Products Laboratory, model TCB-1, serial #26868) from a Fischer Technology fixed gauge (serial #06-19165-01). The source contained an activity of 1.85 MBq (50 uCi) and leak test results were 4.07 kBq (0.11 uCi). The gauge was taken out of service and returned to the manufacturer. This event was also classified as an EQP event.

Event 050599 involved a leaking Sr-90 source (3M Company, model 3F1L, serial #1464) that contained an activity of 2.37 GBq (64 mCi). Smear tests revealed 8.4 kBq (0.227 uCi) of removable activity. The source had been in long term storage pending disposal. The licensee hired a consultant (RAM Services, Incorporated) to package and ship several sources for disposal. Surveys of the storage area revealed no radioactive contamination. Surveys in the work and preparation areas showed slight radioactive contamination below the threshold of 2 kdpm/100 cm2. The areas were decontaminated to background levels. The leaking source, three contaminated sources in the same storage container, the remaining other

22 Sr-90 sources in storage, and all radioactively contaminated materials were subsequently removed for disposal by RAM Services. This event was also classified as an EQP event.

2.7 Equipment

Figure 27 displays the annual counts and trend of the 1569 Equipment (EQP) events that occurred from Fiscal Year 1995 through 2005. Prior to Fiscal Year 2003, the data appear to indicate a decrease in the number of EQP events. Fiscal Year 2003 appeared to break this apparent trend. The addition of Fiscal Year 2004 data appeared to reinforce the overall downward trend. At that point, the statistical trend analysis indicated that this data represented a statistically significant decreasing trend over the 10-year period. Subsequent quarterly updates added a few more events in the recent years and the trend became non-statistically significant. The addition of Fiscal Year 2005 data reinforced the existence of a decreasing trend and the trend once again became statistically significant over the 11-year period. This trend is shown as a sloped line in Figure 27.

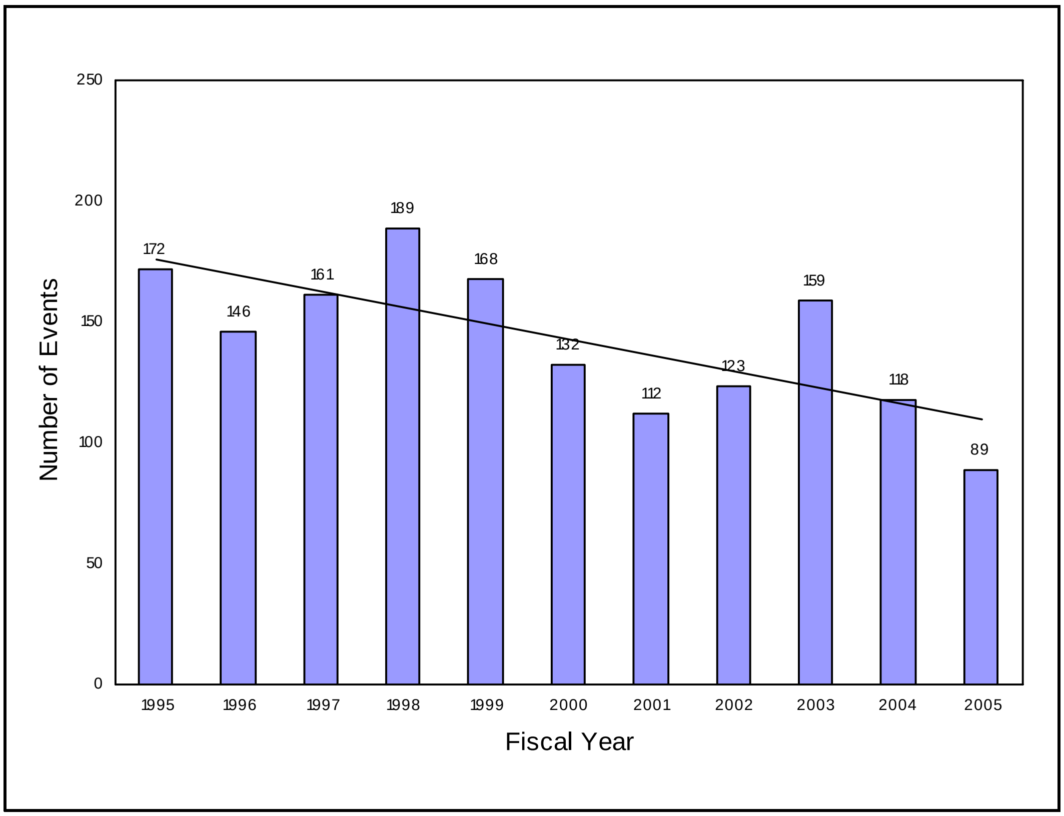


Figure 27. Long-Term Trend of Equipment Events (1569 total)

Figure 28 displays the quarterly counts and trend of the 489 EQP events that occurred during the 16-quarter period. The statistical trend analysis determined that no statistically significant trend in the number of events is indicated. Therefore, changes in EQP numbers over the 16-quarter period represent random fluctuation around the average of the data (shown by the horizontal line).

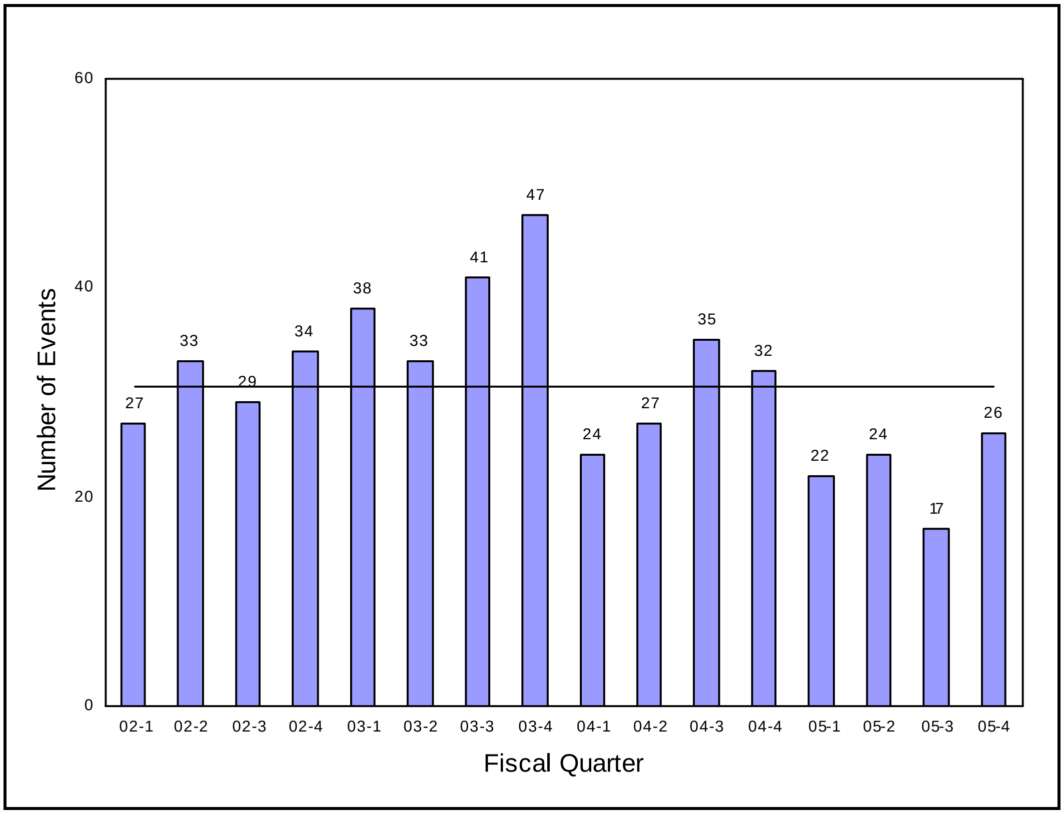


Figure 28. Short-Term Trend of Equipment Events (489 total)

Figures 29 through 31 display the distributions of event causes, EQP problem types based on reporting requirements, and types of equipment for the reportable EQP events in the 16-quarter period. It should be noted that although each individual event has only one cause (Figure 29), the event may involve more than one type of problem or equipment (Figures 30 and 31).

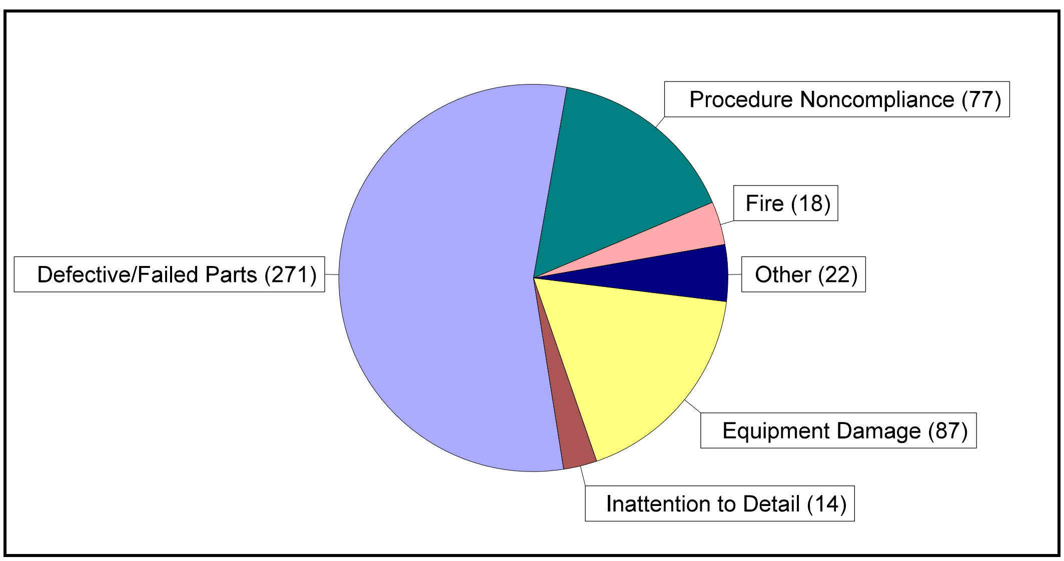


Figure 29. Equipment Event Causes (16 quarters)

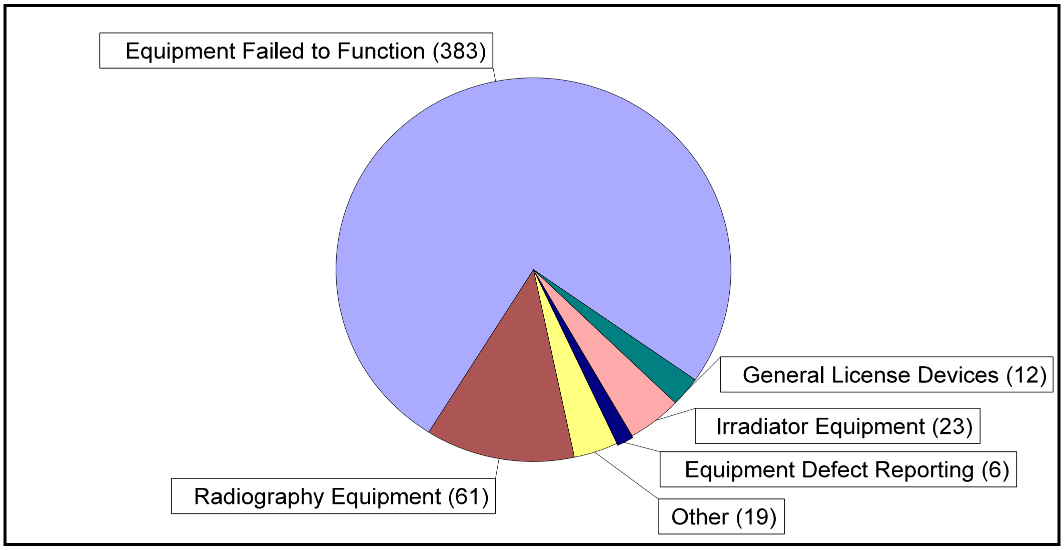


Figure 30. Equipment Event Types (based on reporting requirement - 16 quarters)

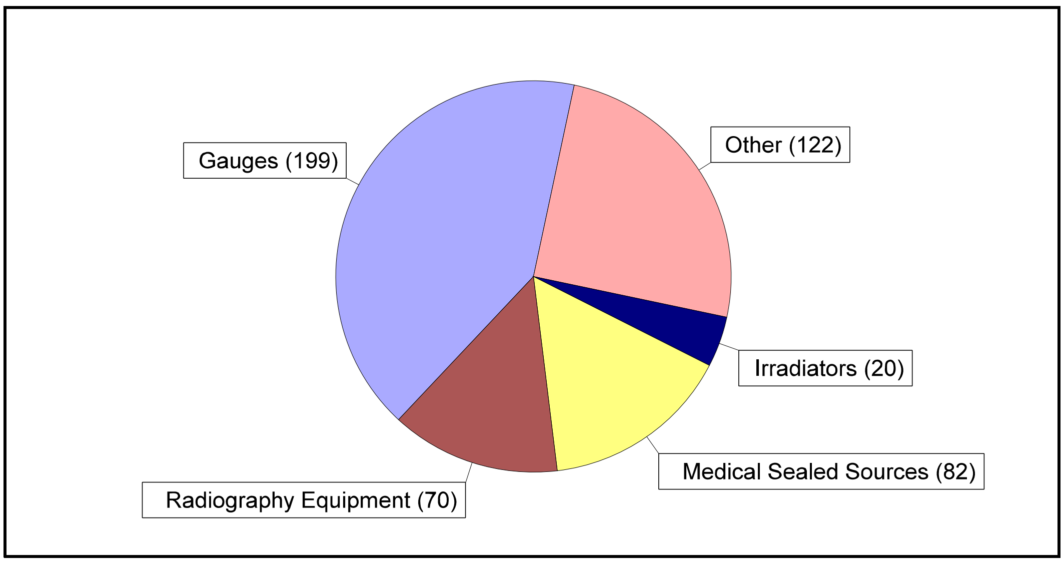


Figure 31. Types of Equipment Involved (16 quarters)

Twenty-six EQP events occurred in Fiscal Quarter 05-4. The event causes, event types, and types of equipment reflected distributions similar to those shown in the pie-charts above for the 16-quarter period. Gauges were involved in two-thirds of the events.

2.8 Transportation

Figure 32 displays the annual counts and trend of the 469 Transportation (TRS) events that occurred from Fiscal Year 1995 through 2005. The addition of Fiscal Year 2005 data reinforces the existence of a decreasing trend reported in previous reports. The statistical trend analysis indicates that this data represents a statistically significant decreasing trend over the 11-year period. Figure 32 displays the this trend as a sloped line.

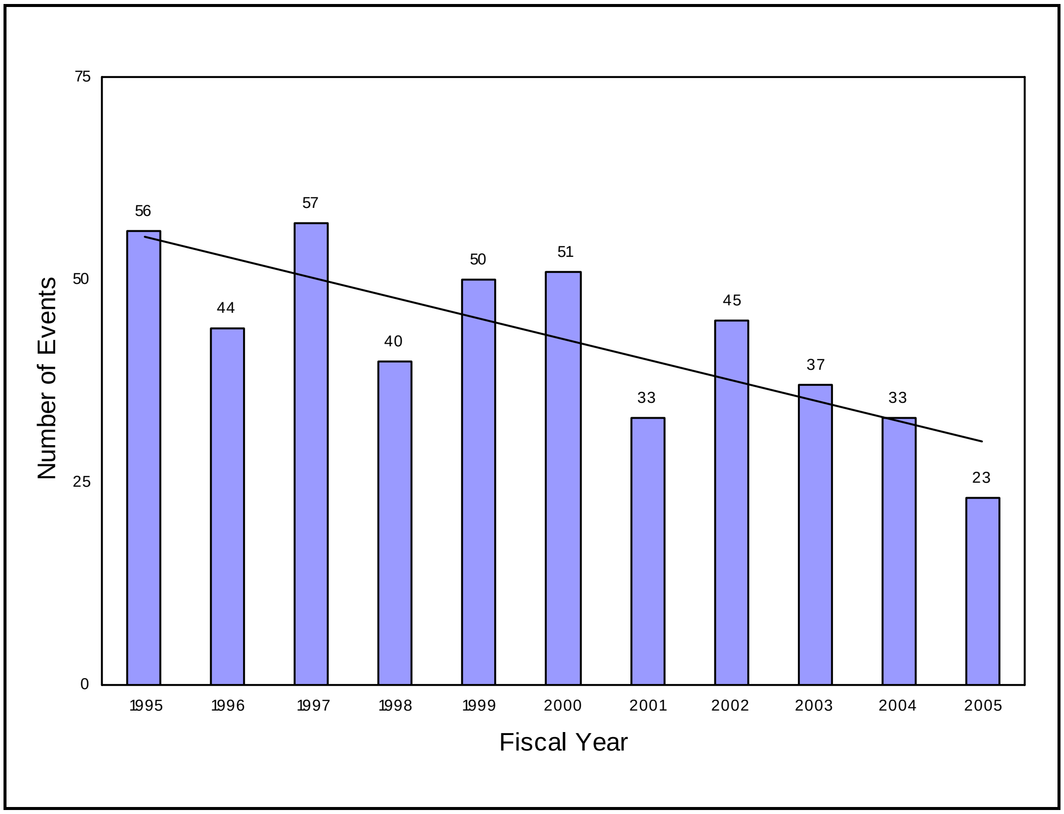


Figure 32. Long-Term Trend of Transportation Events (469 total)

Figure 33 displays the counts and trend of the 138 TRS events that occurred during the 16-quarter period. The addition of Fiscal Quarter 05-4 data and the elimination of Fiscal Quarter 01-4 data further reinforces the existence of a statistically significant trend first reported in the last report. The statistical trend analysis continues to indicate that the data represents a statistically significant decreasing trend. Figure 33 shows this trend as a sloped line

Figures 34 through 36 display the distributions of event causes, TRS problem types based on reporting requirements, and types of material involved in the reportable TRS events in the 16-quarter period. It should be noted that although each individual event has only one cause (Figure 34), the event may involve more than one type of problem or material (Figures 35 and 36).

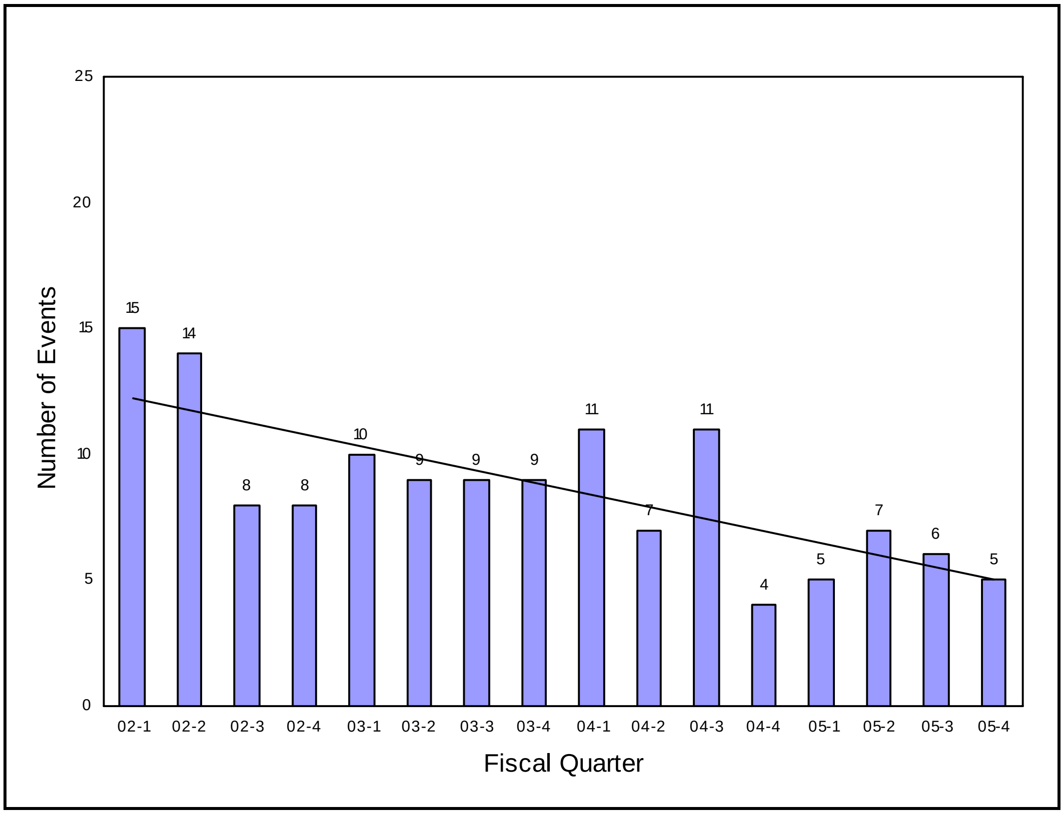


Figure 33. Short-Term Trend of Transportation Events (138 Total)

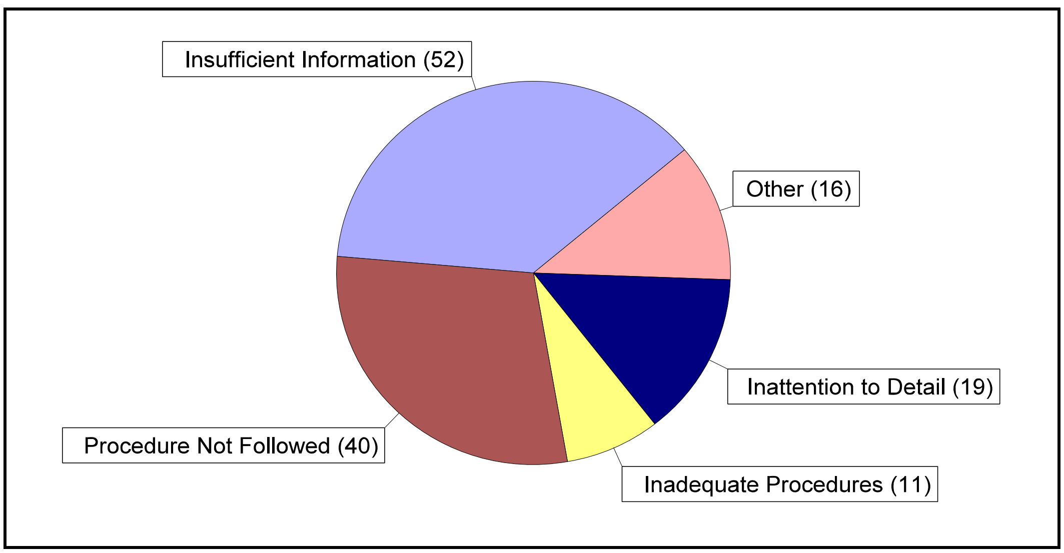


Figure 34. Transportation Event Causes (16 quarters)

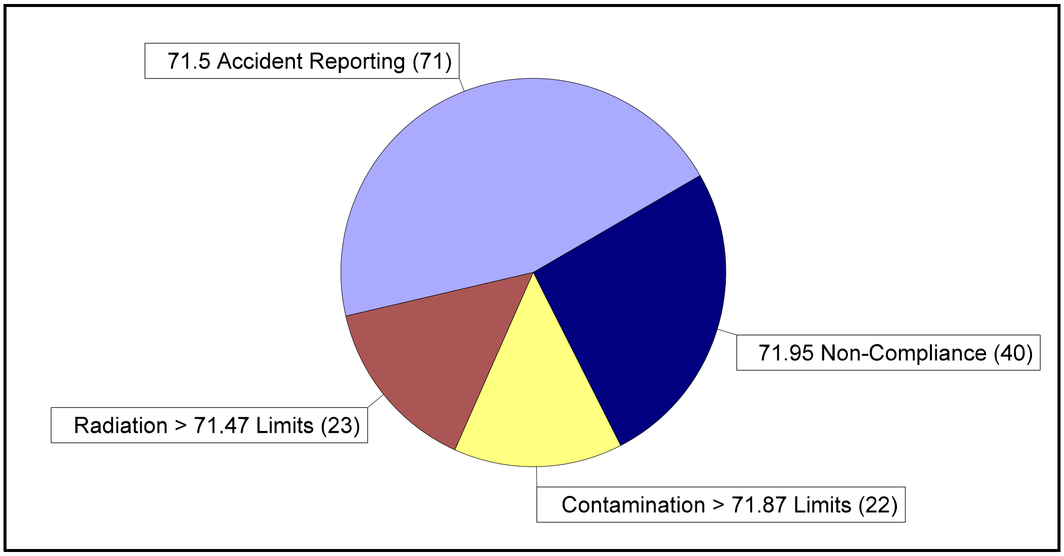


Figure 35. Transportation Problem Types (based on reporting requirements -16 quarters)

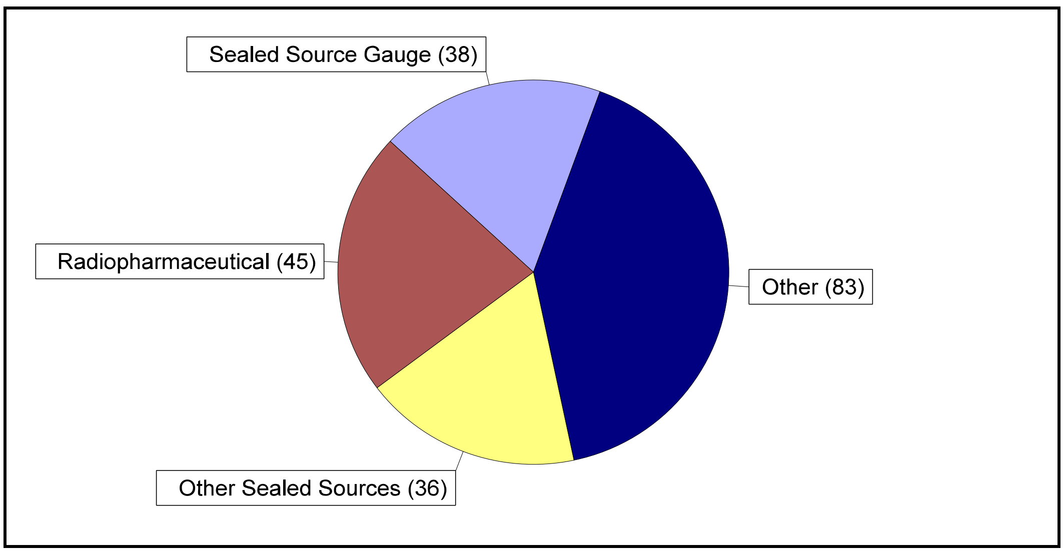


Figure 36. Material Involved in Transportation Events (16 quarters)

Five TRS events occurred in Fiscal Quarter 05-4. The event causes, problem types, and material involved generally reflect distributions similar to those shown in the pie-charts above for the 16-quarter period. The events are summarized below.

Event 050517 involved a truck carrying Tc-99m that was involved in a single-vehicle accident. Approximately seven to nine lead pigs were ejected from the truck and some of those pigs opened, releasing syringes. No fluids leaked out of any of the syringes. The licensee responded to the scene, surveyed the material, and found no radioactive contamination. The material was secured and loaded onto another truck for removal from the accident scene.

Event 050575 involved a well logging vehicle that was involved in a single-vehicle, roll-over accident in a remote area on State Highway 550, south of Ouray, Colorado. The accident resulted in the spill of a small quantity of Sc-46. A shipping container was ejected that contained a total of 7.4 GBq (200 mCi) of Ir-192, 4.4 GBq (120 mCi) of Sc-46, and 4.1 GBq (110 mCi) of Sb-124, all in the form of ProTechnics "Zero Wash" non-soluble tracer beads. The force of the impact broke the valves off two of the reservoirs used for tracer injection and the broken containers landed in the middle of the highway. The police HAZMAT responders moved the broken containers to the side of the road to allow traffic to pass, without checking for radioactive contamination (they did not have a survey meter). Emergency response personnel were checked for contamination when licensee personnel arrived at the scene and none was detected. All spilled material was cleaned including one spot that was reading 0.15 mSv/hour (15 mrem/hour) on contact. The contaminated dirt was returned to the licensee's office for disposal. Spectral analysis of the dirt identified a total activity of less than 37 MBq (1 mCi) of Sc-46, Ir-192, and Sb-124. The Colorado Department of Health initiated an investigation of the incident and performed a confirmatory survey of the area. No additional radioactive contamination was found at the scene. Corrective actions taken by the licensee included providing additional training, generating a new procedure, and obtaining new equipment. This event was also classified as an RLM event.

Event 050631 involved a flatbed truck carrying a Sealand container that overturned on Horn Rapids Road, just outside the Framatome ANP, Inc., uranium fuel fabrication facility. The Sealand container was loaded with uranium oxide powder, packaged inside stainless steel buckets within stainless steel protective overpacks. There were eighteen overpacks in the Sealand container. Personnel from both the licensee and the State of Washington responded to assess the radiological impact. No radioactive contamination or abnormal levels of radiation were detected. There was no visual evidence of physical damage or a breach of containment to the Sealand container. The licensee removed the container from Horn Rapids Road to a warehouse located within the controlled access area to perform further evaluations of the interior of the container and the stainless steel protective overpacks. There was no evidence of radioactive contamination, breach of containment, or significant physical damage to the interior of the Sealand container or overpacks. The licensee further intends to remove each bucket from the overpacks to determine the physical condition and presence of radioactive contamination.

In event 050660, ABX Air discovered a package containing radioactive material that was torn open. The package (UN2915 Radioactive Material, Normal Form, Non-fissile, Class 7, Radioactive White I, TI = 0.0) contained three smaller packages, each 96 inches by 6 inches by 6 inches, which contained three Po-210 rods each. There were nine rods with a total activity of 1.18 GBq (32 mCi). Even though the main package was torn open, the contents were undamaged. Southwest Management Environmental Services was contacted to repackage the shipment.

In event 050702, Global Nuclear Fuel - Americas, LLC., (a uranium fuel fabrication facility) reported that conditions in Certification of Compliance (CoC) #9196 for the Duratek UX-30 overpack were not followed during a shipment. Specifically, the valve cover on the standard 30-B cylinder should have been removed prior to shipment. However, one of three cylinders had a valve cover on the valve. Corrective actions included issuing a stop shipment for all UF6 cylinders, procedure modification, and conducting an internal review.

2.9 Other

Figure 37 displays the annual counts of the 77 Other (OTH) events that occurred from Fiscal Year 1995 through 2005. Figure 38 displays the quarterly counts of the 23 OTH events that occurred during the 16-quarter period. Because OTH events do not fit a defined criteria that ensures consistency within the data, trending is not performed on this data.

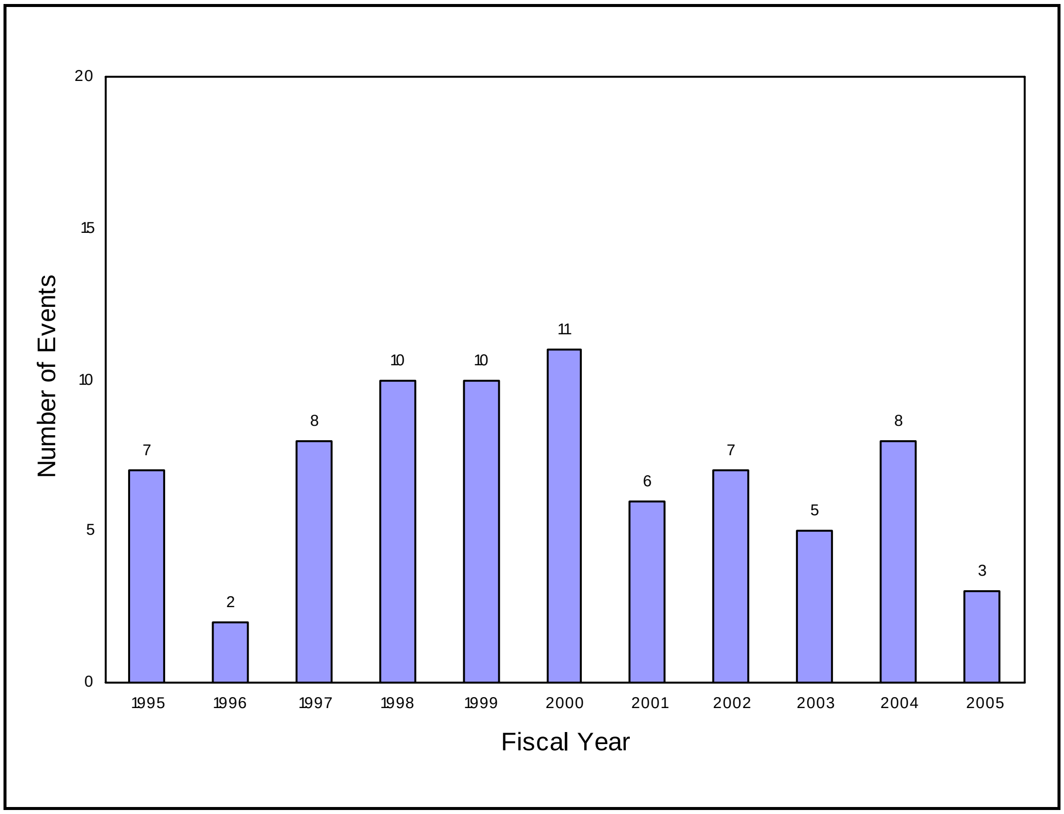


Figure 37. Long-Term Display of Other Events (77 total)

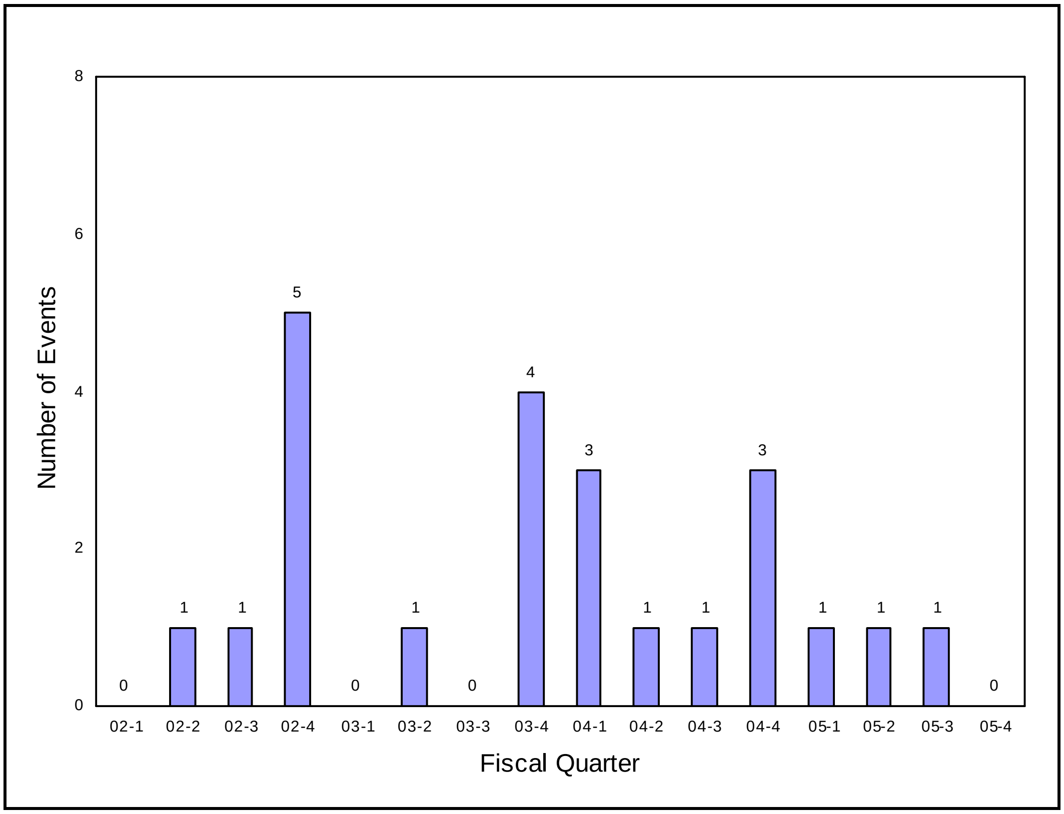


Figure 38. Short-Term Display of Other Events (23 total)

No OTH events occurred in Fiscal Quarter 05-4.

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.

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:
    - Involving the wrong individual, or wrong radiopharmaceutical; or
    - 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:
   - Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
   - When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage.

3. A gamma stereotactic radiosurgery radiation dose:
   - Involving the wrong individual, or wrong treatment site; or
   - 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:
   - Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
   - 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;
   - When the calculated weekly administered dose exceeds the weekly prescribed dose by 30% or more of the weekly prescribed dose; or
   - 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:
   - 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);
   - Involving a sealed source that is leaking;
   - When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
   - 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:
   - Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
   - 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.

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.

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.

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 a broad range of reportable events that do not specifically fit into one of the previous categories. This event type may also include events not reportable to the NRC but are included in the NMED program for informational purposes.

Appendix B

Statistical Trending Methodology

Appendix B

Statistical Trending Methodology

Trending - General

The following is a general discussion of statistical trending techniques.

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

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

Fitting a Straight Line to Data

Consider a linear function

$$f(x) = \alpha + \beta x \qquad (1)$$

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

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

$$\hat{\alpha} = \bar{y} - \hat{\beta}\bar{x} .$$

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

$$\hat{y} = \hat{\alpha} + \hat{\beta}x ,$$

and an estimate of σ is

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

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

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

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

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

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

$$SSE + SSR = SST ,$$

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

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

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-square, and is defined by:

$$r^2 = \frac{SSR}{SST}.$$

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 1.0 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

$$F = \frac{(n-2)r^2}{1-r^2}$$

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. The calculations were made both for an 9-year time period, and for a shorter 16-quarter time period. When the calculated F exceeded the 95th percentile, the trend line was shown on the graph and identified as being statistically significant. Otherwise, a horizontal line was plotted at the average of the associated data.

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

- The data are counts, and thus are discrete rather than being normally distributed. This problem is most pronounced when the counts are relatively low or sparse. Also, normally-distributed data in general can be negative, but the counts are always greater than or equal to zero.

- Variation in counts tends to increase as the counts increase. If the events occur at random, with a constant occurrence rate in a particular year or quarter, then the variance of the count for that year or quarter is equal to the mean or average for that year or quarter. Thus, the assumption of a constant variance for the data in each year may not apply.

- Finally, more than one count can be associated with a single reported incident in a single event category. This situation would occur, for example, if several pieces of equipment fail in an event or if several types of overexposure occur. In these cases, the data are not independent.

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

Taking logarithms of the counts and then applying the LS methods 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 least squares 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

Revision of Data Contained in the Third Quarter Fiscal Year 2005 Report

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Revision of Data Contained in the Third Quarter Fiscal Year 2005 Report

The NMED is a dynamic database with new reports and revisions to previous reports being added on a continuing basis. This activity can result in additions or subtractions to data that was published in previous issues of this report. Numerical changes in NMED numbers can result from several different types of technical changes to coded data. The most common types of changes to database records are:

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

Figures C-1 through C-9 below show net numerical differences to the 16-quarter data previously published in the Third Quarter Fiscal Year 2005 report. A positive value indicates that the data has increased from that published in the previous report, while a negative value indicates a decrease from the previous report.

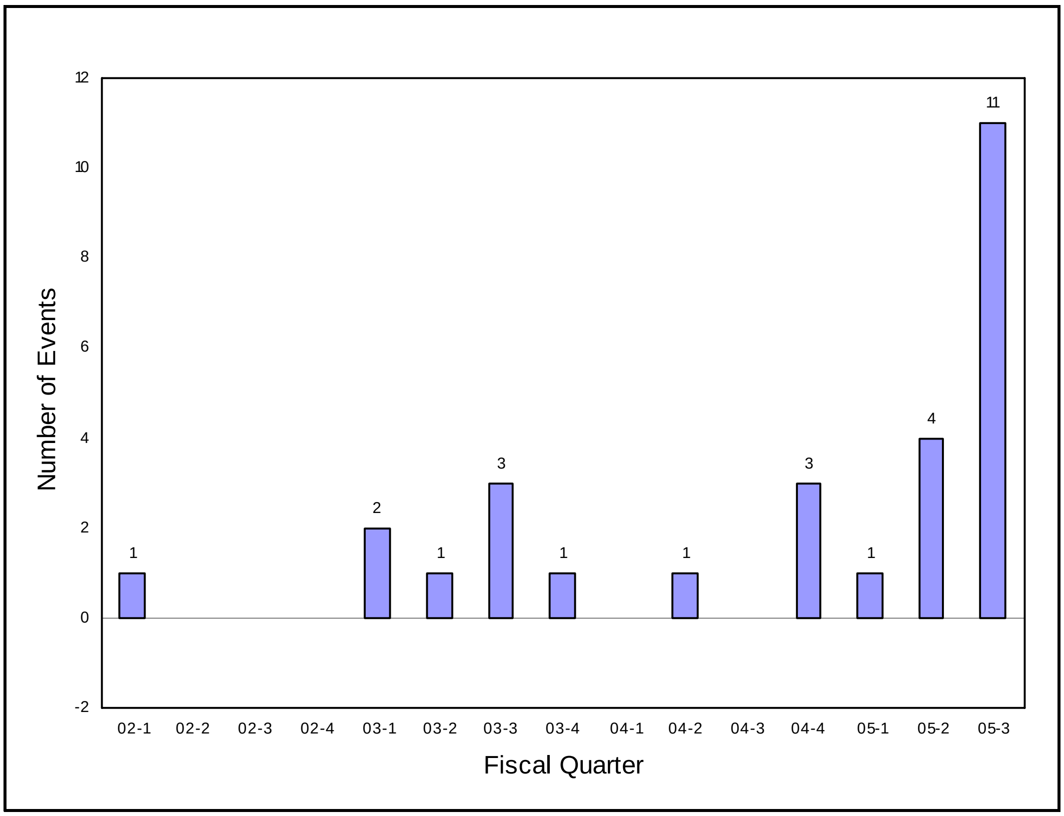

Figure C-1. Net Changes to All NMED Event Data (short-term display)

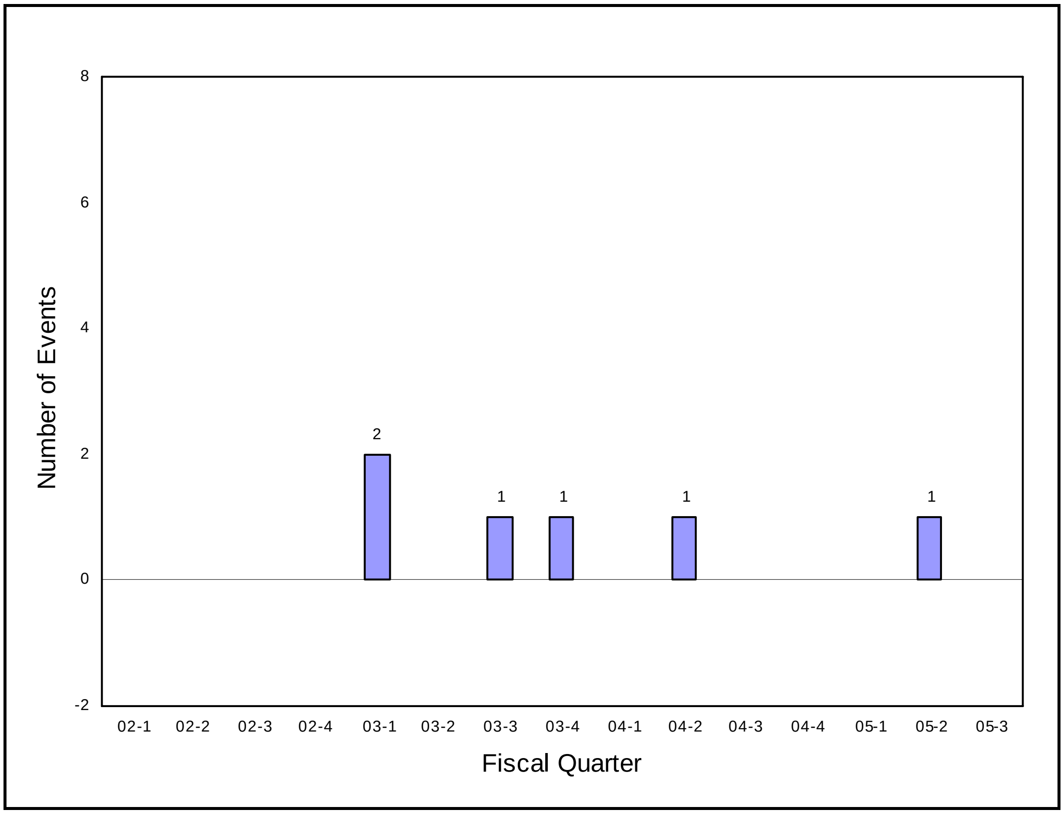

Figure C-2. Net Changes to MED Data (short-term display)

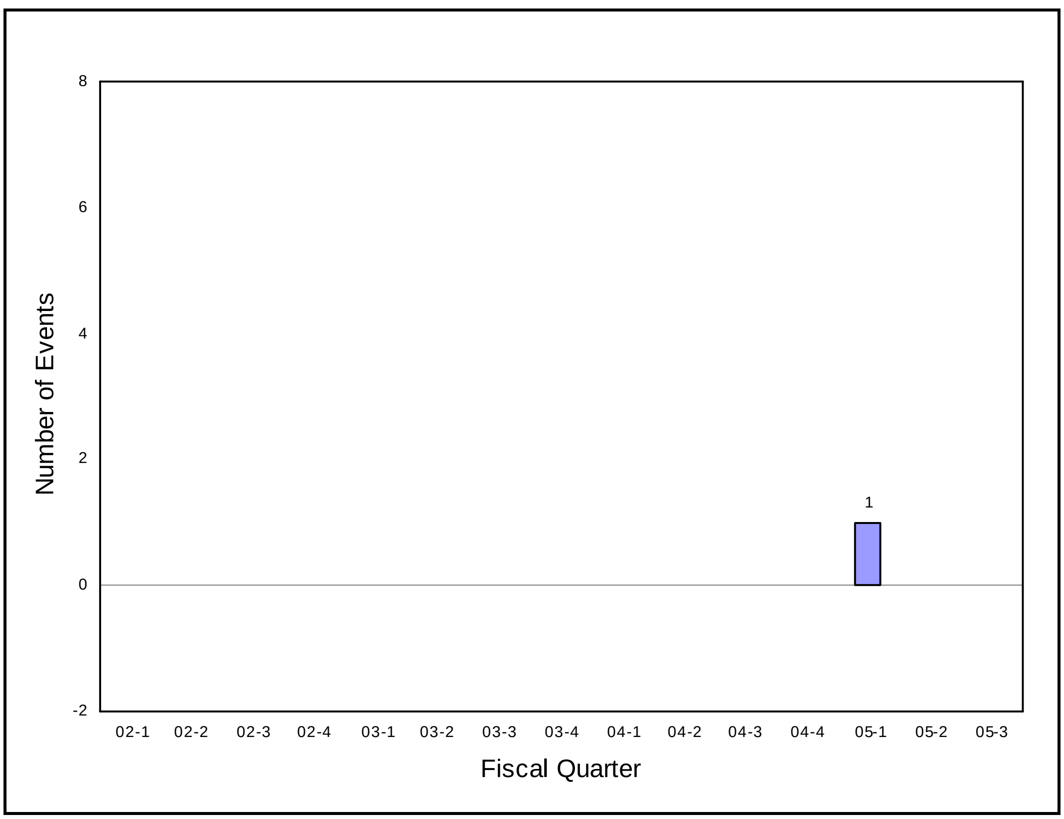

Figure C-3. Net Changes to EXP Event Data (short-term display)

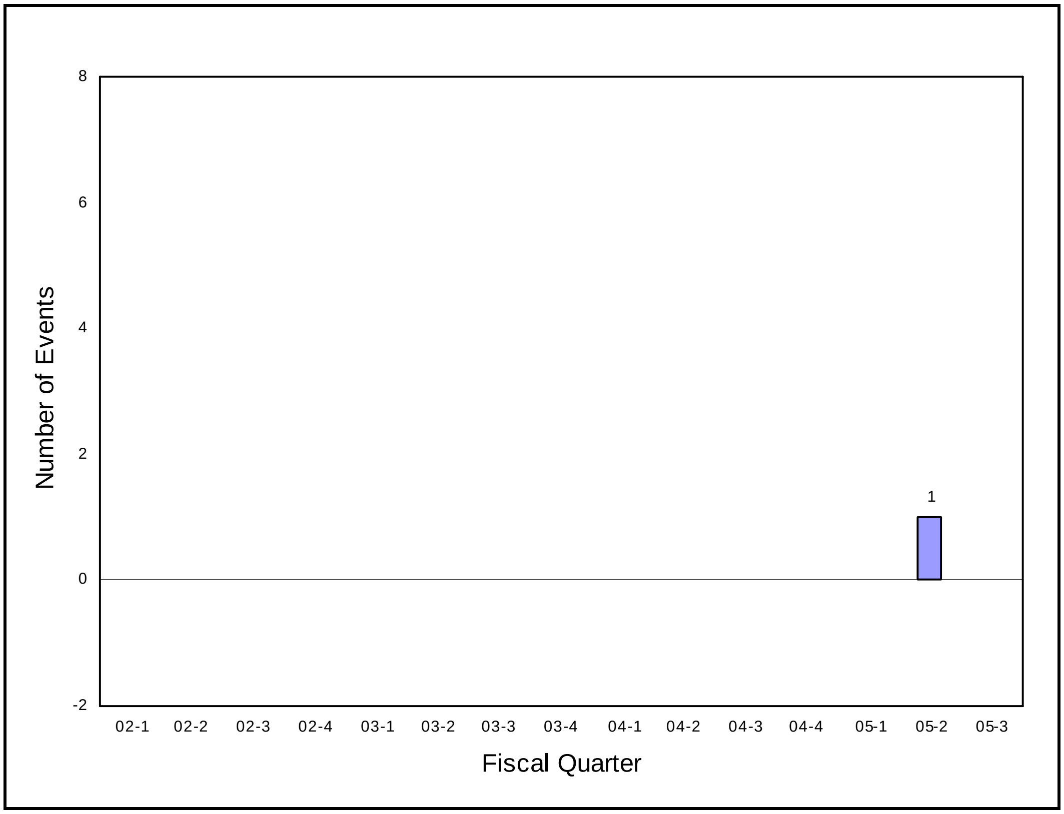

Figure C-4. Net Changes to RLM Event Data (short-term display)

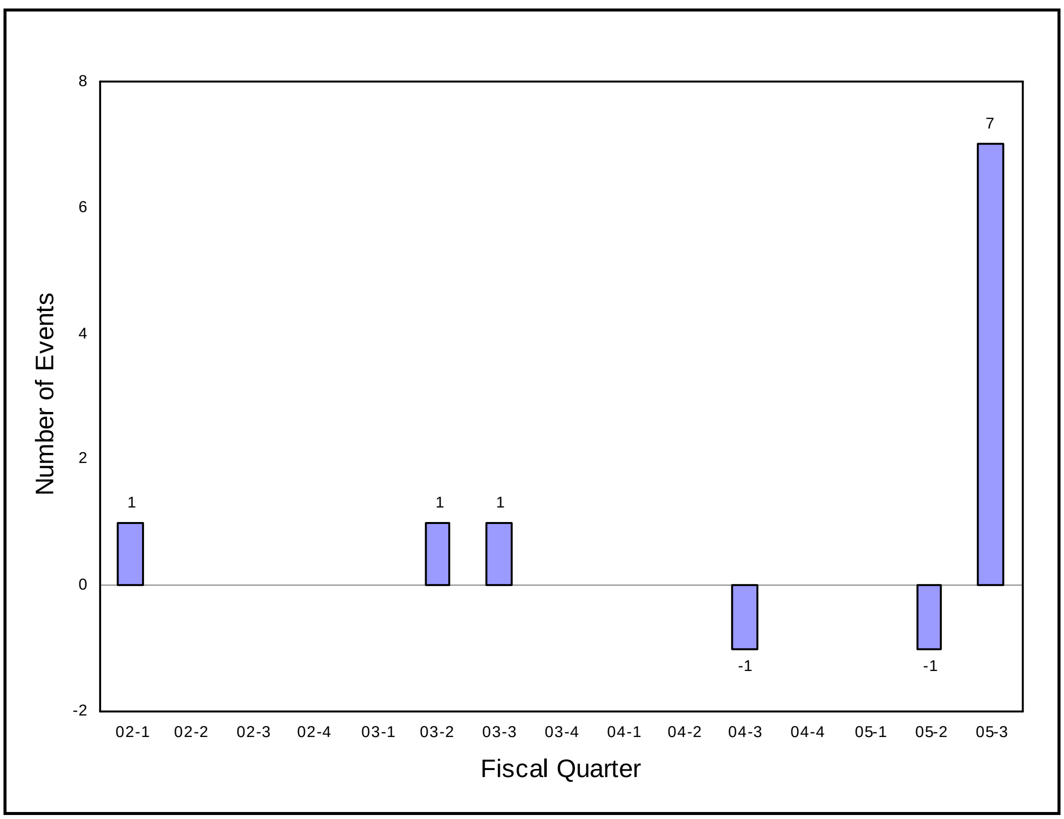

Figure C-5. Net Changes to LAS Event Data (short-term display)

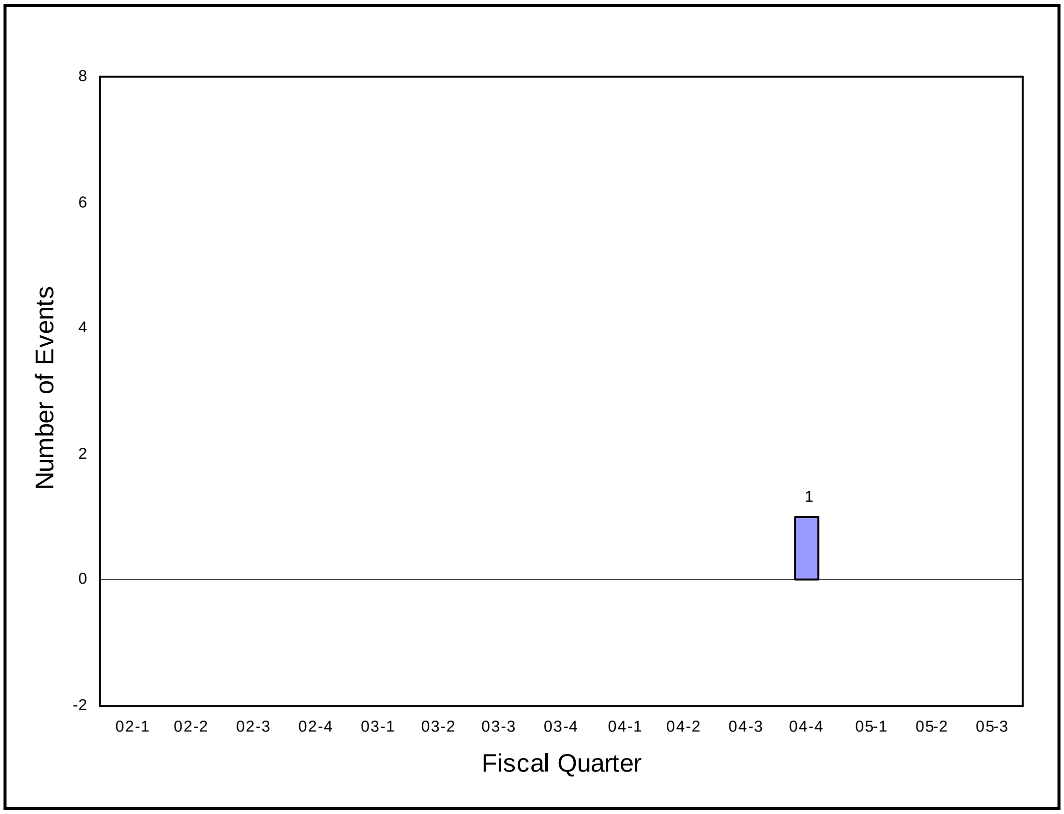

Figure C-6. Net Changes to LKS Event Data (short-term display)

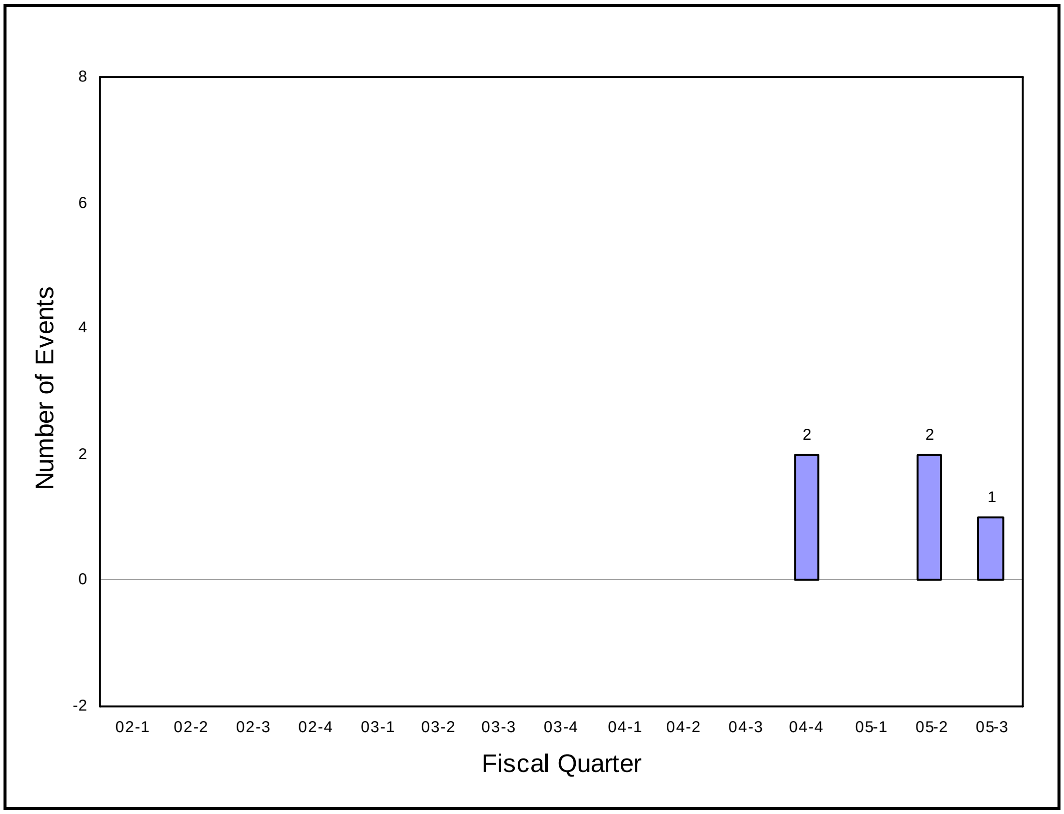

Figure C-7. Net Changes to EQP Event Data (short-term display)

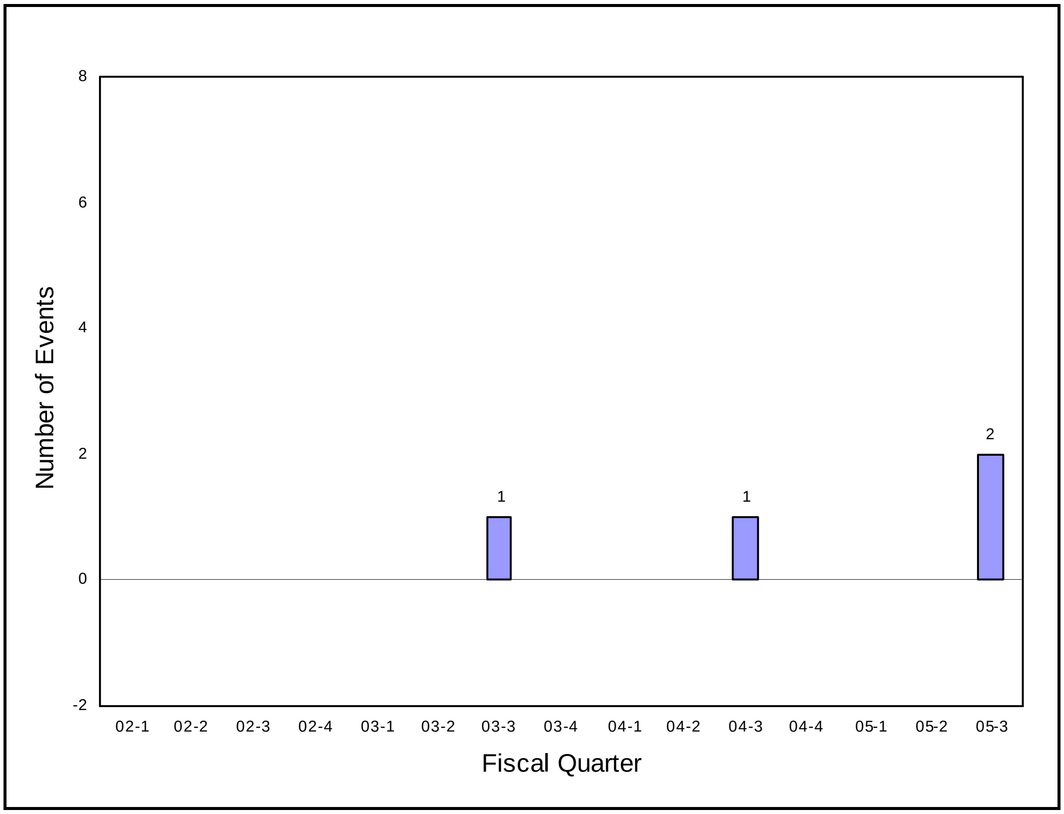

Figure C-8. Net Changes to TRS Event Data (short-term display)

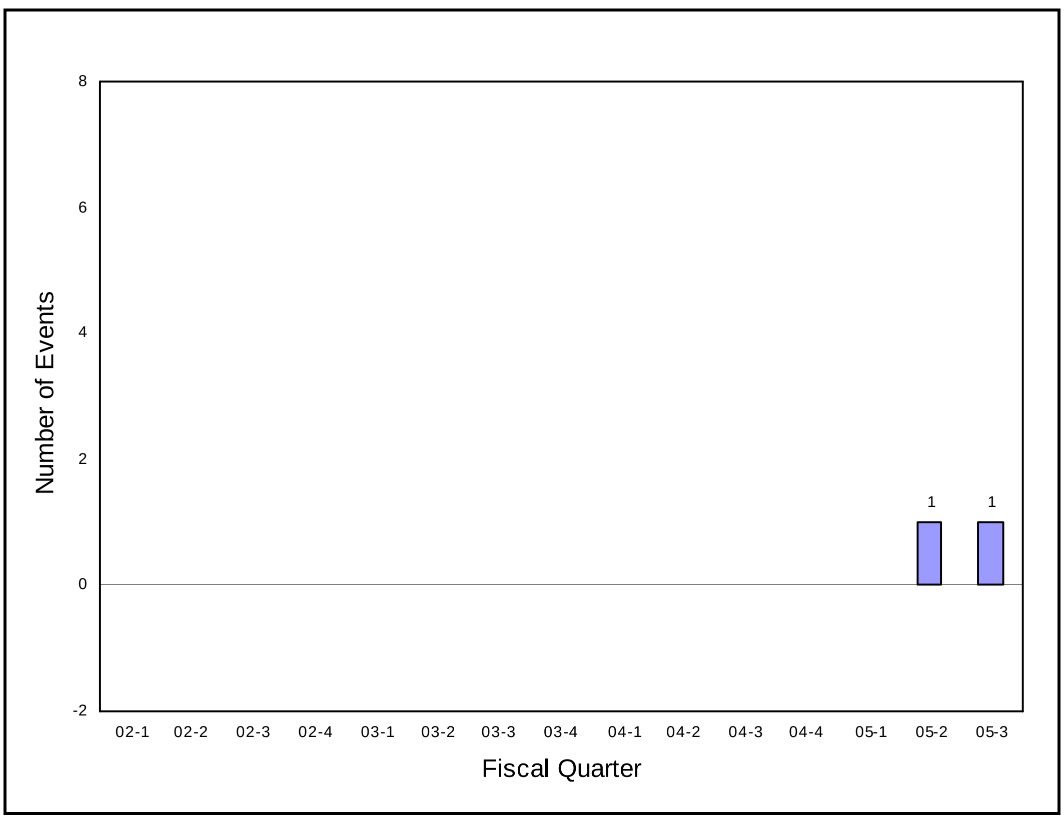

Figure C-9. Net Changes to OTH Event Data (short-term display)