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

Stephen B. Conroy, INL

Robert L. Sant, INL

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

Idaho National Laboratory
Risk, Reliability, and NRC Programs Department
Idaho Falls, Idaho 83415

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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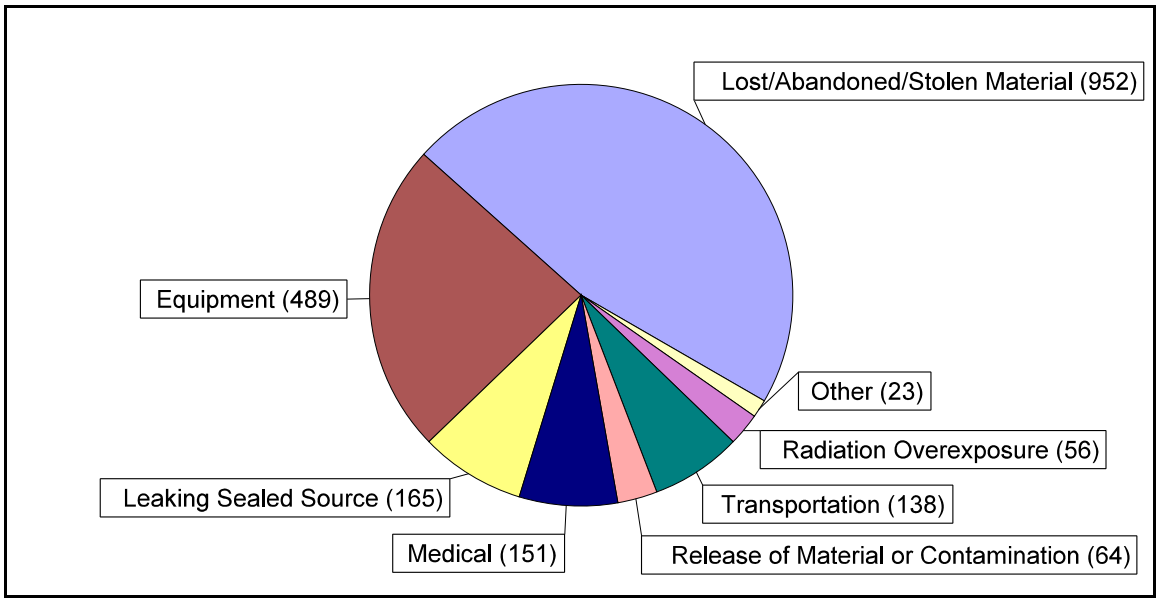
EXECUTIVE SUMMARY

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.

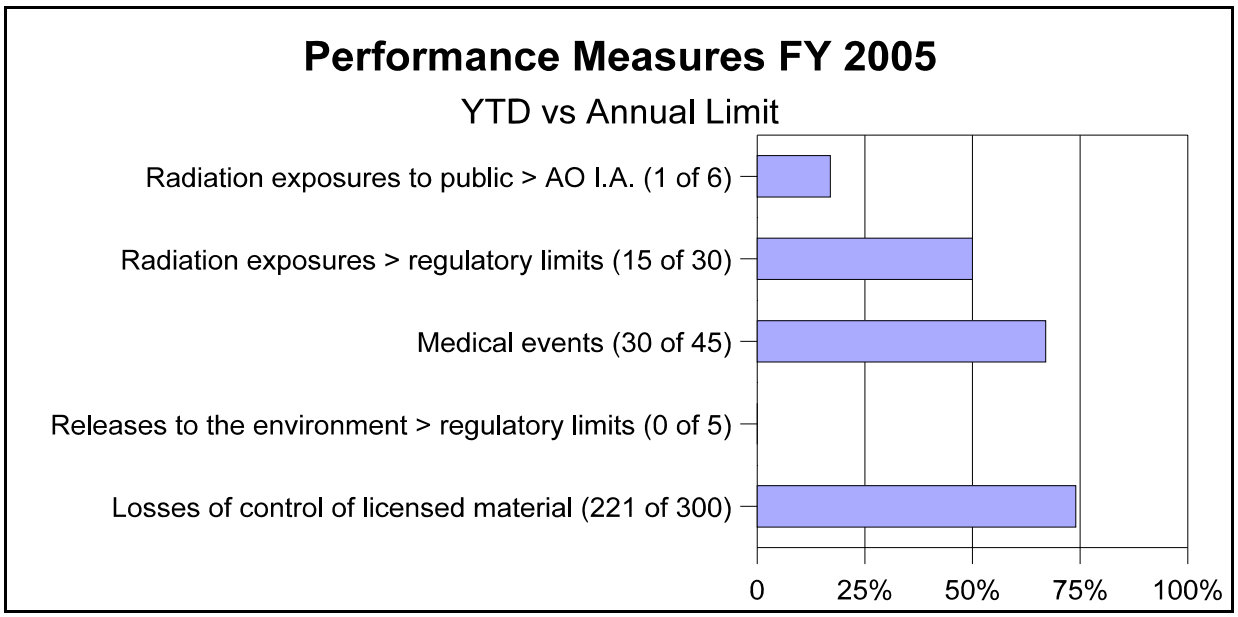
During the 16-quarter period, the event reporting rate was about 2.5 events per 100 licensees annually for all events, and about 0.5 events per 100 licensees annually for medical events. This was based on an estimate of about 21,809 material licensees (about 4,511 NRC licensees and 17,298 Agreement State 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.

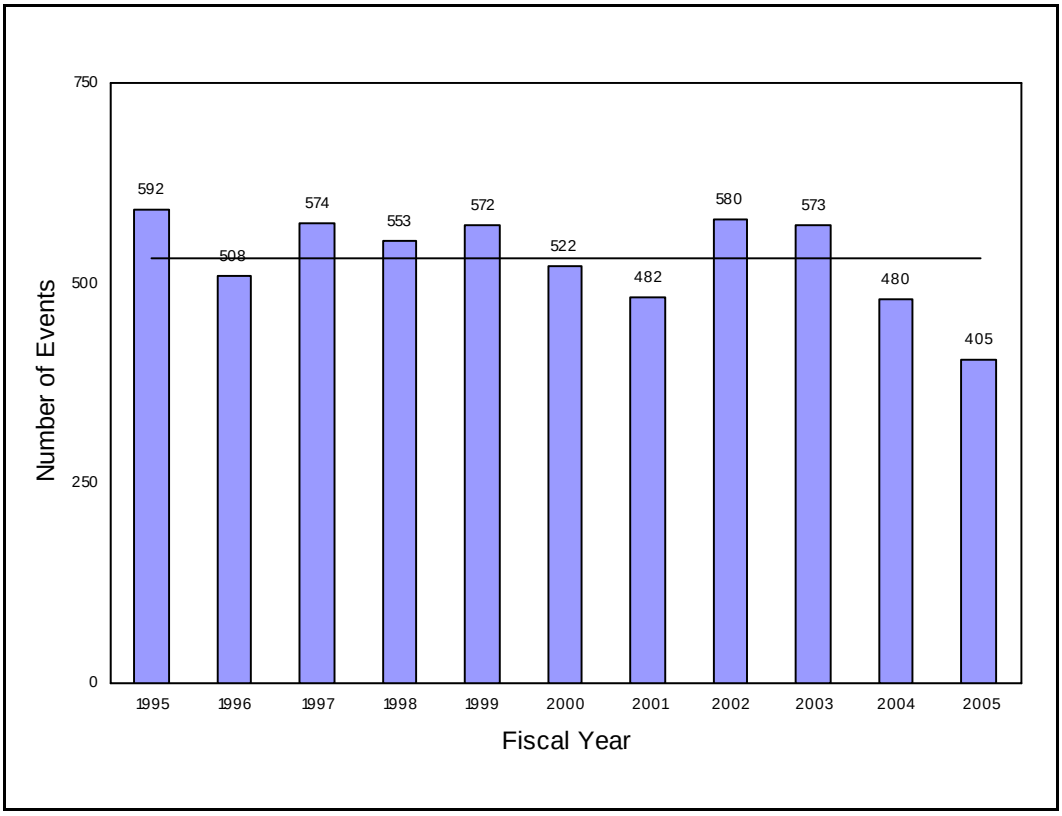


Figure 1. Long-Term Trend of All NMED Events (5841 total)

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.

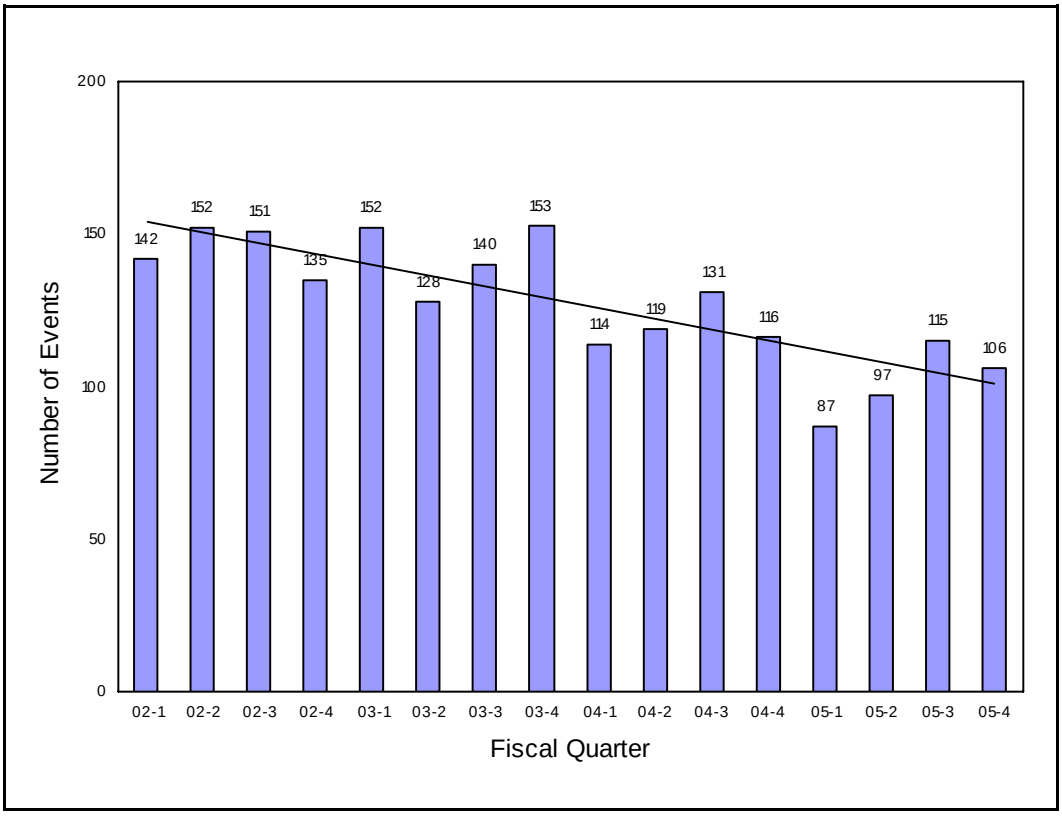


Figure 2. Short-Term Trend of All NMED Events (2038 total)

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).

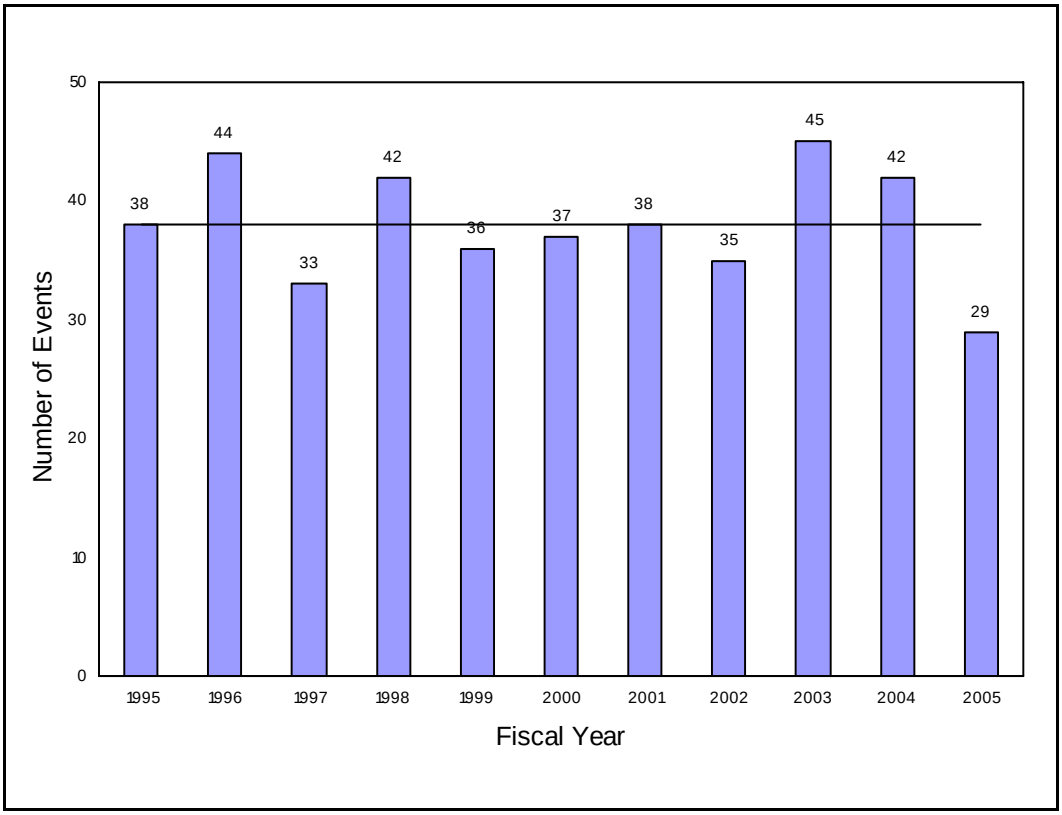


Figure 3. Long-Term Trend of Medical Events (419 total)

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).

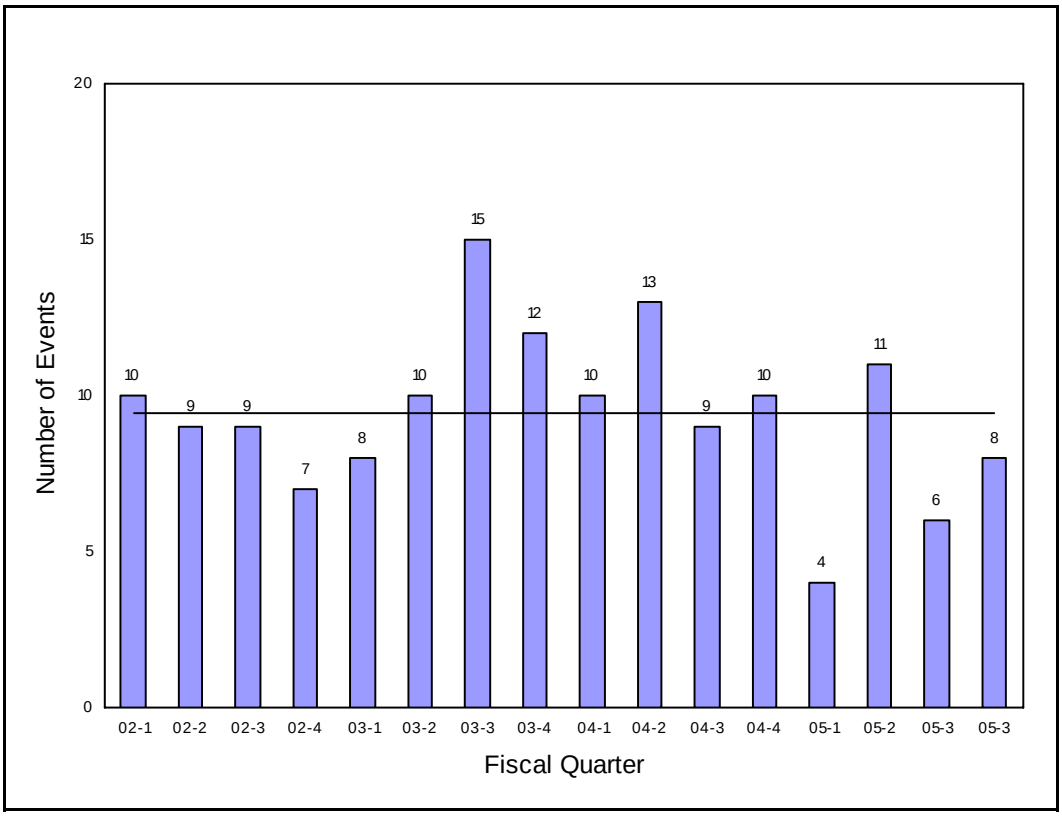


Figure 4. Short-Term Trend of Medical Events (151 total)

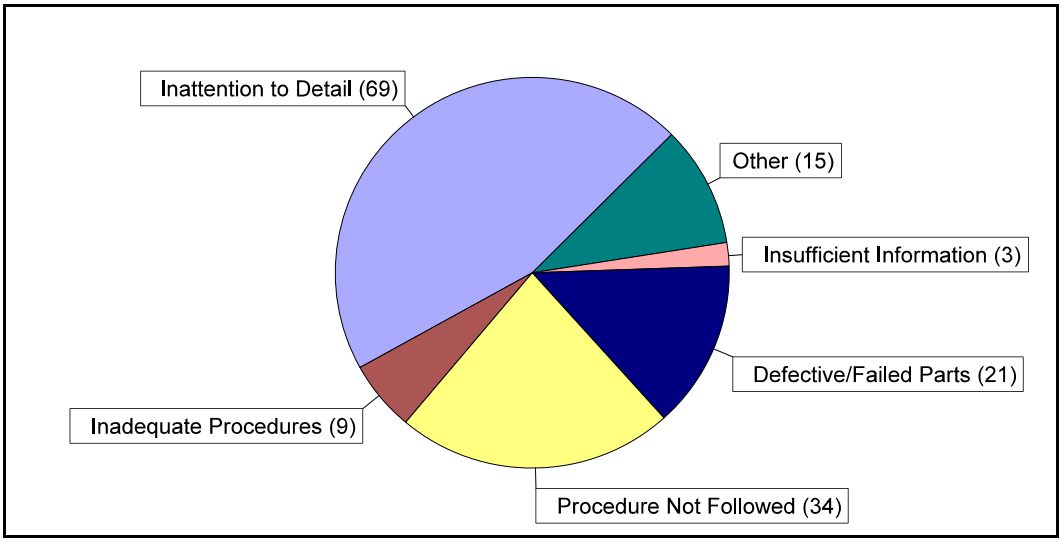


Figure 5. Medical Event Causes (16 quarters)

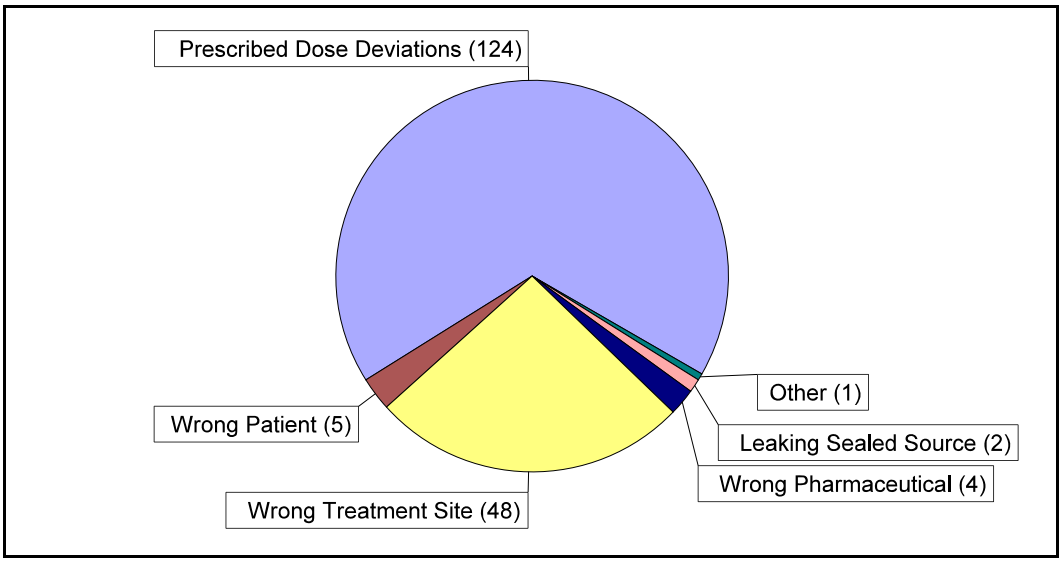


Figure 6. Medical Event Problems (based on reporting requirements - 16 quarters)

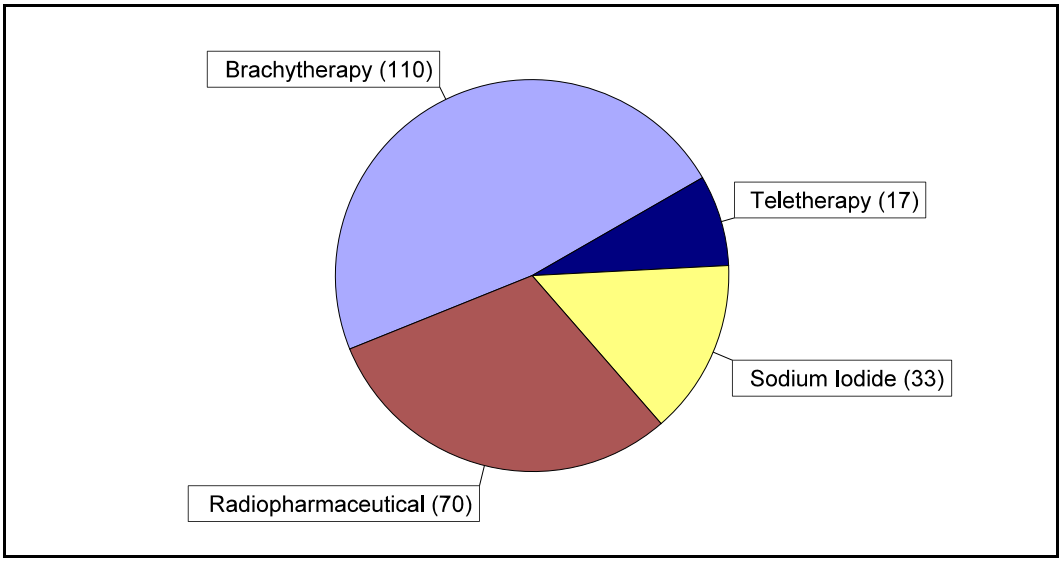


Figure 7. Medical Procedures Performed (16 quarters)

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).

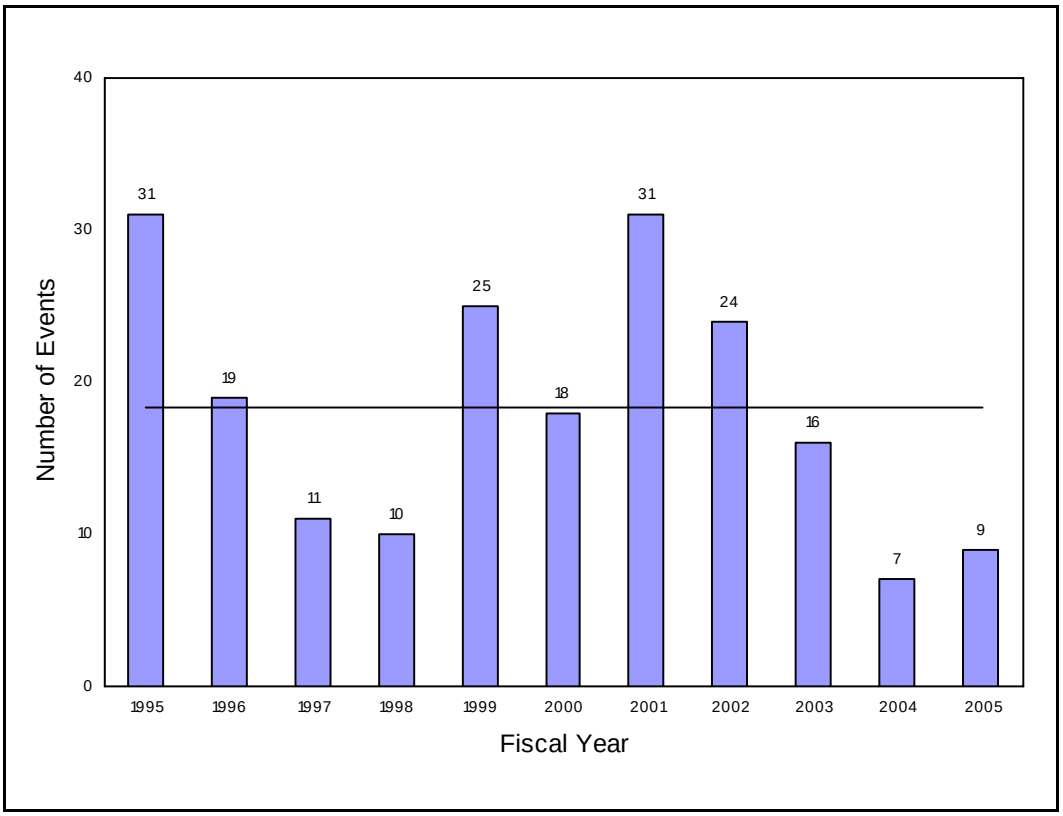


Figure 8. Long-Term Trend of Radiation Overexposure Events (201 total)

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.

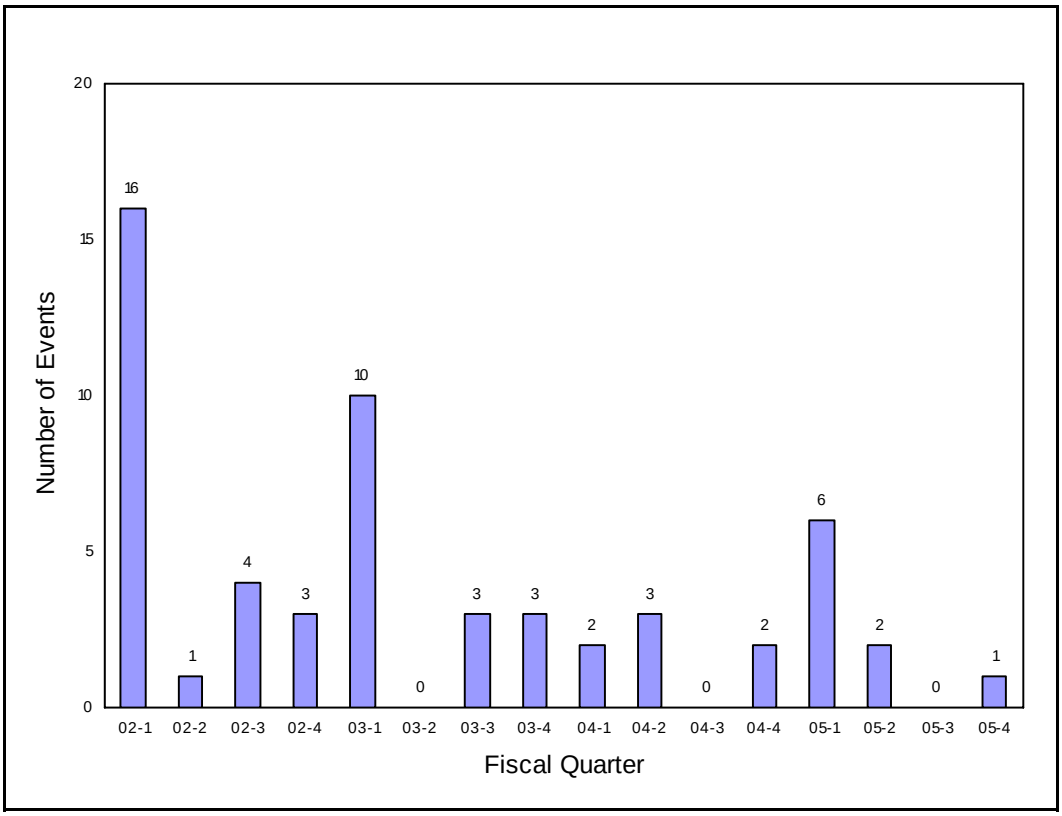


Figure 9. Short-Term Trend of Radiation Overexposure Events (56 total)

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.

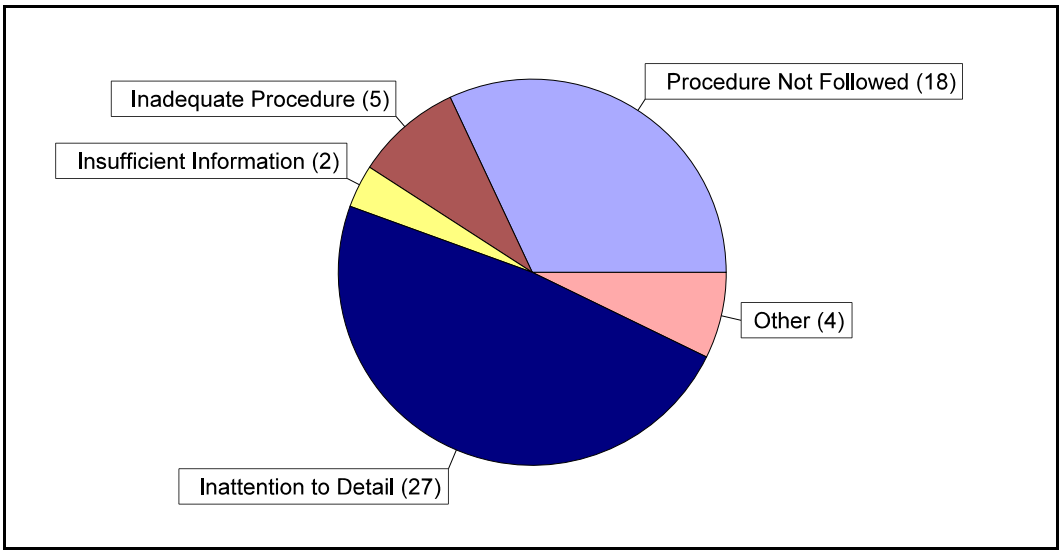


Figure 10. Radiation Overexposure Event Causes (16 quarters)

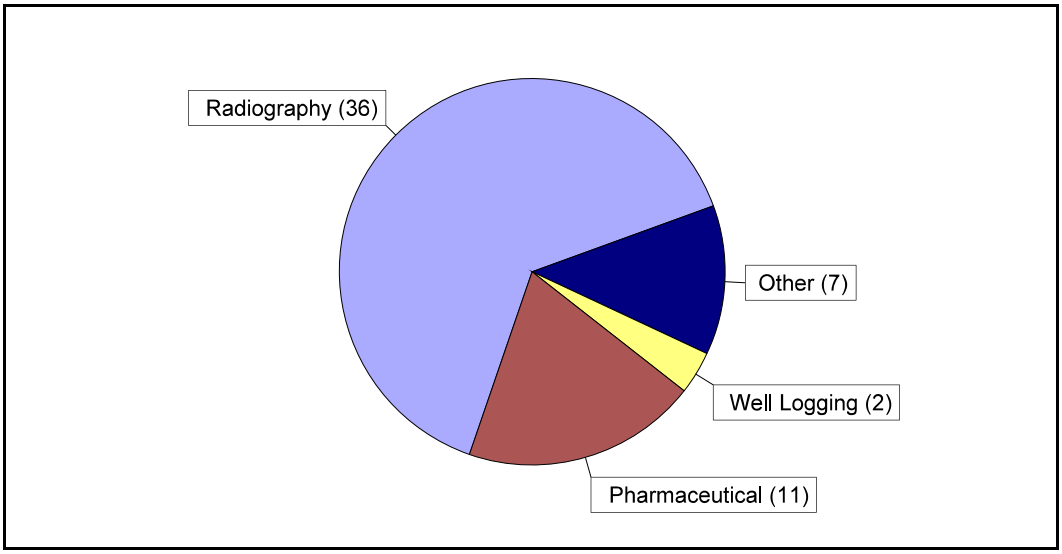


Figure 11. Radiation Overexposure Event Work Activities (16 quarters)

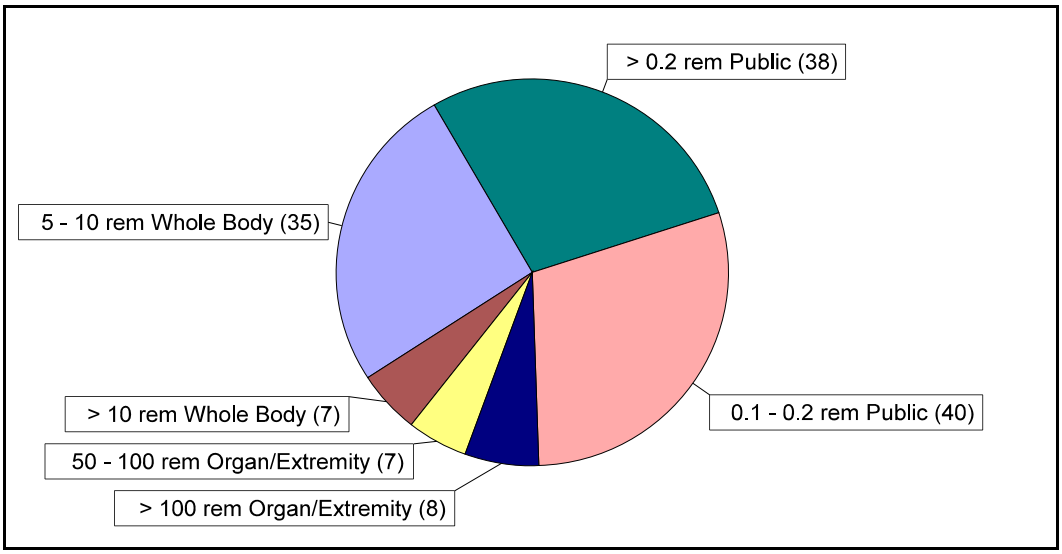


Figure 12. Radiation Overexposure Dose Types (Occupational or Public) and Ranges (16 quarters)

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.

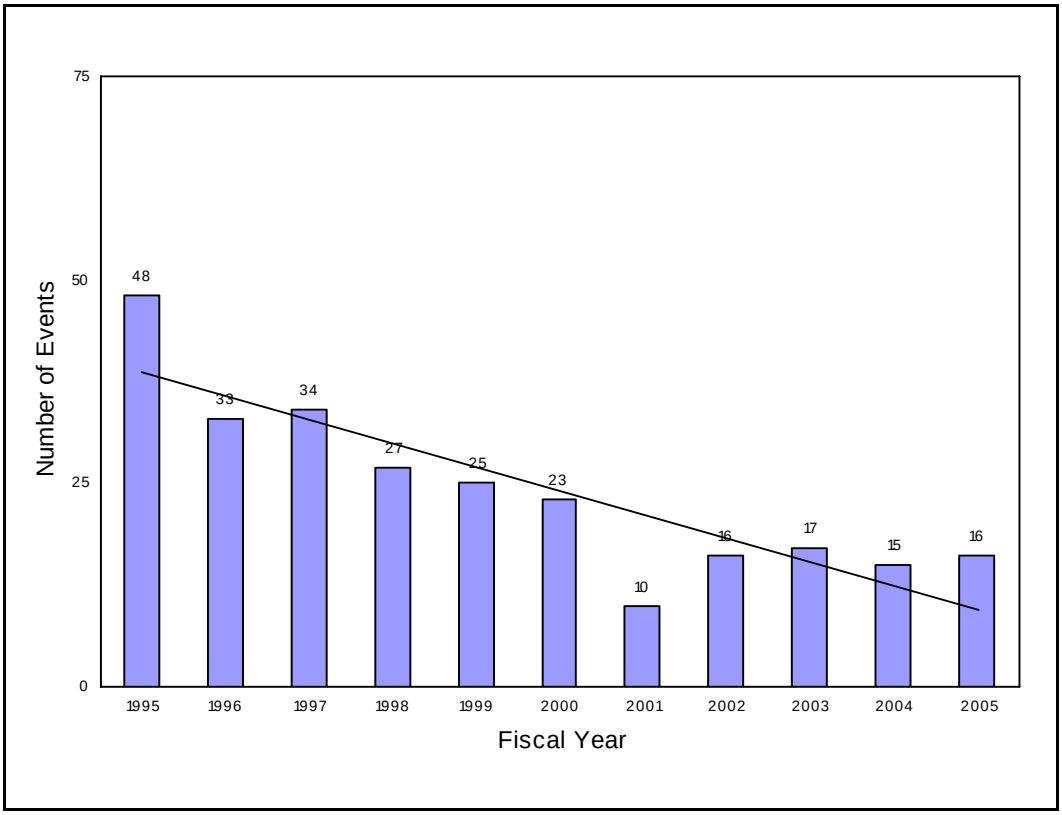


Figure 13. Long-Term Trend of Release of Licensed Material or Contamination Events (264 total)

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).

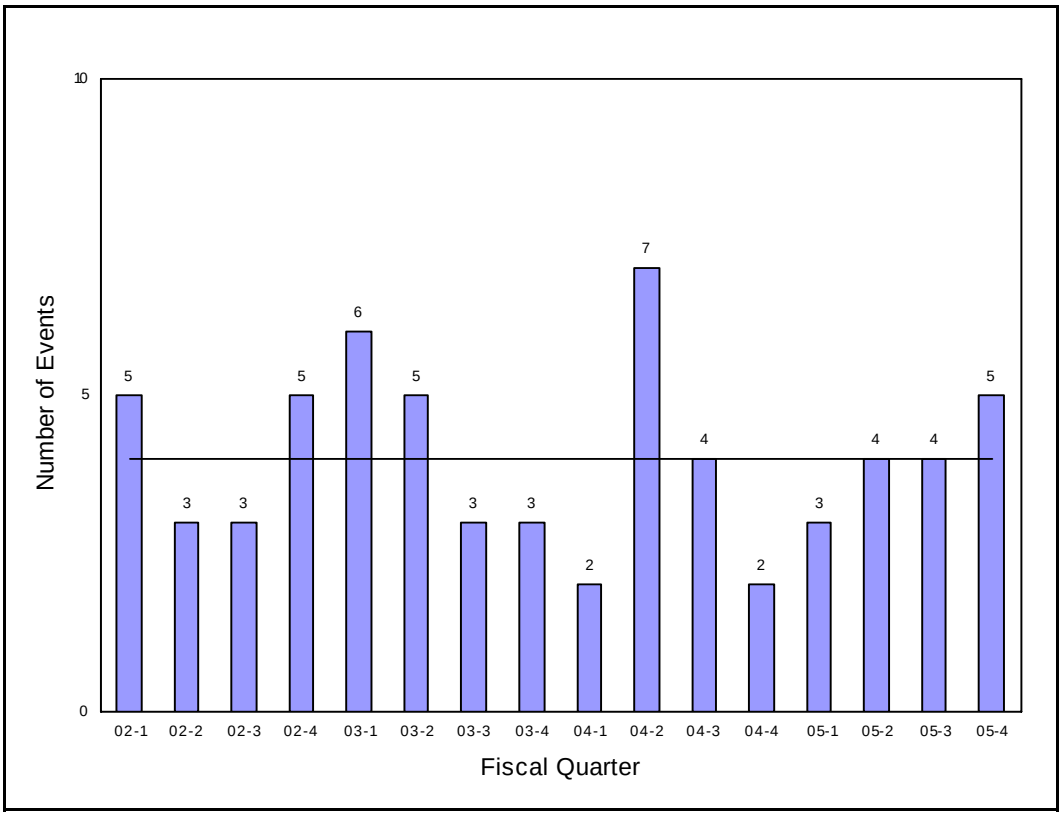


Figure 14. Short-Term Trend of Release of Licensed Material or Contamination Events (64 total)

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).

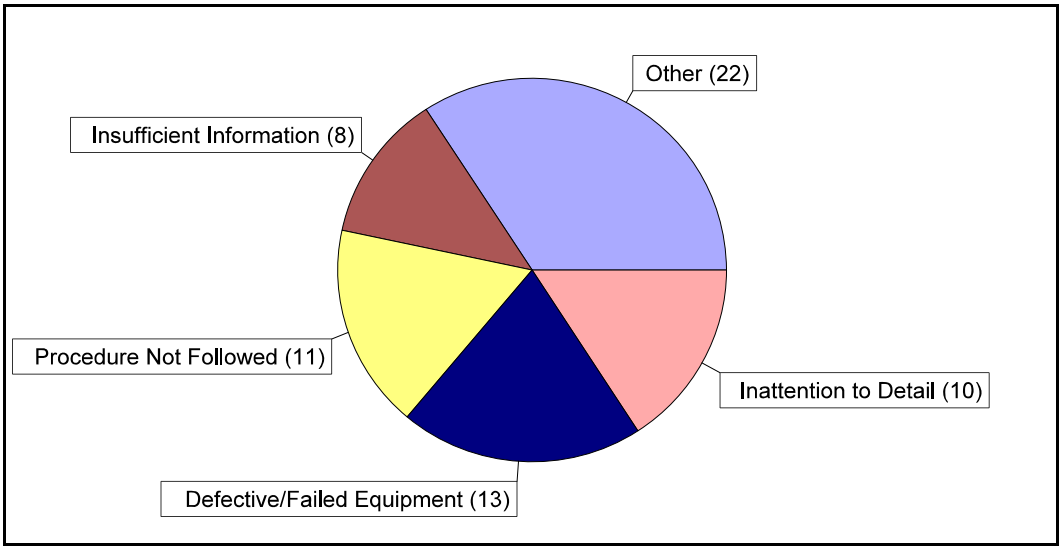


Figure 15. Release of Licensed Material or Contamination Event Causes (16 quarters)

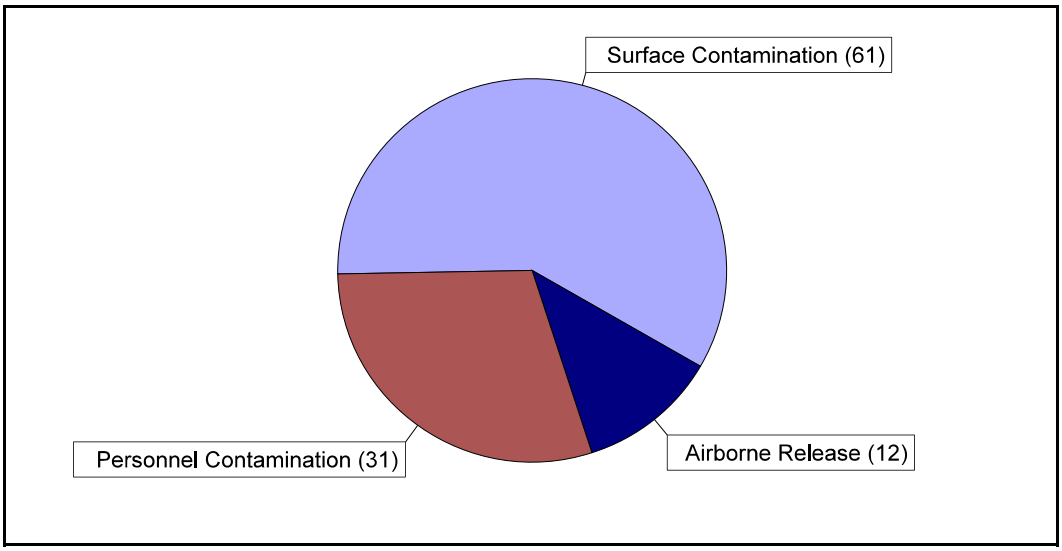


Figure 16. Release and Contamination Media (16 quarters)

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 UF4, 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).

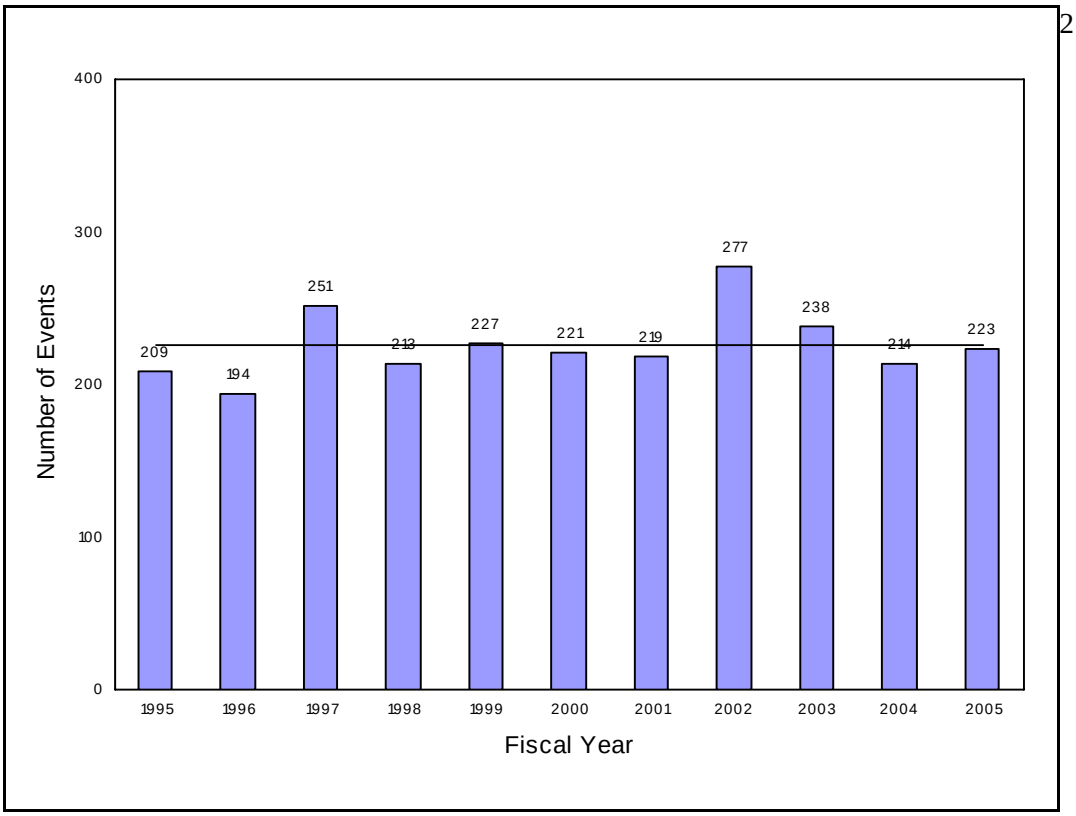


Figure 17. Long-Term Trend of Lost/Abandoned/Stolen Material Events (2486 total)

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).

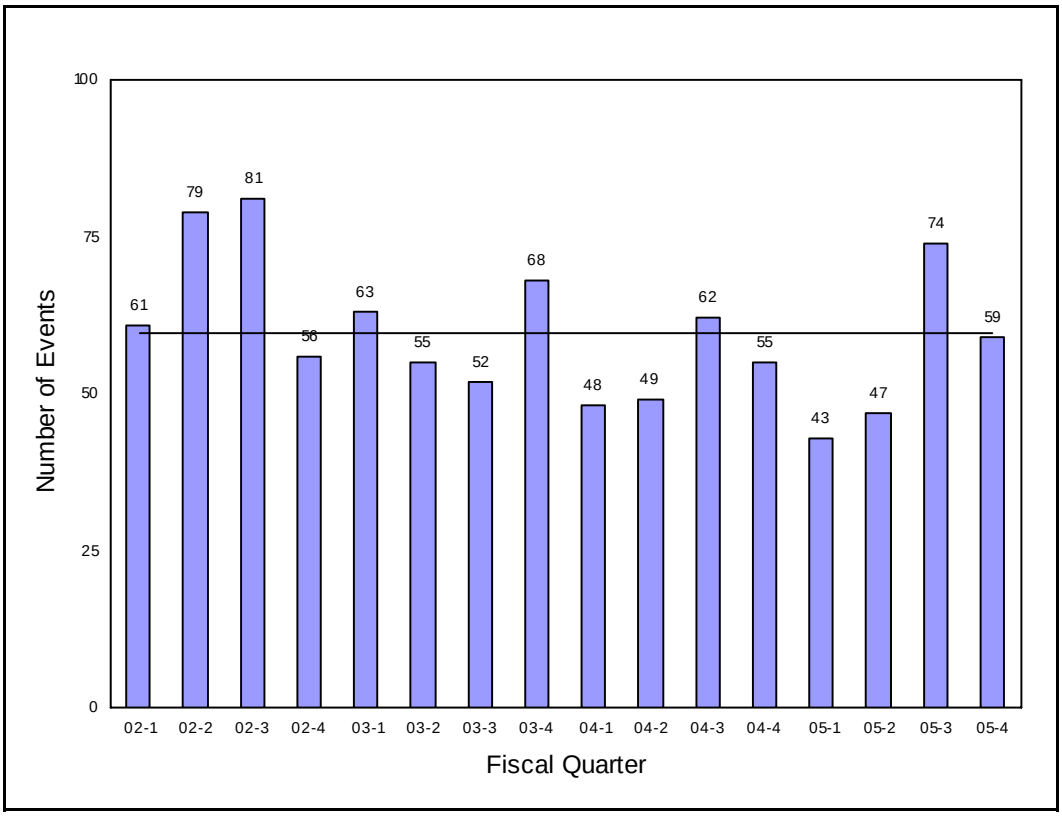


Figure 18. Short-Term Trend of Lost/Abandoned/Stolen Material Events (952 total)

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.

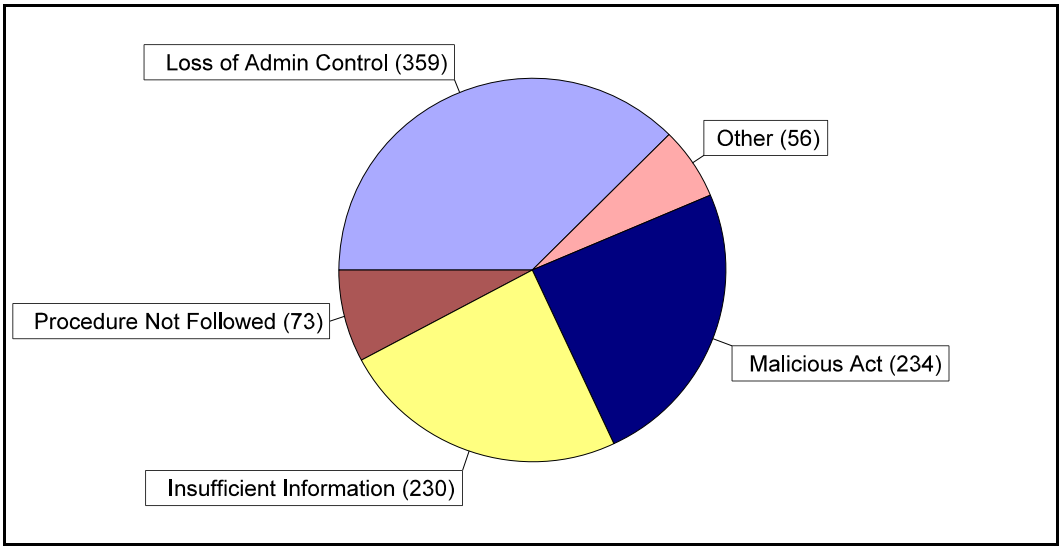


Figure 19. Lost/Abandoned/Stolen Material Event Causes (16 quarters)

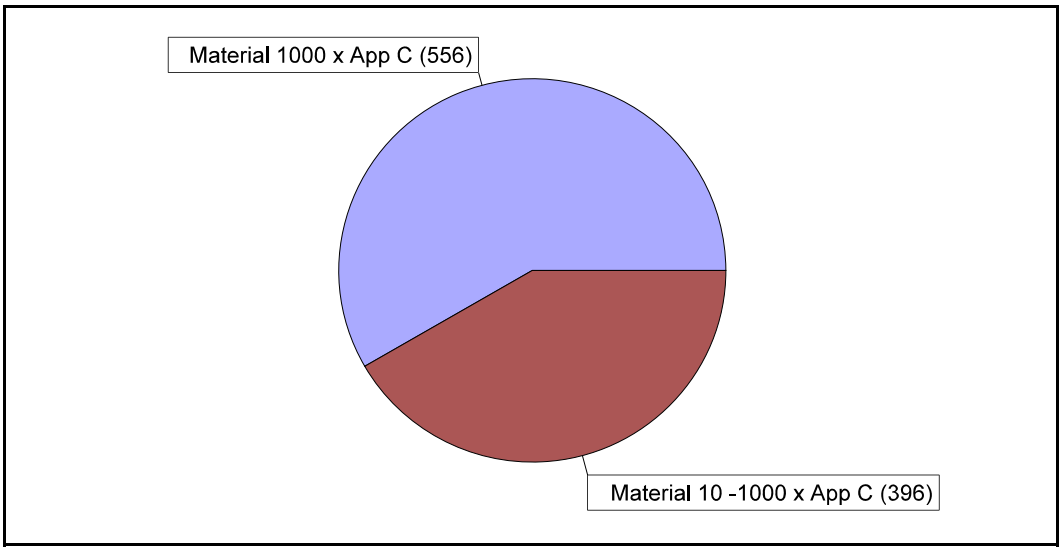


Figure 20. Lost/Abandoned/Stolen Material Event Material Types (based on reporting requirements - 16 quarters)

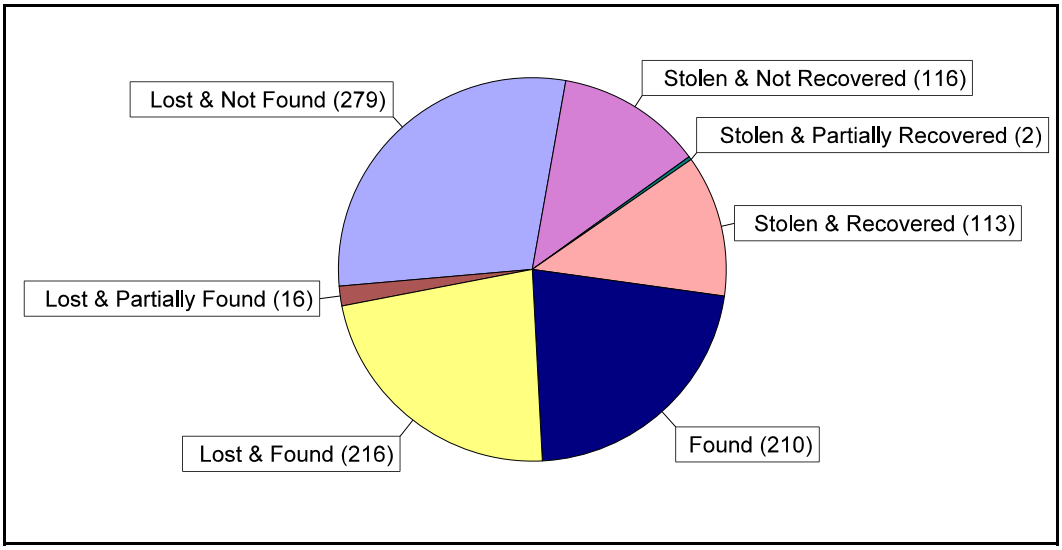


Figure 21. Nature of Loss Associated with Lost/Abandoned/Stolen Material Events (16 quarters)

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).

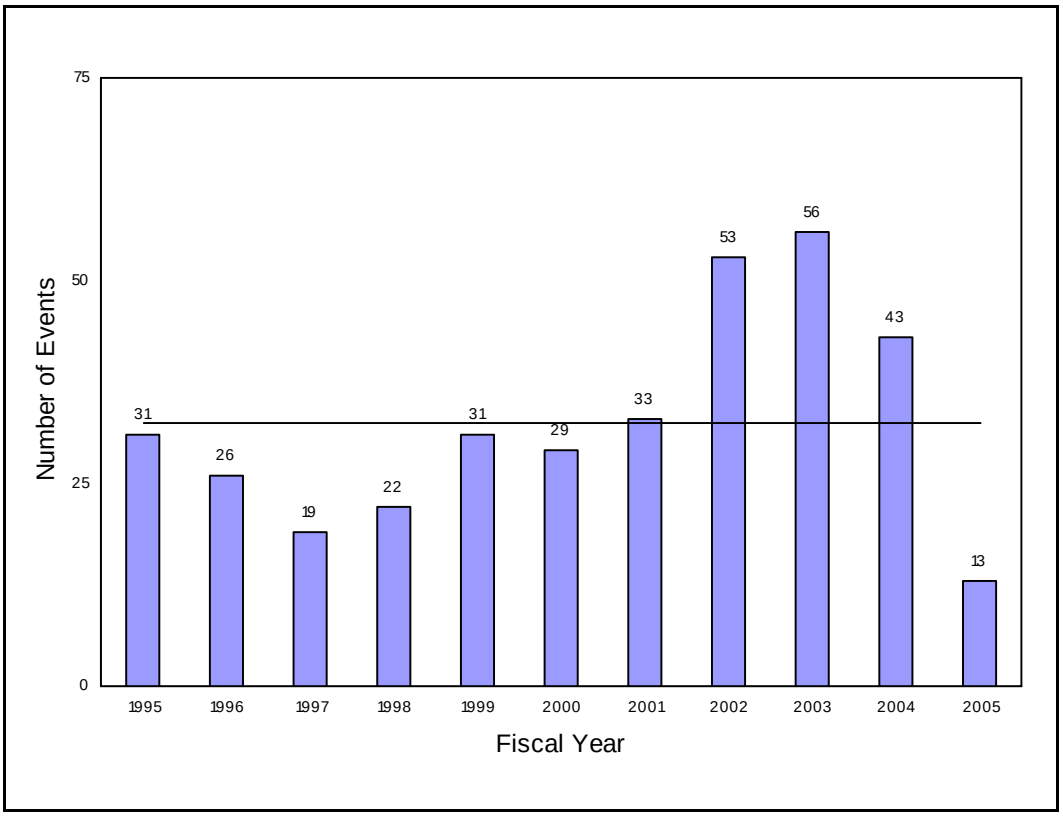


Figure 22. Long-Term Trend of Leaking Sealed Source Events (356 total)

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).

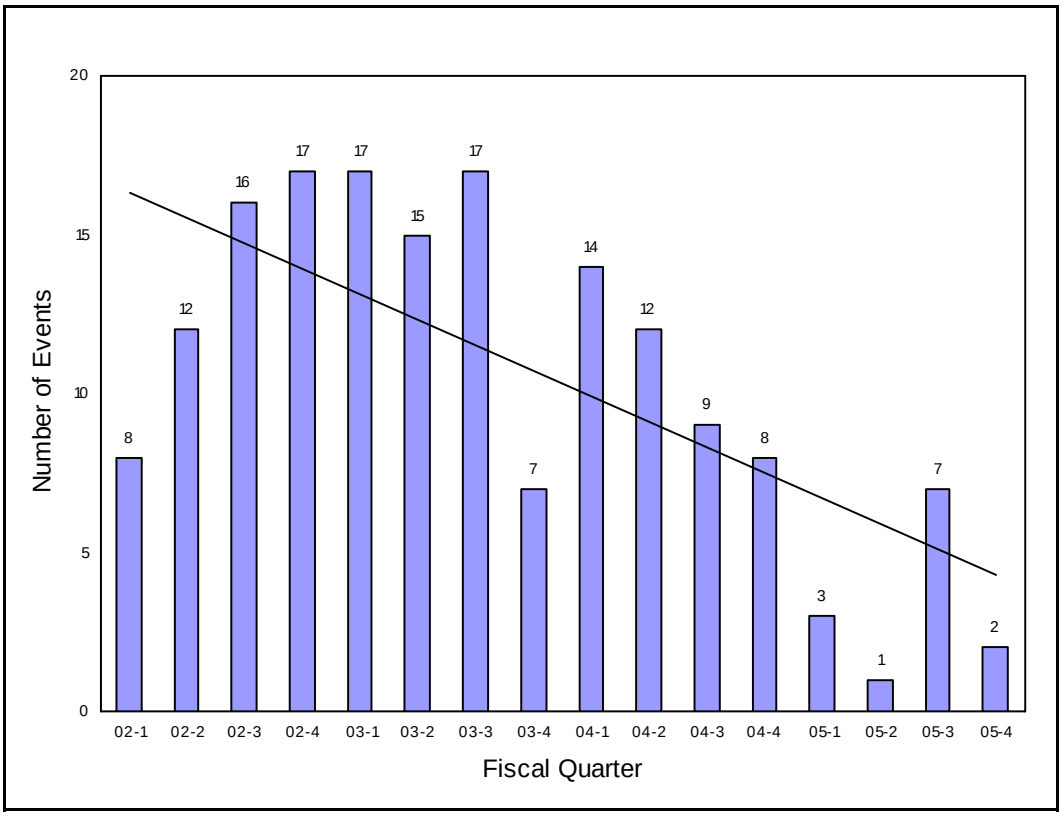


Figure 23. Short-Term Trend of Leaking Sealed Source Events (165 total)

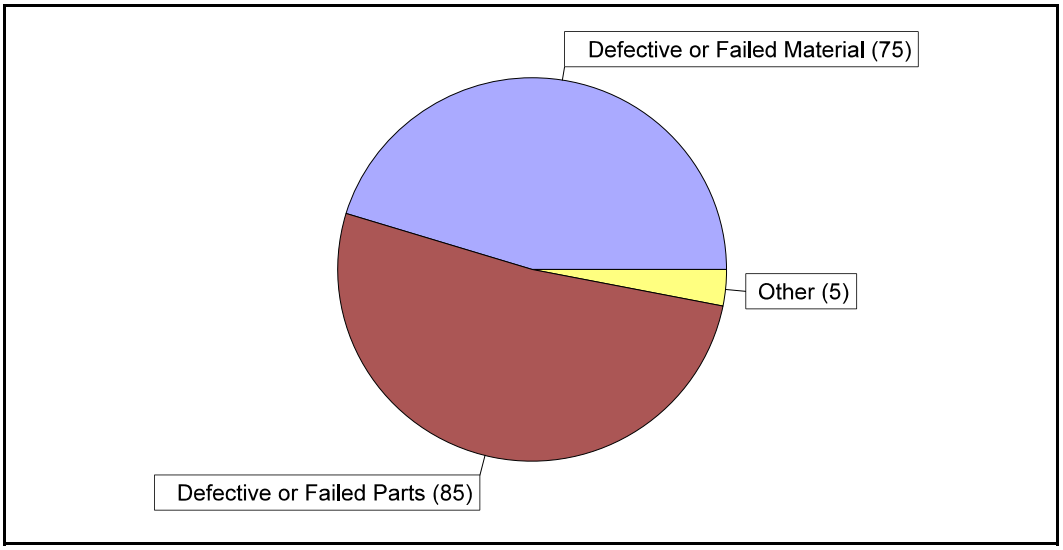


Figure 24. Leaking Sealed Source Event Causes (16 quarters)

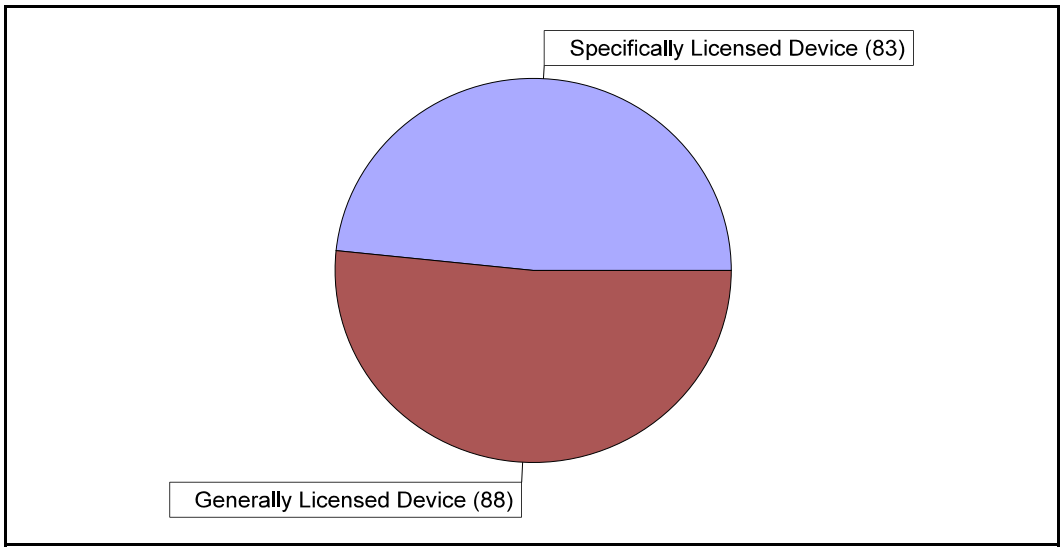


Figure 25. Leaking Sealed Source Device Types (based on reporting requirement - 16 quarters)

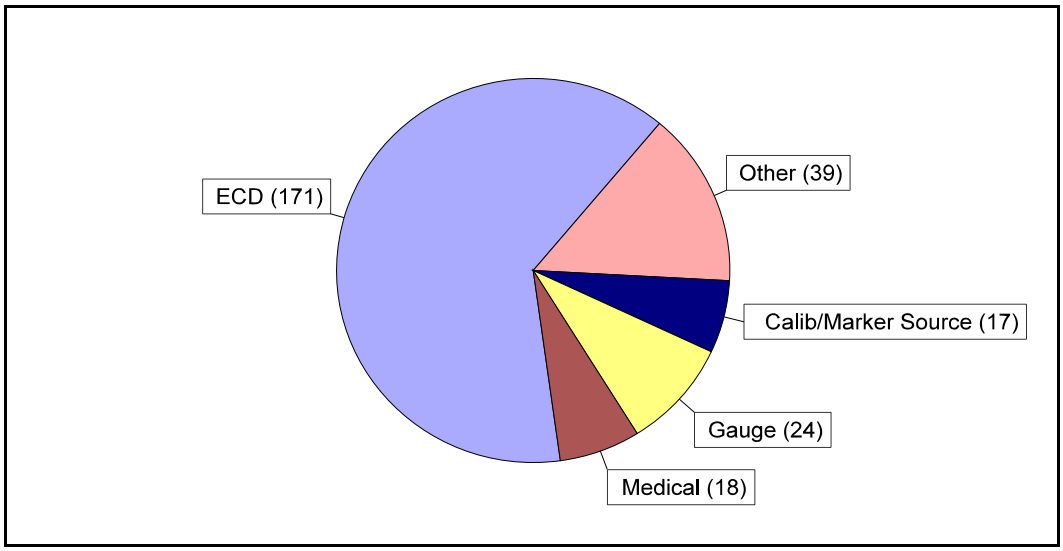


Figure 26. Leaking Sealed Source Types (16 quarters)

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.

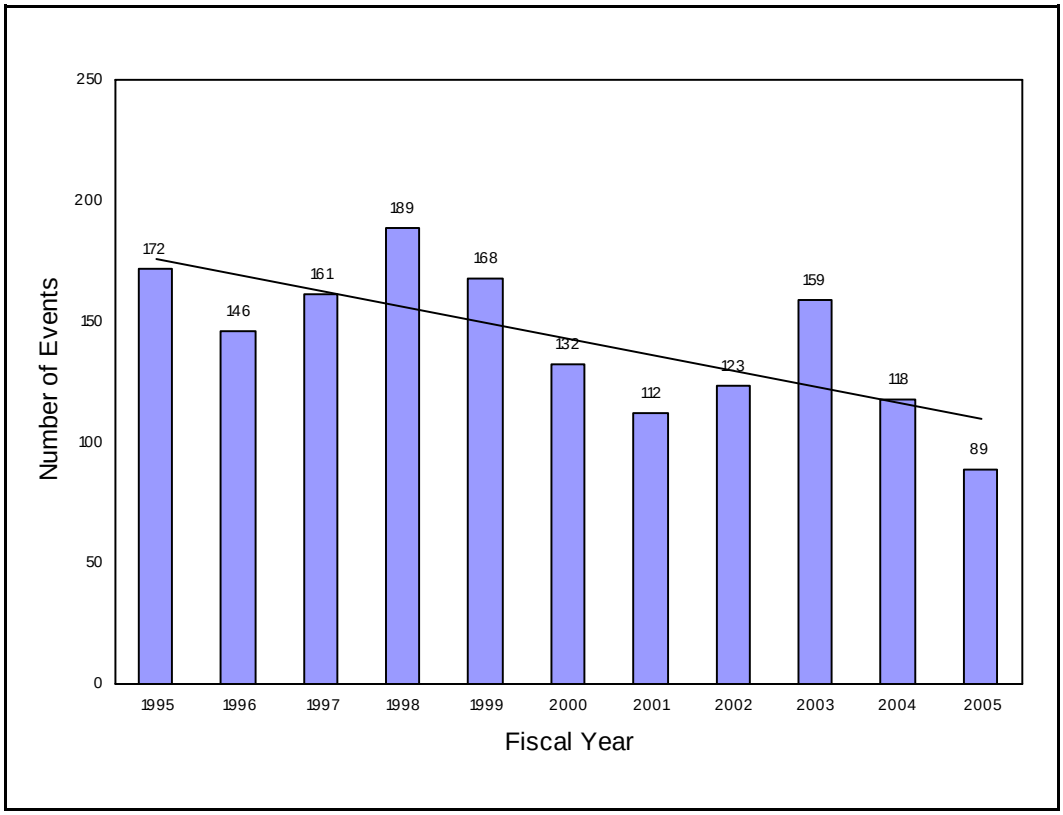


Figure 27. Long-Term Trend of Equipment Events (1569 total)

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).

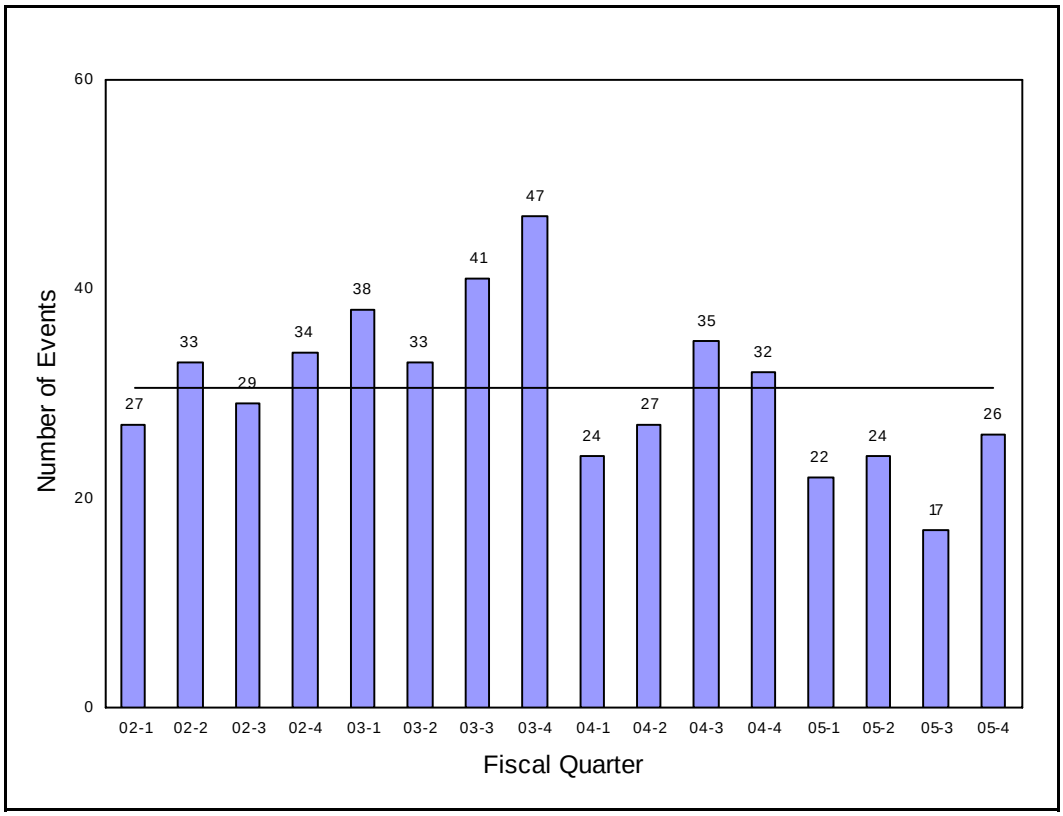


Figure 28. Short-Term Trend of Equipment Events (489 total)

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).

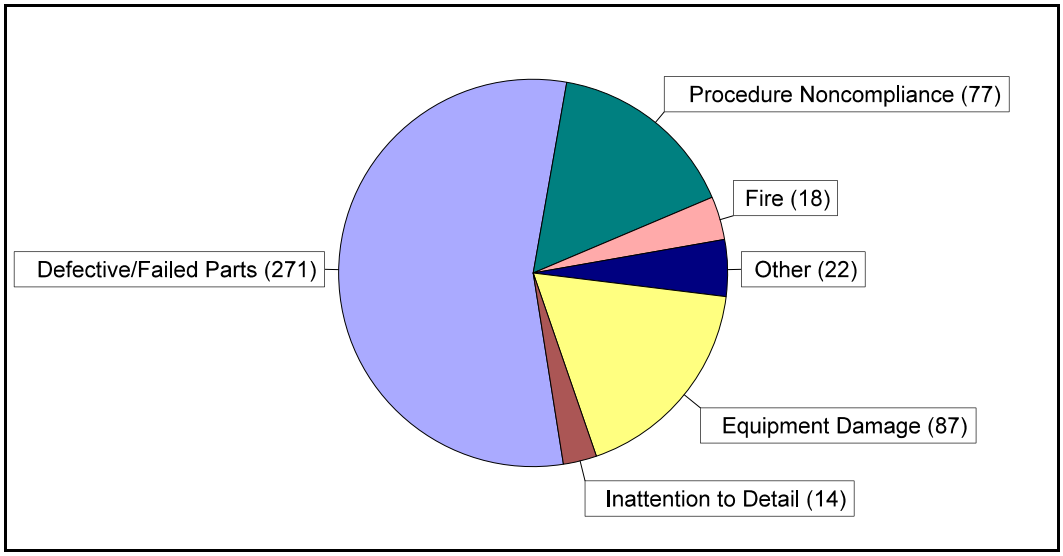


Figure 29. Equipment Event Causes (16 quarters)

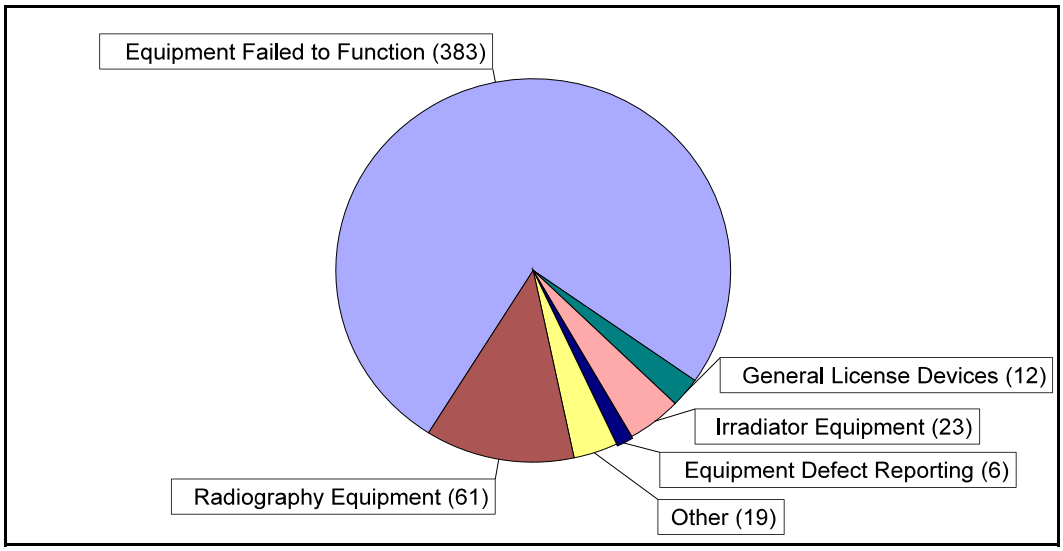


Figure 30. Equipment Event Types (based on reporting requirement - 16 quarters)

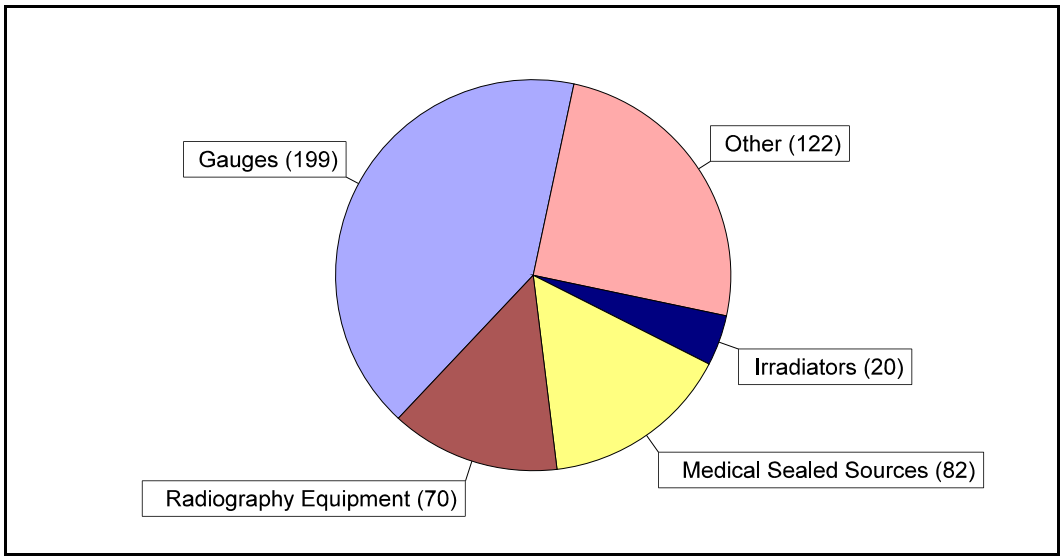


Figure 31. Types of Equipment Involved (16 quarters)

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.

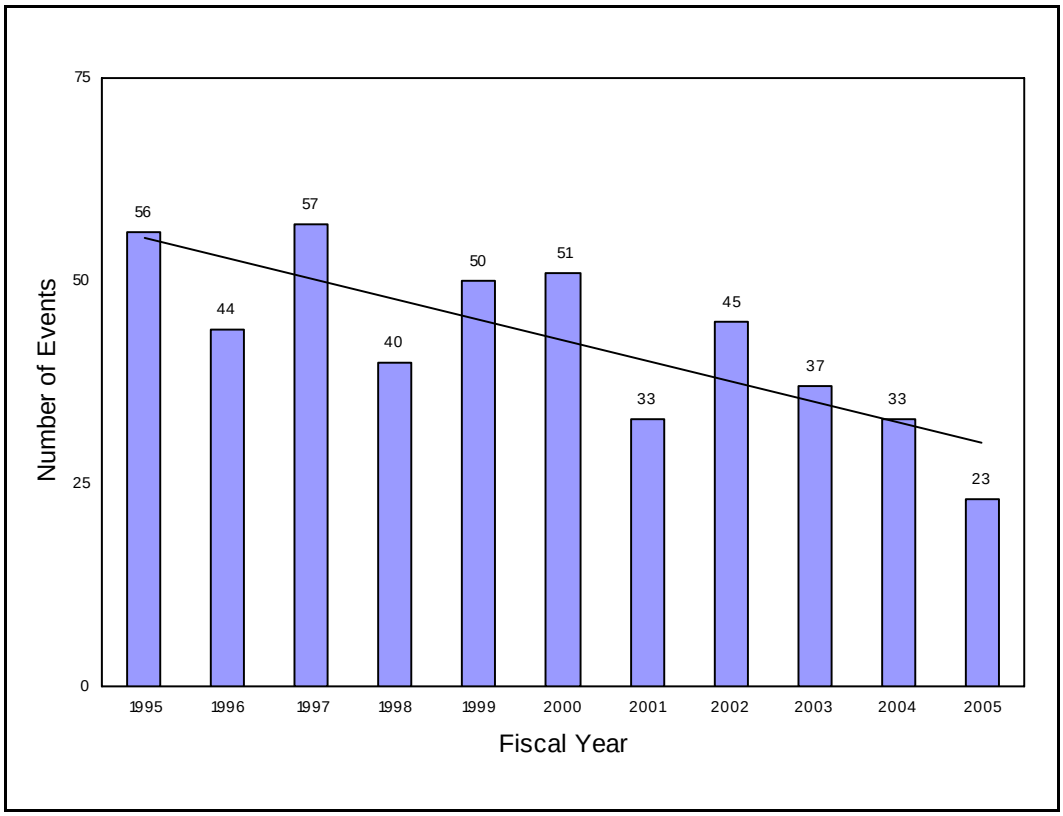


Figure 32. Long-Term Trend of Transportation Events (469 total)

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).

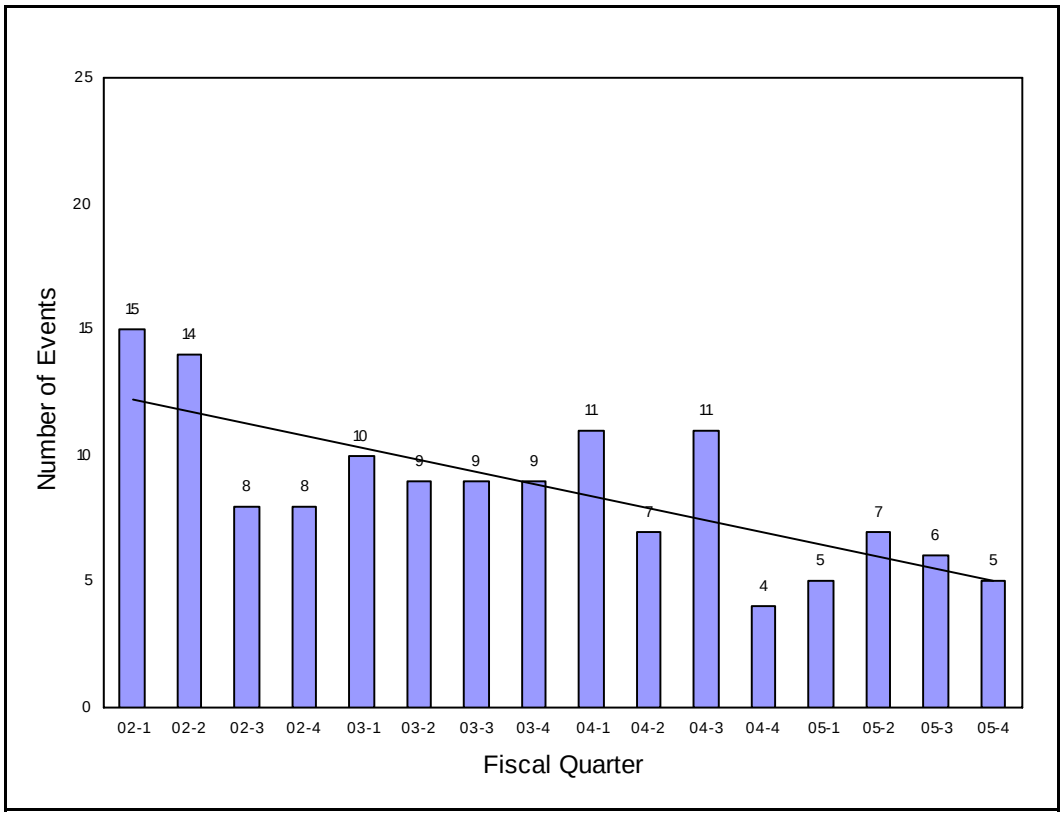


Figure 33. Short-Term Trend of Transportation Events (138 Total)

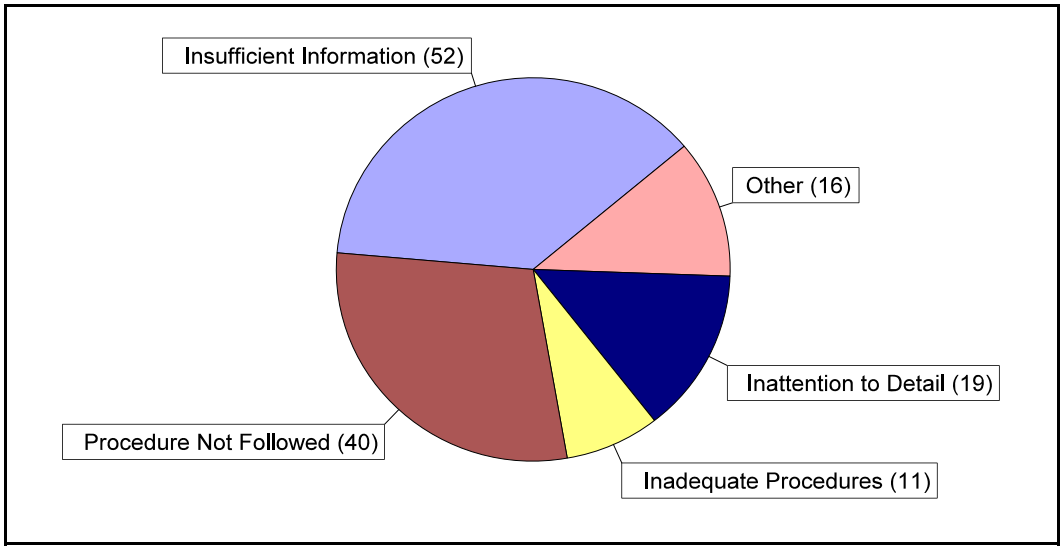


Figure 34. Transportation Event Causes (16 quarters)

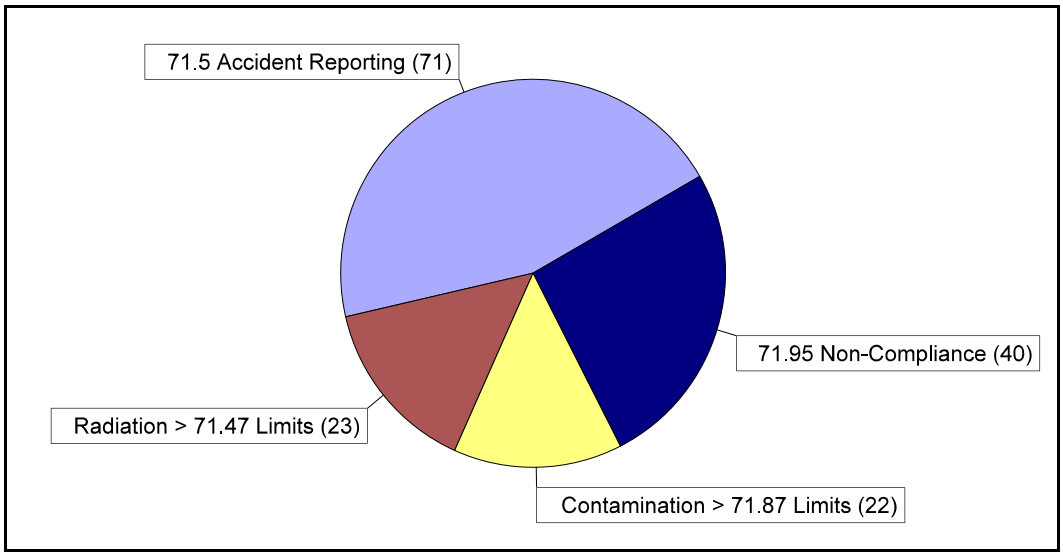


Figure 35. Transportation Problem Types (based on reporting requirements -16 quarters)

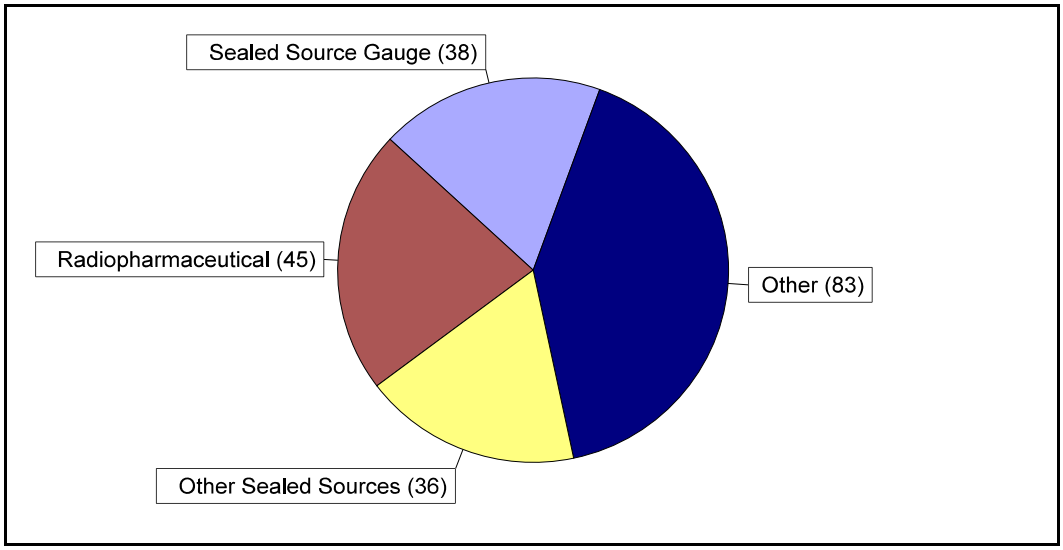


Figure 36. Material Involved in Transportation Events (16 quarters)

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.

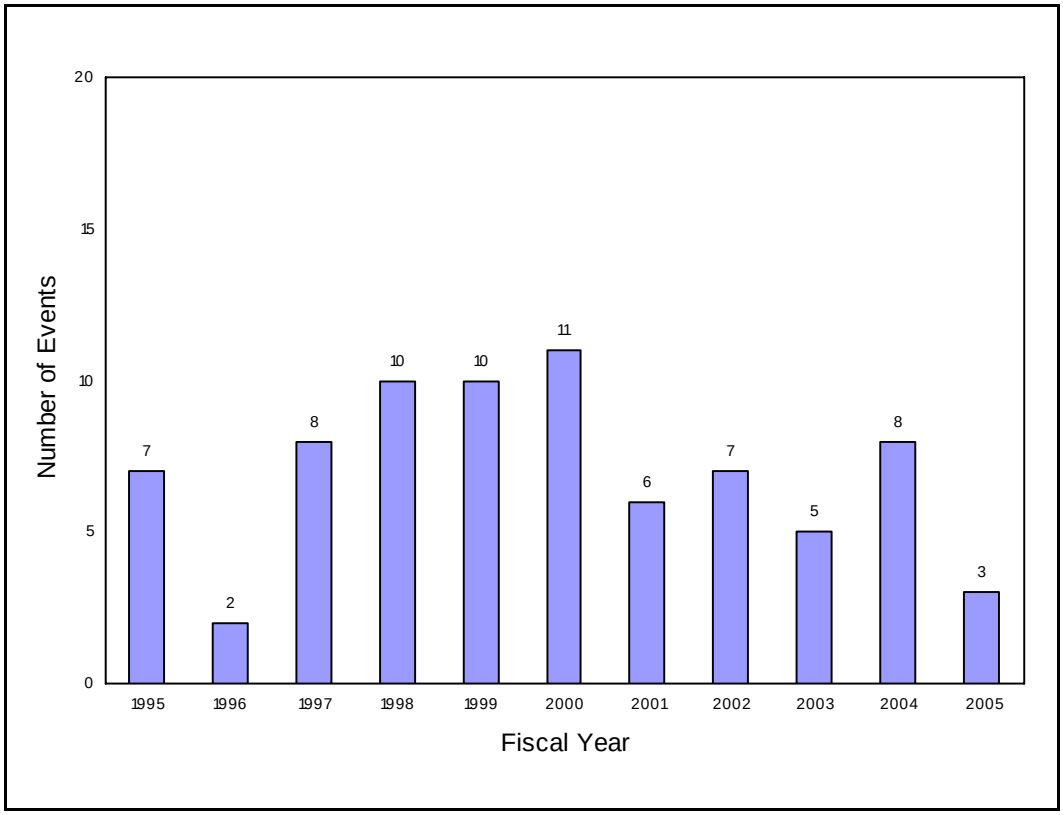


Figure 37. Long-Term Display of Other Events (77 total)

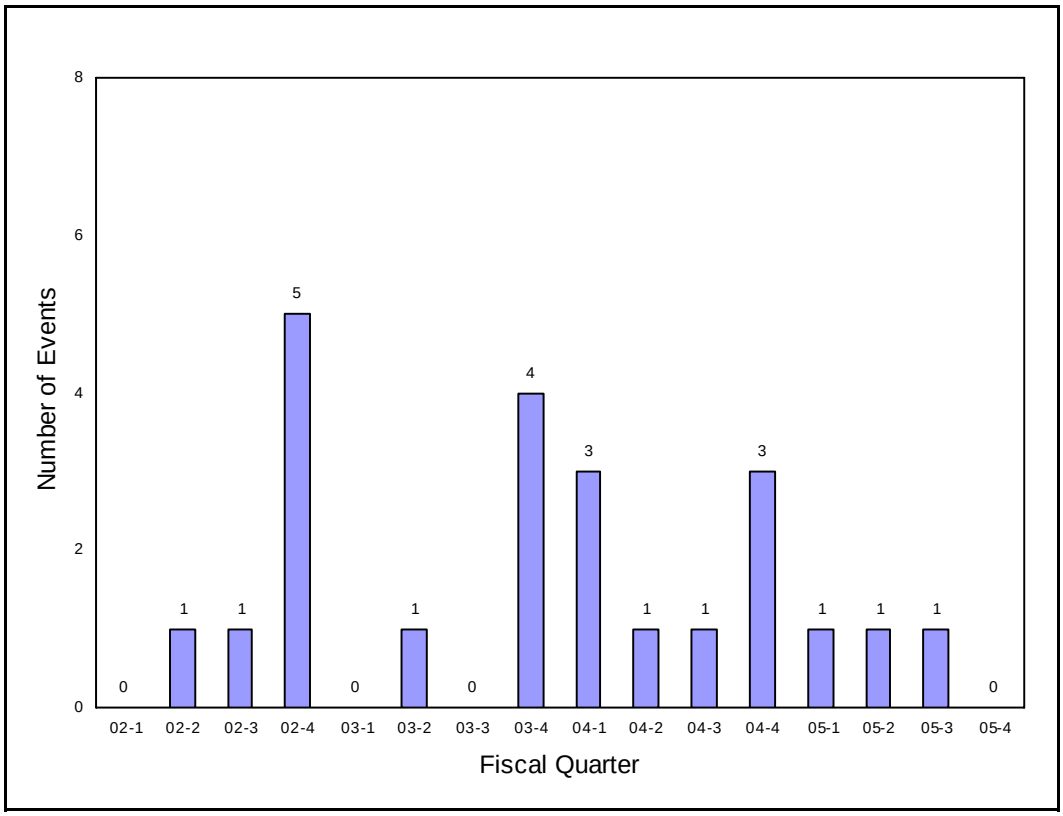


Figure 38. Short-Term Display of Other Events (23 total)

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 β=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.

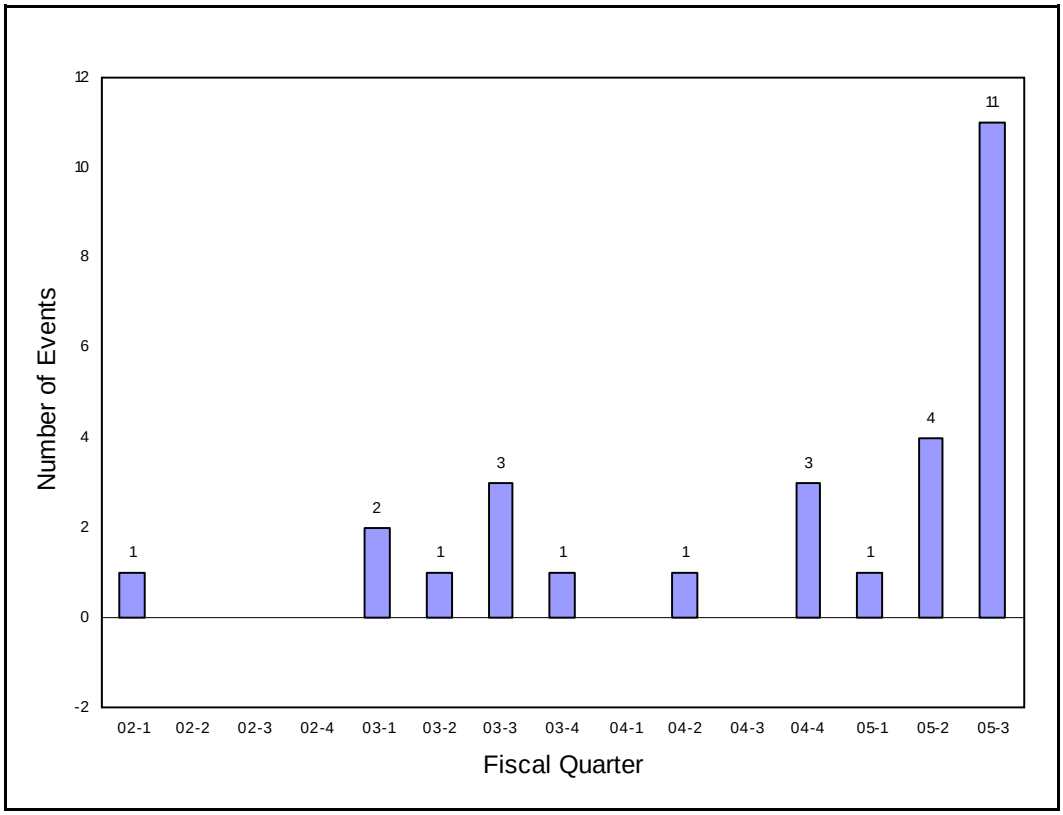

Figure C-1. Net Changes to All NMED Event Data (short-term display)

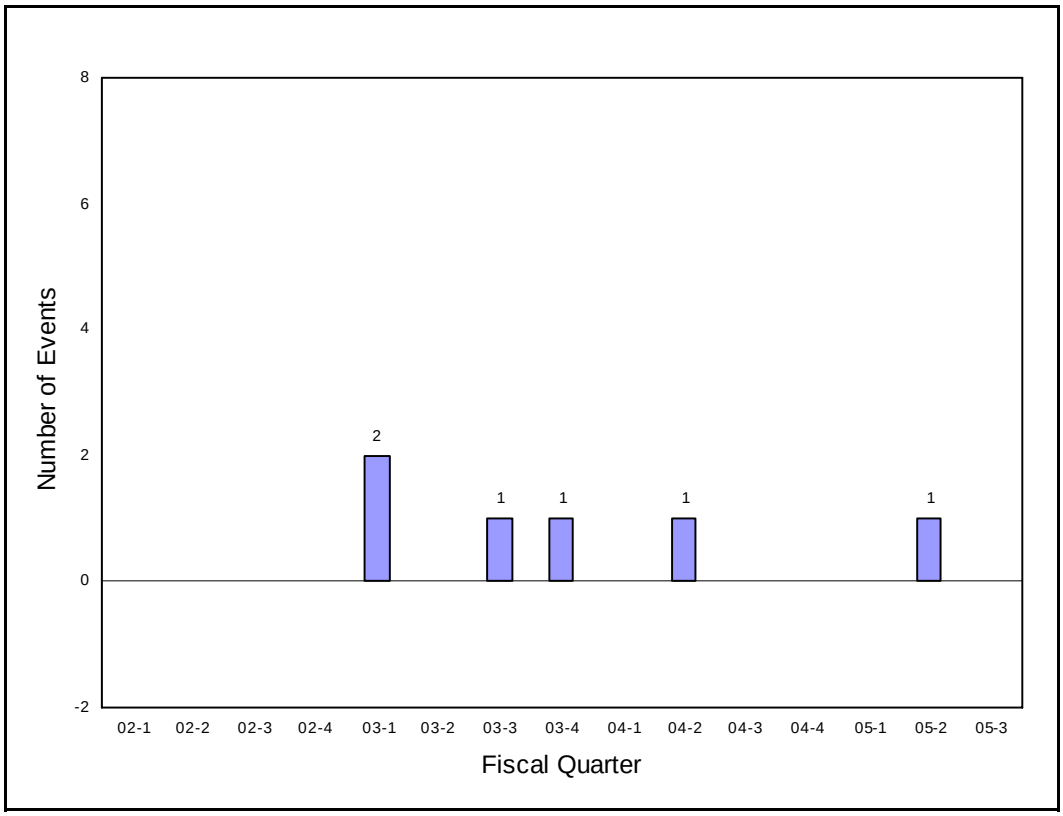

Figure C-2. Net Changes to MED Data (short-term display)

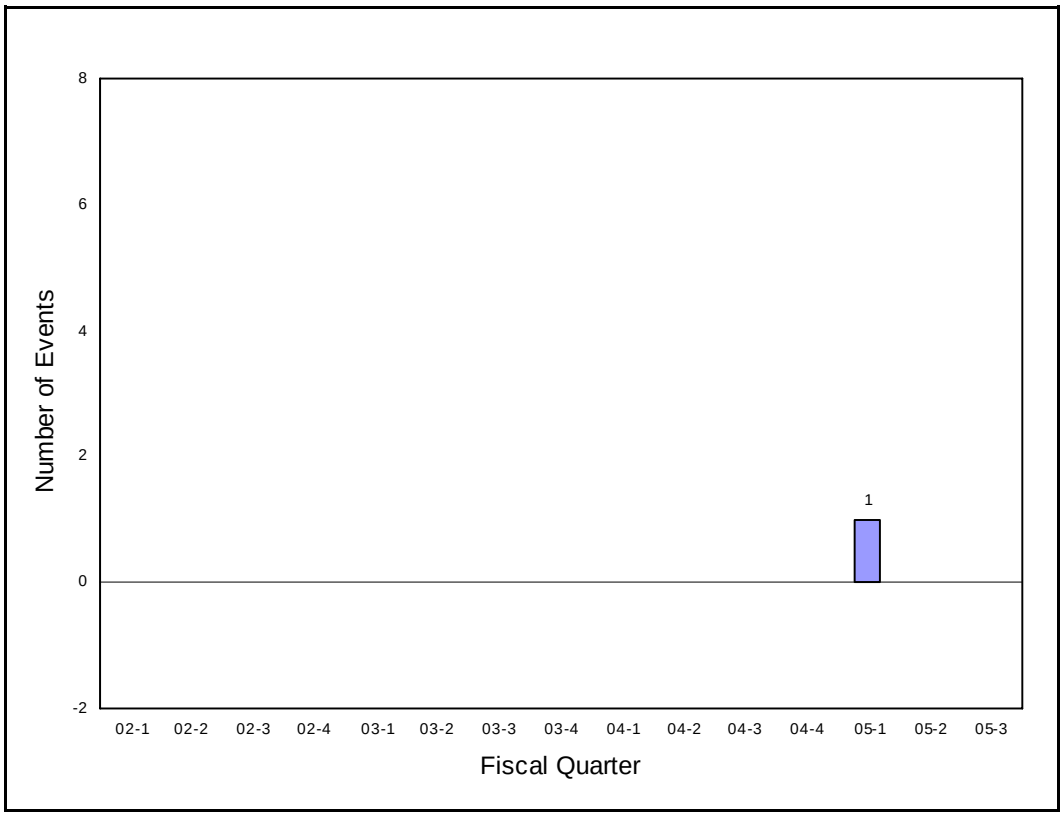

Figure C-3. Net Changes to EXP Event Data (short-term display)

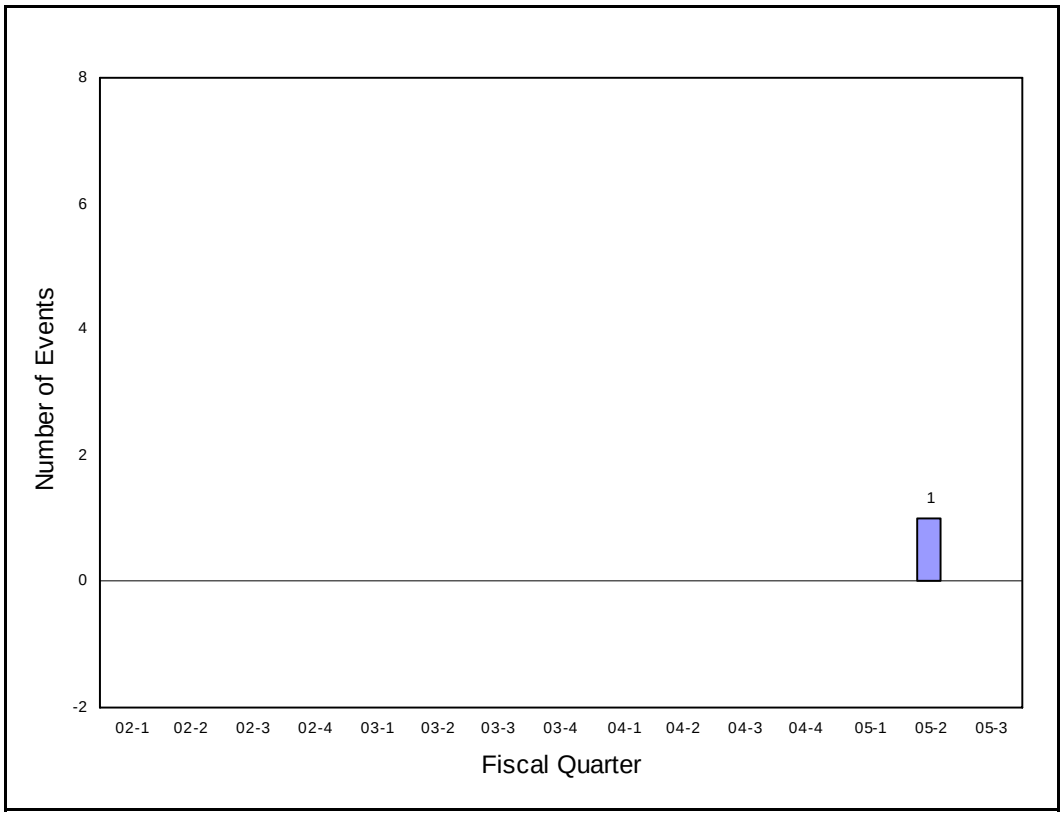

Figure C-4. Net Changes to RLM Event Data (short-term display)

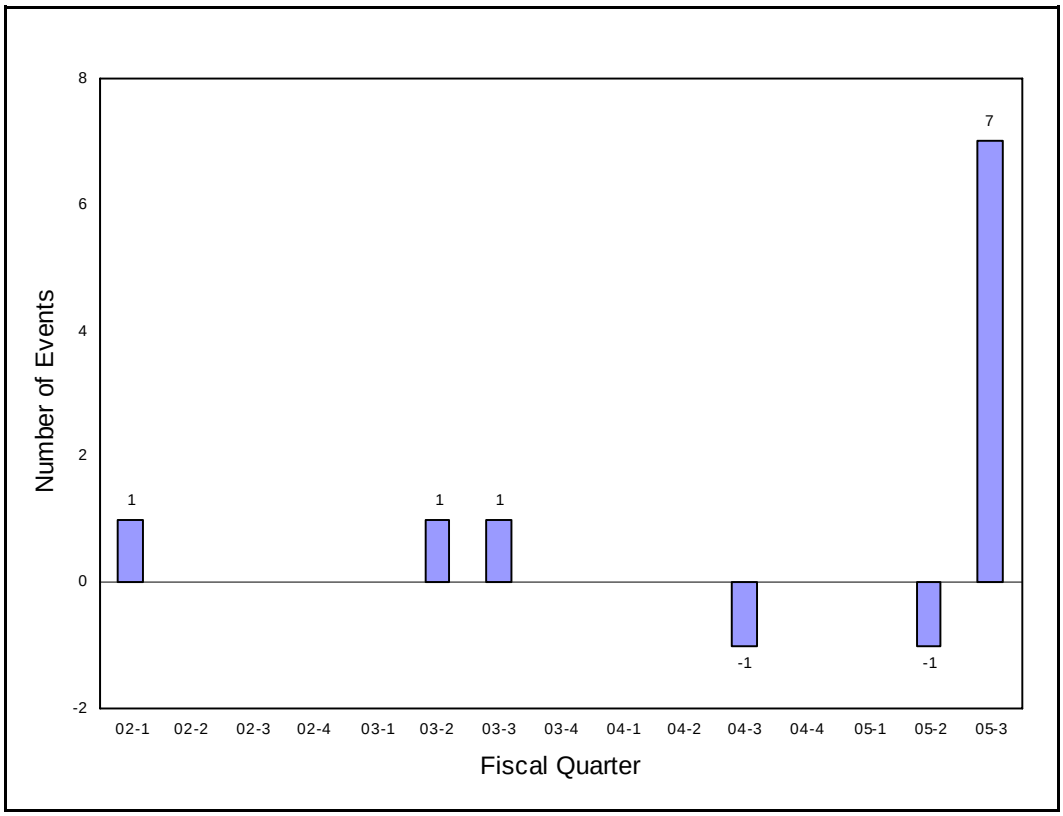

Figure C-5. Net Changes to LAS Event Data (short-term display)

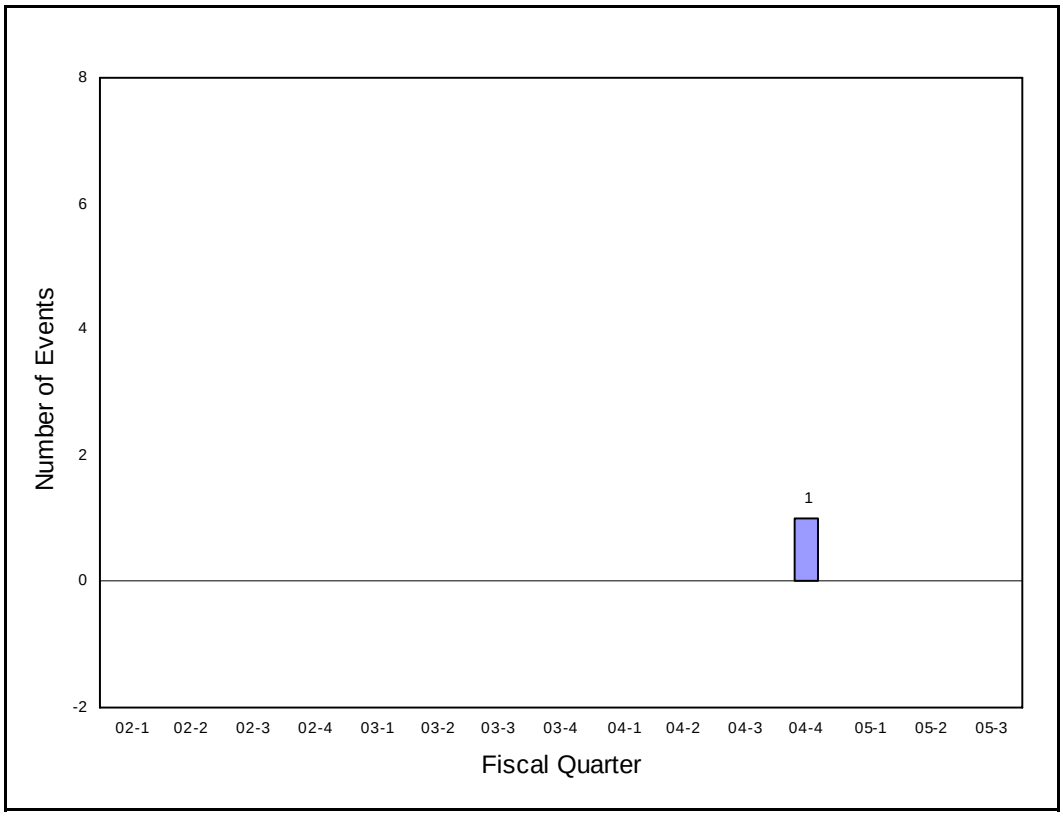

Figure C-6. Net Changes to LKS Event Data (short-term display)

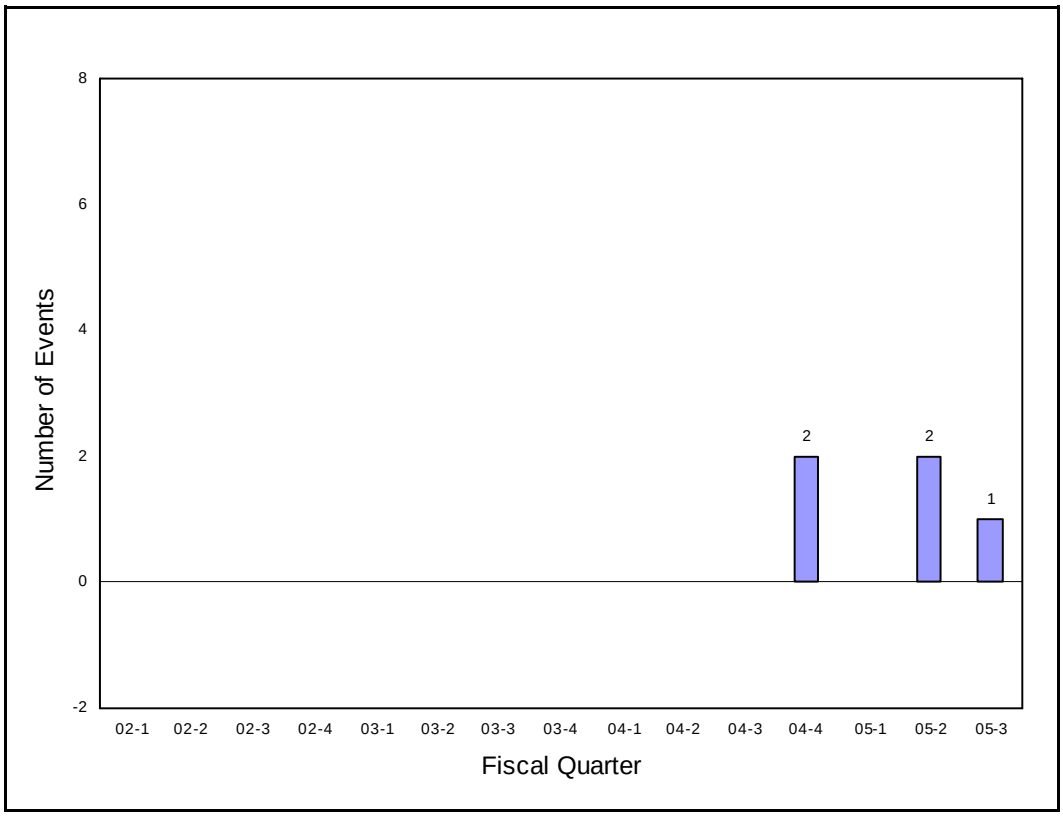

Figure C-7. Net Changes to EQP Event Data (short-term display)

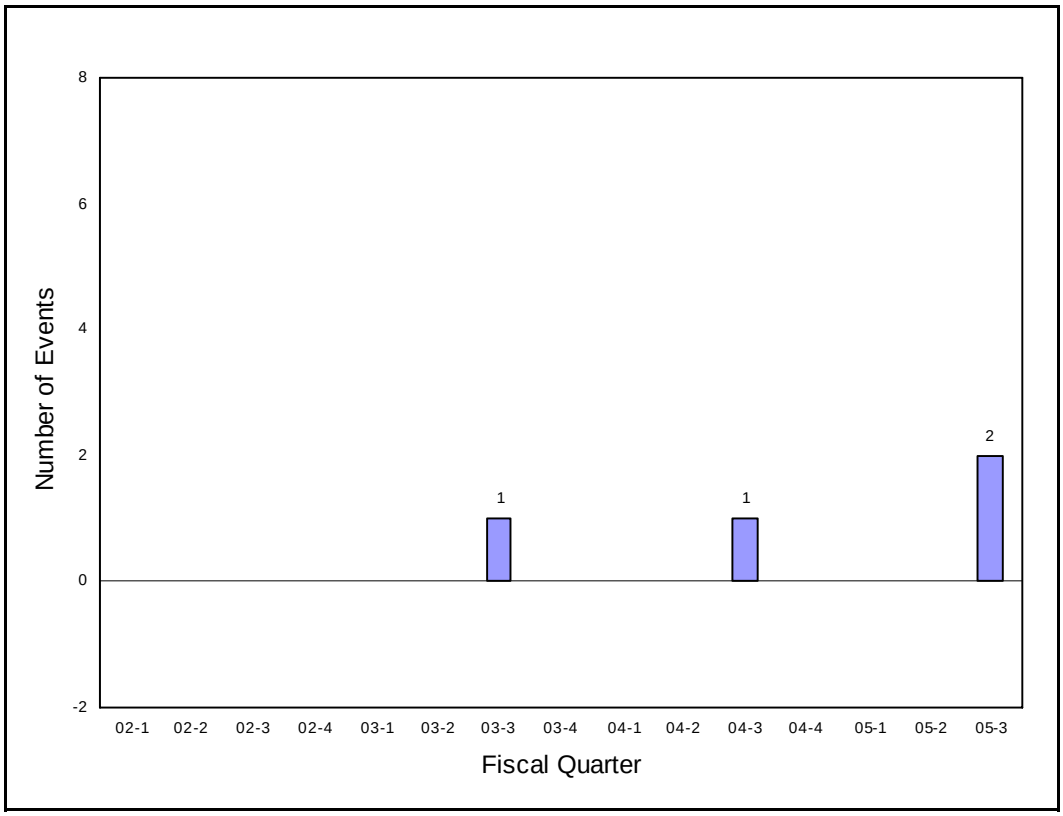

Figure C-8. Net Changes to TRS Event Data (short-term display)

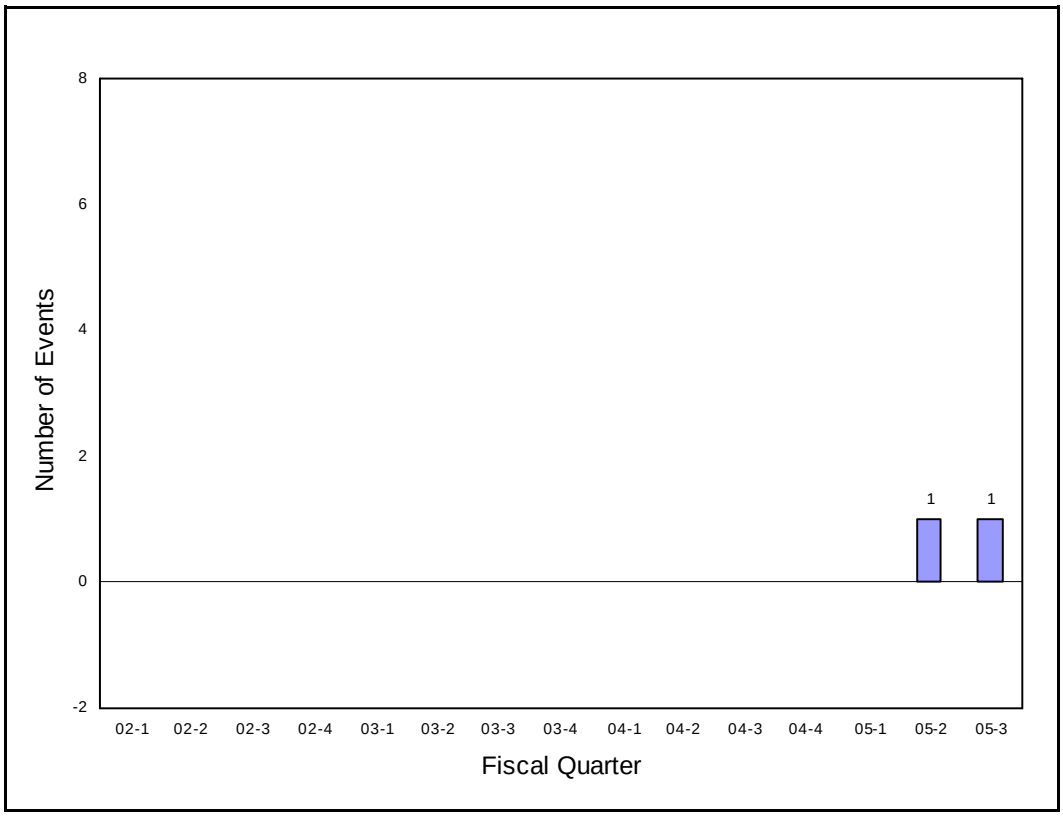

Figure C-9. Net Changes to OTH Event Data (short-term display)