

POLICY ISSUE
(Information)

April 11, 2016

SECY-16-0050

FOR: The Commissioners

FROM: Scott W. Moore, Acting Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE
PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS
FISCAL YEAR 2015

PURPOSE:

This paper provides the 14th annual report on significant nuclear materials issues and licensee performance trends in the Materials and Waste Programs pursuant to Staff Requirements Memorandum (SRM) SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated February 25, 2003 (ML030560328) and following revised criteria identified in SECY-11-0132, "Revision of the Criteria for Identifying Nuclear Material Licensees for Discussion at the Agency Action Review Meeting," dated September 20, 2011 (ML112280111). This report covers fiscal year (FY) 2015. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2015, the staff evaluated significant nuclear materials issues and performance trends based on aggregated information obtained from operating experience associated with reportable events and generic concerns affecting the industry. With the exception of the review of escalated enforcement actions, this evaluation included both the U.S. Nuclear Regulatory Commission (NRC) and Agreement State licensees. The staff concluded, from the assessment

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of the overall performance data, that there are no discernible adverse performance trends or generic concerns and that public health and safety were protected. The staff identified no nuclear materials licensees that met the criteria, as described in SECY-11-0132, for identifying nuclear materials licensees for discussion at the Agency Action Review Meeting (AARM).

BACKGROUND:

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

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

On September 16, 2008, the staff issued SECY-08-0135 "Revision of the Criteria for Identifying Nuclear Materials Licensees for Discussion at the Agency Action Review Meeting," (ML082480564), which provided a revision to the criteria provided in Table 1 of SECY-02-0216 for determining nuclear materials licensees that warrant discussion at the AARM. The criteria were revised to provide additional clarity and incorporate the NRC's current policies and procedures. In response to SRM-M090514, dated June 1, 2009, the staff again revised the criteria for identifying nuclear material licensees for discussion at the AARM to include an additional criterion to address licensees who previously were discussed at the AARM, but whose corrective actions were ineffective in correcting the underlying issues. The information regarding that revision to the criteria for identifying nuclear materials licensees for discussion at the AARM was provided to the Commission in SECY-11-0132, "Revision of the Criteria for Identifying Nuclear Material Licensees for Discussion at the Agency Action Review Meeting," dated September 20, 2011.

DISCUSSION:

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

The aggregated information used to evaluate significant adverse performance issues and performance trends was obtained through existing processes and systems and includes the following information: strategic outcomes and performance measures data; annual assessment

of events reported to the Nuclear Material Events Database (NMED); Abnormal Occurrence (AO) data; generic and/or special event study results; data derived through escalated enforcement actions; and significant licensee performance issues that were identified based on the criteria described in SECY-11-0132. The following sections represent an evaluation of this information followed by overall conclusions of the licensee performance in the Materials and Waste Programs.

Strategic Outcomes and Performance Measures Data

The NRC staff focused on verification and validation of data generated by the NRC and the Agreement States to determine the impact on strategic outcomes and performance measures related to nuclear materials events, as reported in NRC's FY 2015 Performance and Accountability Report (PAR). In the FY 2015 PAR, the agency reported two AOs that met or exceeded the performance indicator for "Number of radiation exposures that meet or exceed AO criteria I.A.1 (unintended radiation exposure to an adult), I.A.2 (unintended radiation exposure to a minor), or I.A.3 (radiation exposure that has resulted in unintended permanent functional damage to an organ or physiological system)." However, there was only one event that met this set AO criteria for FY 2015. The staff inadvertently included an event as a potential AO in an internal performance report. However, after further technical review, the event was determined not to be a potential AO, but the internal tracking was not updated to remove the reference. The agency is taking steps to review its processes to verify the accuracy of the performance indicator results reported in all future documents to prevent recurrence. The event that met AO criteria I.A.2, was due to a false negative pregnancy test that the licensee performed approximately 1.5 hours before the dosage administration and the patient's lack of awareness that she was pregnant. There were zero occurrences in the other safety and security strategic goal performance indicators for the materials program, thus meeting the FY 2015 targets.

Assessment of Data Reported to NMED

The NMED contains records of events involving nuclear materials reported to the NRC by its licensees, Agreement States, and non-licensees. These reported events are sorted by the event reporting requirements as defined in the NRC regulations. The event reports are evaluated to identify safety significant events and their causes. NMED data is analyzed for the main event types, is aggregated for evaluation of potential trends, and is presented in an annual summary report (NMED Annual Report). For the purposes of the NMED Annual Report data, it should be noted that a single occurrence/event report may be captured in multiple NMED event categories (e.g., a report may describe a loss of licensed material that also resulted in a radiation overexposure). A copy of the FY 2015 NMED Annual Report is available in Enclosure 1. Copies of previous NMED Annual Reports may be found at <http://nmed.inl.gov/>.

In order to account for the potential random fluctuations in the event data from year to year and to assess a trend of the data, the data from the last 10 FYs are reviewed. For the 10-year period from FY 2006 through FY 2015, a total of 5,651 events (1,639 NRC and 4,012 Agreement State) associated with materials licensees were reported to NRC, compared to 5,650 events that were reported for the previous 10-year period, from FY 2005 through FY 2014. For the current 10-year period, the review of the data shows that the total number of events per year is relatively stable.

Although the total data indicated no statistically significant performance trends, there were some statistically significant trends related to narrow sections of the data (See Enclosure 1, page 4, Table 1, Summary of Trending Analysis). For example, the number of total NRC events, and NRC events related to equipment failures indicated statistically significant decreasing trends. The summary table also shows one statistically significant increasing trend in Agreement State medical events. However, based on the analysis of the events, enforcement, and performance metrics data for the current 10-year period, a specific reason was not identified for the statistical trends found in the report. It should be noted that as a result of the transfer of authority from the NRC to four Agreement States during this 10-year period, the percentage of NRC events decreases as Agreement State events increases, though the total number of events stays roughly the same. In addition, the NRC has performed outreach efforts with Agreement States to improve understanding of medical event criteria. The increasing trend of Agreement State medical events may also reflect better reporting. Furthermore, the NRC issued NRC Information Notice 2014-06, "Damage of Industrial Radiographic Equipment Due to Falling Equipment and Improper Mounting," in April 2014, which should contribute to a continued decrease in equipment events.

For FY 2015, 34 of the 489 NMED events were considered to be of higher significance and are described in the FY 2015 NMED Annual Report. The breakdown of these significant events by category was as follows:

- 14 lost/abandoned/stolen material events
- 11 medical events classified as AOs or potential AOs
- 3 radiation overexposure events requiring reporting within 24 hours
- 4 equipment related events
- 1 fuel cycle process event requiring immediate reporting
- 1 "other" event classified as a potential AO, involving radiation exposure to the embryo/fetus of a woman undergoing medical treatment

For the 14 significant lost/abandoned/stolen material events, it should be noted that two of the nuclear material sources were classified as Category 1 and eight were Category 2 under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004), all these sources were subsequently recovered. Four events involved Category 3 sources, three of which were subsequently recovered. The fourth event involved a plutonium powered pacemaker that was buried with a deceased patient, and was not recovered. A summary of the significant events that took place in FY 2015 is provided in the Executive Summary of the enclosed NMED Annual Report (Pages xi – xii), and a detailed description of the significant events and events of interest is provided in the main body of the report for the specific event categories.

Overall analysis of the data reported to NMED did not identify any significant issues that warrant specific action or policy changes.

AO Data

The staff determined that seventeen events involving nuclear materials were identified as AOs during FY 2015. Fifteen of the events occurred at facilities licensed by Agreement States, and two at facilities licensed by the NRC. One of the NRC's AOs involved radiation exposure to an embryo/fetus. The remaining NRC AO was a medical event as defined in Title 10 of the *Code of Federal Regulations* Part 35, "Medical Use of Byproduct Material." All 15 medical events involving Agreement States licensees were classified as medical events. The 17 AOs for FY 2015, is a number that is within the statistical variation of previous years' average of 14 ± 6 since FY 2006. The number of identified medical AOs is approximately 0.0003 percent of the number of medical procedures performed annually. The staff does not believe there are presently any trends or significant safety concerns among medical licensees, and continues to monitor licensees' performance and provide prompt follow up response when warranted.

It should also be noted that of the 17 AO events, only 13 of the events occurred in FY 2015. The remaining four AOs occurred and were reported previously, and the NRC's evaluation was completed in FY 2015. As described in the Strategic Outcomes and Performance Measures Data section above, only 1 of these 17 AO events met AO Criteria I.A.2, and was included in the FY 2015 PAR.

The AO numbers in the FY 2015 NMED Annual Report and FY 2015 AO Report differ slightly since the two reports cover different time periods and data sets. The FY 2015 NMED Annual Report covers only those AOs that occurred in FY 2015 (this includes events that occurred in FY 2015 where a final AO determination has been made, as well as events that occurred in FY 2015 where a final AO determination has not yet been made). The FY 2015 AO Report covers all AOs that were determined to be AOs in FY 2015 (this includes events that occurred in FY 2015 where a final AO determination has been made, and events that were reported prior to FY 2015 but a final AO determination was not made until FY 2015). This data is summarized in Table 1 below.

<i>Table 1. Number of AO's and Potential Abnormal Occurrences (PAO) reported in the FY15 AO Report and FY15 NMED Report</i>				
	Number of AO/PAO's occurring in FY15	Number of AO/PAO's occurring prior to FY15, but determination made in FY15	Number of AO's occurring in FY16, but included in FY15 AO Report	Total Number of AO's reported
FY15 AO Report	13	3	1	17
FY15 NMED Annual Report	13	1	0	14

In addition to the 14 AOs described in the FY15 NMED Annual Report, there was one AO previously captured in the FY13 NMED Annual Report, and one AO previously captured in the FY14 NMED Annual Report as PAO for which additional information was required. The missing information has been provided in FY15, and a final AO determination has been made for these two events in the FY15 AO Report. Furthermore, one other AO event occurred on October 1, 2015, and was included in the FY15 AO Report since a final AO determination has been made.

This event does not appear in the FY15 NMED Annual Report, due to the event date, however it will be included in the FY16 NMED Annual Report.

Overall analysis of the AO events did not identify any significant performance trends or generic concerns.

Special Event Study Results

In February 2016, the staff performed a special study to evaluate events involving Lost, Abandoned, or Stolen (LAS) Category 1 and 2 sources for a 10-year time period from FY 2006 through FY 2015. The study sought to expand on the event tracking and evaluation performed on a continuous basis by the staff by assessing causes for the events to determine whether any common failure causes exist. The study, which includes descriptions of each of the 2 Category 1 and 32 Category 2 source events (excluding irretrievable well logging sources) over the 10-year period, is provided in Enclosure 2.

Both of the Category 1 events involved shipping errors by a common carrier. Of the Category 2 events, 11 were a result of shipping errors, 12 were a result of falling off of work trucks or being left at work sites, and 6 were a result of theft. Three additional events were a result of other causes including tornado, building eviction, and truck being swept away by moving water. All of the sources involved in these events were subsequently recovered, aside from a single Category 2 event in July 2011, where a radiography device was stolen from the darkroom of a truck parked at a hotel. An extensive search was performed, including a fly-over survey conducted by the Department of Energy using a fixed wing plane, but the device was not located.

The 34 total Category 1 and 2 events were found to be fairly spread out in date and cause of occurrence, and did not reveal significant repetitive or safety issues that warrant specific agency action. The study also did not identify any gap or inadequacy in agency policy. The NRC has in place procedures to monitor the occurrence of LAS events and to promptly respond to emerging events that have the potential to endanger public health and safety.

Data Derived Through Escalated Enforcement Actions

Escalated enforcement actions in the Materials and Waste Programs include civil penalties and Notices of Violation (NOV) for Severity Level I, II, and III violations, as well as Orders and Demands for Information. The Enforcement Program Annual Report is issued on a calendar year (CY) basis and CY escalated enforcement data was included in past years in the Annual Report to the Commission on Licensee Performance in the Materials and Waste Programs. For 2015, the Office of Enforcement provided fiscal year data in order to present a consistent reporting interval for all reports of performance in the Materials and Waste Programs. In FY 2015, the NRC issued 39 escalated enforcement actions involving NRC materials licensees (including fuel cycle facilities). The escalated enforcement actions issued in FY 2015 include: 1 Severity Level II and 8 Severity Level III NOVs with proposed civil penalties; 26 Severity Level III NOVs with no civil penalty, and 4 Orders. Two of the 4 Orders involved the imposition of civil penalties, and 2 Confirmatory Orders were issued to confirm commitments associated with Alternative Dispute Resolution agreements. Eleven of the 39 escalated enforcement actions involved issuance of proposed civil penalties totaling \$129,500, and imposed civil penalties totaling \$10,500.

For FY 2015, the number of escalated enforcement actions for the Materials and Waste Programs decreased by seven (15 percent) from the number of actions issued in FY 2014. The number of escalated enforcement actions issued to materials licensees and fuel cycle facilities in the last 5 years shows a decreasing trend from 76 actions in FY 2011 to 39 actions in FY 2015. This trend is mainly due to a decrease in the number of escalated enforcement actions issued to gauge users, radiographers and hospitals over the past 5 years. The staff's analysis of the materials enforcement trend is not conclusive, however, a key causal factor has been identified that accounts for a substantial portion of the overall trend: During the past 5 years, the number of cases involving security-related increased controls violations has significantly decreased. This is an indication of improved compliance with materials security requirements that have been implemented.

Licensees Identified with Significant Performance Issues

SECY-11-0132 defines the criteria used to identify licensees with significant performance issues and licensees that warrant the highest level of NRC management attention. The criteria target the most critical issues involving very serious events (those triggering NRC's strategic level measures), significant licensee issues, or licensee performance trends. For FY 2015, no nuclear materials licensees were identified that met the criteria in SECY-11-0132 for discussion at the AARM.

OVERALL PERFORMANCE CONCLUSIONS:

Based on the review of event data and assessment of key events, the staff concludes that the Materials and Waste Programs are functioning effectively to protect public health and safety. Based on staff review and subsequent revisions in 2008 and 2011 to the criteria for identifying nuclear materials licensees that warrant discussion at the AARM, staff has concluded that the current criteria are effective and valid, and appear to be working efficiently. For FY 2015, all lost or stolen nuclear materials sources classified as Category 1 through 3 in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (2004) were recovered, except for a single Category 3 event involving a pacemaker that was buried with a deceased patient, and was not recovered. The staff identified no nuclear materials licensees that met the criteria, as described in SECY-11-0132, for identifying nuclear materials licensees for discussion at the AARM.

COORDINATION:

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

/RA Joel Munday for/

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Enclosures:

1. Nuclear Material Events Database
Annual Report FY 2015
2. LAS Material Event Study
(FY2006-2015)

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