POLICY ISSUE
Information

April 8, 2015 SECY-15-0058

FOR: The Commissioners

FROM: Catherine Haney, 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 2014

PURPOSE:

This paper provides the thirteenth 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) 2014. This paper does not address any new comments or resource implications.

SUMMARY:

For FY 2014, 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

CONTACT: Robert Sun, NMSS/MSTR
(301) 415-3421

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 AARM.

BACKGROUND:

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

In response 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

NRC staff focused on verification and validation of data generated by NRC and the Agreement States to determine the impact on strategic outcomes and performance measures related to nuclear materials events, as reported in NRC's "Fiscal Year 2014 Performance and Accountability Report." There was one occurrence related to nuclear materials listed that was reported as meeting Safety Goal 5, "Number of events with radiation exposures to the public or occupational workers that exceed Abnormal Occurrence Criterion I.A.3." This occurrence has since been found to have been listed in error. The FY 2015 Performance and Accountability Report will include an update and explanation of the initial result reported. The Safety Goal 5 target of less than or equal to 2 is still met despite the error. There were zero occurrences in the other safety and security performance measures, thus meeting the FY 2014 targets.

Assessment of Data Reported to NMED

The NMED contains records of events involving nuclear materials reported to NRC by its licensees, Agreement States, and non-licensees. These reported events are sorted by the event reporting requirements as defined in 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 2014 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 2005 through FY 2014, a total of 5,650 events (1,720 NRC and 3,930 Agreement State) associated with materials licensees were reported to NRC, compared to 5,634 events that were reported for the previous 10-year period, from FY 2004 through FY 2013. 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 total number of the NRC events, NRC lost/abandoned/stolen materials events, NRC medical events, and NRC leaking sealed source events 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 event, 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.

For FY 2014, 31 of the 524 NMED events were considered to be of higher significance and are described in the FY 2014 NMED Annual Report. The breakdown of these significant events by category was as follows:

- 8 lost/abandoned/stolen material events involving a total of 8 sources
- 11 medical events classified as AOs or potential AOs
- 4 radiation overexposure events requiring reporting within 24 hours
- 1 contamination event requiring immediate reporting;
- 2 equipment related events which are both also classified as radiation overexposure events
- 4 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 eight significant lost/abandoned/stolen material events, it should be noted that none of the nuclear material sources were classified as Category 1 under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004). Five Category 2 sources and three Category 3 sources were lost, all of which were subsequently recovered. A summary of the significant events that took place in FY 2014 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 thirteen events involving nuclear materials were identified as AOs during FY 2014. Twelve of the events occurred at facilities licensed by Agreement States, and one at a facility licensed by the NRC. One of the Agreement State AOs involved radiation exposure to an embryo/fetus. The remaining twelve AOs were medical events as defined in 10 CFR Part 35, “Medical Use of Byproduct Material.” The staff does not believe that these represent a generic concern.

It should also be noted that of the thirteen AO events, only eleven of the events occurred in FY 2014. The remaining two AOs occurred and were reported previously, and the NRC’s evaluation was completed in FY 2014.

The AO numbers in the FY 2014 NMED Annual Report and FY 2014 AO Report differ slightly since the two reports cover different data sets. The FY 2014 NMED Annual Report covers only those AOs that occurred in FY 2014 (this includes events that occurred in FY 2014 where a final

AO determination has been made, as well as events that occurred in FY 2014 where a final AO determination has not yet been made). The FY 2014 AO Report covers all AOs that were determined to be AOs in FY 2014 (this includes events that occurred in FY 2014 where a final AO determination has been made, and events that were reported prior to FY 2014 but a final AO determination was not made until FY 2014). This data is summarized in Table 1 below.

Table 1. Number of AO's and PAO's reported in the FY14 AO Report and FY14 NMED Report

	Number of AO's occurring in FY14	Number of Potential AO's (PAO) occurring in FY14	Number of AO's occurring prior to FY14, but determination made in FY14	**Total Number of AO's/PAO's reported**
FY14 AO Report	11	0	2	**13**
FY14 NMED Report	11	1	0	**12**

The staff's analysis and evaluation found that human error was a main contributor to the root causes of many of these AO events. Reported causes for the thirteen events include inadequate communication, inadequate procedures, inability of the pregnancy test to provide a positive determination so close to conception, failure to confirm or reconfirm the correct treatment site or parameters, failure to accurately identify the treatment site, possible malfunction of a treatment applicator or planning system, and complications or changes in patient anatomy.

In addition to the thirteen AOs that were identified in the FY 2014 AO report, the staff has identified one additional AS event that occurred in FY 2014 (captured in the FY 2014 NMED Annual Report) and one additional Agreement State event that occurred in FY 2013 (captured in the FY 2013 NMED Annual Report), that are potential AOs for which additional information is required. The staff is working with the Agreement State licensees to obtain the necessary information and these events will be included in a future report.

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

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 2014, the Office of Enforcement provided data in order to present a consistent reporting interval for all reports of performance in the Materials and Waste Programs. In FY 2014, NRC issued 46 escalated enforcement actions involving NRC materials licensees (including fuel cycle facilities). The escalated enforcement actions issued in FY 2014 include: 1 Severity Level II and 8 Severity Level III NOVs with proposed civil penalties; 1 Severity Level II and 29 Severity Level III NOVs with no civil penalty, and 7 Orders. Two of the 7 Orders involved the imposition of civil penalties, and 1 Confirmatory Order was issued to confirm commitments associated with

an Alternative Dispute Resolution (ADR) agreement. Eleven of the 46 escalated enforcement actions involved issuance of civil penalties totaling $75,600.

For FY 2014, the number of escalated enforcement actions for the Materials and Waste Programs increased by three (7 percent) from the number of actions issued in FY 2013. The number of escalated enforcement actions issued to materials licensees and fuel cycle facilities in the last 5 years shows a decreasing trend from 82 actions in FY 2010 to 46 actions in FY 2014. This trend is mainly due to a decrease in the number of escalated enforcement actions issued to hospitals and fuel cycle facilities over the past 5 years. The staff notes that during the first 4 years of this period there was also a significant decrease in the number of actions issued to gauge users; however in FY 2014, the number of escalated actions issued to gauge users returned to more typical numbers when compared to FY 2013. The staff's analysis of the materials enforcement trend is not conclusive, however, several causal factors have been identified that account for a substantial portion of the overall decrease. The number of cases involving security-related increased controls violations has decreased over this time period. Fuel cycle facilities have implemented improvements in the areas of problem identification and correction and safety culture. In addition, the severity level examples for violations at fuel facilities were changed in the Enforcement Policy to be more risk-informed, reducing the number of escalated enforcement actions issued.

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 2014, 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. 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. 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/

Catherine Haney, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Nuclear Material Events Database
Annual Report FY 2014