POLICY ISSUE
INFORMATION

April 2, 2014 SECY-14-0035

FOR: The Commissioners

FROM: Brian E. Holian, Acting Director
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS FISCAL YEAR 2013

PURPOSE:

This paper provides the twelfth 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). This report covers fiscal year (FY) 2013. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2013, 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 of the overall performance data, that there are no discernible adverse performance trends or generic concerns and that public health and safety were protected.

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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 2011, the criteria for identifying nuclear material licensees for discussion at the AARM was revised again to include an additional criterion to address licensees who previously were discussed at the AARM but their 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 event, as reported in NRC's "Fiscal Year 2013 Performance and Accountability Report." The metric for the strategic outcomes is zero occurrences, and there were no occurrences related to nuclear materials that met any of the safety or security strategic outcomes for FY 2013. Also, the safety and security performance measure targets were met in FY 2013.

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 any 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 2013 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 an average trend of the data, the data from the last 10 FYs are reviewed. For the 10-year period from FY 2004 through FY 2013, a total of 5,634 events (1,807 NRC and 3,827 Agreement State) associated with materials licensees were reported to NRC, compared to 5,802 events that were reported for the previous 10-year period, from FY 2003 through FY 2012. For the current 10-year period, the review of the data shows that the total number of events per year is relatively stable and very small in comparison with the large number of radioactive materials use activities per year.

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, and NRC medical 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 the transfer of licensees from the NRC to Agreement State authority during this 10-year period could result in increasing numbers of Agreement State events and decreasing numbers of NRC events. 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 2013, 15 of the 415 NMED events were considered to be of higher significance and are described in the FY 2013 NMED Annual Report. The breakdown of these significant events by category was as follows:

- four lost/abandoned/stolen material events involving a total of 12 sources;
- six medical events classified as AOs or potential AOs;
- one radiation overexposure event requiring reporting within 24 hours;
- one contamination event requiring immediate reporting;
- one fuel cycle process event requiring immediate reporting; and
- two "other" events classified as AOs, both involving radiation exposure to the embryo/fetus of a woman undergoing medical treatment.

For the four 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). Ten Category 2 sources and two Category 3 sources were lost, all of which were subsequently recovered. A summary of the significant events that took place in FY 2013 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 ten events in FY 2013 involving nuclear materials were identified as AOs. All ten events occurred at facilities licensed by Agreement States. Two of the AOs involved radiation exposure to an embryo/fetus. The remaining eight AOs were medical events as defined in 10 CFR Part 35, "Medical Use of Byproduct Material." Given that the number of medical-related AOs is small in comparison with the significantly large number of medical procedures performed annually, the staff does not believe that these events represent a generic concern.

The staff's analysis and evaluation found that human error was a main contributor to the root causes of these AO events. Reported causes for the ten events include inadequate communication, inability of the pregnancy test to provide a positive determination so close to conception, failure to confirm the correct treatment site or parameters, possible malfunction of a treatment applicator or planning system, and probable development of collateral vessels around the tumor between initial treatment planning and treatment delivery.

Four of the eight medical event AOs involved high dose rate remote afterloader (HDR) treatments. In response to recent HDR medical events, the NRC issued Information Notice 2013-16, Importance of Verification of Treatment Parameters for High Dose Rate Remote Afterloader Administrations (ML13058A306).

In addition to the ten AOs that were identified in the FY 2013 AO report, the staff has identified an additional three events (one NRC and two Agreement State) that took place in FY 2008 through FY 2013 that are potential AOs for which additional information is required. The staff is working with the NRC and 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.

Special Event Study Results

In December 2013, the staff performed a special study to evaluate events involving radiography for a 10-year time period from FY 2004 through FY 2013. The study involved all types of radiography events including equipment issues; radiation overexposures; lost, abandoned, or stolen material; leaking sealed sources; release of licensed material or contamination; and transportation events. A graph and trend analysis of the number of events for each year is provided in Enclosure 2, Figure 1. A description of the statistical methods used in the trend analysis is provided in Enclosure 1, Appendix B.

The numerical analysis of the total number of events shows a statistically significant increase over the 10-year period. However, the staff notes that the 10-year time frame was arbitrarily selected, and analyses of both a shorter, 8-year time period (see Enclosure 2, Figure 2) and a longer, 12-year time period (see Enclosure 2, Figure 3) show a flat trend line, with the FY 2004 and FY 2005 data as slight outliers with smaller numbers of events. Additional review by the staff identified a number of possible explanations for the rising number of events including an increase in radiography volume due to rising oil and gas exploration, an increase in the number of radiography licensees, and an increased licensee awareness of reporting requirements triggered by the 2005 NRC issuance of RIS 2005-15, Reporting Requirements for Damaged Industrial Radiographic Equipment (http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200515.pdf). The staff also notes that the number of occurrences of radiography events across the 10-year period is exceedingly low compared to the large number of opportunities for failure--conservative estimates of the failure rate are well below 0.1 percent.

Enclosure 2, Figure 4 shows a graph of the number of radiography events by type for the 10-year time period from FY 2004 through FY 2013. The staff notes that equipment related malfunctions led to a high proportion of the radiography events. A detailed review of the radiography events related to equipment malfunction in FY 2013 identified an unusually high number (14) in which radiography sources could not be retracted because the associated guide tubes or drive cables were damaged after the sources were extended. In 12 of these events, the damage resulted when components of radiography devices were crushed by falling construction equipment or when radiographic devices fell from inadequate placement or supports. In two events, the exterior surfaces of the radiography drive cables were melted by the beam of mirrors at solar power generating stations. It appears that all of these events could have been avoided with better equipment mounting or routing techniques. Six similar events occurred in FY 2012 and 10 occurred in FY 2011. As a result of this study, the staff is planning to issue a generic communication to licensees to raise awareness of the need for proper mounting of radiography equipment at work sites.

In conclusion, this study of radiography events did not reveal significant repetitive or safety issues that warrant specific agency action other than considering issuance of a generic communication such as an Information Notice. The study also did not identify any gap or inadequacy in agency policy. The NRC has in place procedures to monitor the occurrence of radiography 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 (DFI). The Enforcement Program Annual Report is issued on a calendar year (CY) basis and CY escalated enforcement data was included in recent years in the Annual Report to the Commission on Licensee Performance in the Materials and Waste Programs. For 2013, the Office of Enforcement provided FY data in order to present a consistent reporting interval for all reports of performance in the Materials and Waste Programs. In FY 2013, NRC issued 43 escalated enforcement actions involving NRC materials licensees (including fuel cycle facilities). The escalated enforcement actions issued in FY 2013 include 3 Severity Level II NOVs, 36 Severity Level III NOVs, and 4 Orders. Three of the four Orders were Confirmatory Orders that were issued to confirm commitments associated with Alternative Dispute Resolution (ADR) agreements. The fourth Order was issued to formalize the licensee's commitment to take certain corrective actions. Six of the 43 escalated enforcement actions involved issuance of a civil penalty.

For FY 2013, the number of escalated enforcement actions for the Materials and Waste Programs decreased by 15 from the number of actions issued in FY 2012. The number of escalated enforcement actions issued to materials licensees and fuel cycle facilities in the last four years shows a decreasing trend from 81 actions in FY 2010 to 43 actions in FY 2013. This is mainly due to a decrease in the number of escalated enforcement actions issued to gauge users, radiographers, and fuel cycle facilities over this period. The staff's analysis of the materials enforcement trend has not been conclusive, however, several causal factors have been identified that account for a substantial portion of the decrease. The number of cases involving security-related increased controls violations has decreased over this time period. For gauge users, the Severity Level (SL) of certain violations was changed from SL III to SL IV in 2011, reducing the number of escalated actions issued thereafter. 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 2013, no nuclear materials licensees were identified that met the criteria in SECY-11-0132 for discussion at the AARM. Two nuclear material licensees discussed in FY 2012 with classified matter protection program issues were issued Severity Level II violations in FY 2013. These licensees

no longer require additional NRC oversight and, as such, do not meet the criteria in SECY-11-0132.

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 the enclosure of 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.

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Enclosures:
1. Nuclear Material Events Database Annual Report FY 2013
2. Radiography Event Special Study Breakdown

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