

POLICY ISSUE
(Information)

DATE: March 27, 2017 **SECY-17-0042**

FOR: The Commissioners

FROM: Marc L. Dapas, 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 2016

PURPOSE:

This paper provides the 15th 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-08-0135, "Revision of the Criteria for Identifying Nuclear Materials Licensees for Discussion at the Agency Action Review Meeting," dated September 16, 2008, as well as 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) 2016. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2016, the staff evaluated significant nuclear materials issues and licensee performance trends based on aggregated information obtained from operating experience associated with

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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 licensee performance trends or generic concerns and that public health and safety was maintained. The staff identified one nuclear materials licensee that met the criteria, as described in SECY-11-0132, for discussion at the Agency Action Review Meeting (AARM).

BACKGROUND:

On June 28, 2002, the Commission issued SRM M020501, "Briefing on Results of Agency Action Review Meeting – Reactors, 9:00 A.M., Wednesday, May 1, 2002, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)," 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, 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, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," (ML030560328) 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 SRM-SECY-02-0216 (ML030560328), which approved the staff's proposed process for evaluating materials licensees with performance issues for discussion at the AARM, and providing 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 the associated SRM, the staff again revised the criteria for identifying nuclear material licensees for discussion at the AARM to include an additional criterion pertaining to licensees who previously were discussed at the AARM, but whose corrective actions were ineffective in correcting the underlying performance 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 issues and licensee 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 licensee performance trends that builds on existing processes and systems and has minimal impact on staff resources.

The aggregated information used to evaluate significant issues and licensee 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 present the results of the staff's evaluation with respect to this information followed by overall conclusions of 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 the NRC's FY 2016 Performance and Accountability Report (PAR). In the FY 2016 PAR, the agency reported two AOs from the Nuclear Materials Users Business Line 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)." The two AOs reported are less than the performance goal of three AOs. There were no occurrences in the other safety and security strategic goal performance indicators for the materials program. Therefore, the FY 2016 target is met. Copies of the FY 2016 PAR may be found at <https://www.nrc.gov/docs/ML1632/ML16320A585.pdf>.

Assessment of Data Reported to NMED

The NMED contains records of events involving nuclear materials reported to the NRC by its licensees, the Agreement States, and non-licensees. These reported events are sorted by the event reporting requirements as defined in the NRC's regulations. The event reports are evaluated to identify those that are considered to be safety significant and their associated 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, 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 2016 NMED Annual Report is provided as Enclosure 1. Copies of previous NMED Annual Reports may be found at <http://nmed.inl.gov/>.

To account for random fluctuations in the event data from year to year and to assess any trends, the data from the last 10 fiscal years (FYs) are reviewed. For the 10-year period from FY 2007 through FY 2016, a total of 4,949 events (984 NRC and 3,965 Agreement State) associated with materials licensees were reported to the NRC, compared to 5,651 events that were reported for the previous 10-year period from FY 2006 through FY 2015. For the current 10-year period, the data indicates 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 more focused aspects of the data (See Enclosure 1, page 4, Table 1, Summary of Trending Analysis). For example, the number of events involving NRC licensees, and those events involving lost/abandoned/stolen materials reflected statistically significant decreasing trends. However, based on the analysis of the events,

enforcement, and performance metrics data for the current 10-year period, the staff did not identify a specific reason for these observed trends. However, the staff did note 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 decreased as Agreement State events increased, though the total number of events stayed roughly the same. In addition, the NRC has performed outreach efforts with Agreement States to improve the understanding of medical event criteria. Furthermore, the NRC issued 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. Finally, the decreasing trend may be attributed in part to the issuance of Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," and the associated increasing general awareness of security requirements for radioactive materials.

For FY 2016, 27 of the 454 NMED events were considered to be of higher significance and are described in the FY 2016 NMED Annual Report. The breakdown of these significant events by category was as follows:

- 11 lost/abandoned/stolen material events,
- 7 medical events classified as AOs or potential AOs,
- 2 radiation overexposure events requiring reporting within 24 hours,
- 3 equipment-related events,
- 1 sealed source leaking event,
- 2 transportation-related events, and
- 1 "other" event classified as a potential AO, involving radiation exposure to the embryo/fetus of a woman undergoing medical treatment.

For the 11 significant lost/abandoned/stolen material events, none of the nuclear material sources were classified as Category 1, and 6 were classified as Category 2 under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004). All of these sources were subsequently recovered. Five events involved Category 3 sources, all of which were subsequently recovered. A summary of the significant events that occurred in FY 2016 is provided in the Executive Summary of the enclosed NMED Annual Report (Pages ix – x), and a detailed description of each event is provided in the main body of the report.

Based on its analysis of the data reported to NMED, the staff did not identify any significant issues that warrant specific action or policy changes.

Fuel Cycle Operating Experience

The Fuel Cycle Operating Experience Program is designed to support technical and licensing staff, inspectors, and management by providing insights that can inform future inspections and licensing reviews. Using event data from 2012 to 2016, two analyses were performed and the linear regressions suggest that the trend in annual events per year at fuel cycle facilities ranges from relatively stable to slightly decreasing. Over the course of the 5-year period, 11 of the 93 events were screened as safety-significant. Each safety-significant event was reviewed in detail to identify the causal and contributing factors that led to the event. Some of the recurring causal factors were configuration management, failure to adhere to procedures, and inadequate maintenance.

AO Data

Eleven events involving nuclear materials were identified as AOs during FY 2016. Eight events involved Agreement State licensees and three events involved NRC licensees. One Agreement State event involved radiation exposure to an embryo/fetus. Six Agreement State events were medical events, as defined in Title 10 of the *Code of Federal Regulations* Part 35, "Medical Use of Byproduct Material." One Agreement State event was associated with radiography operations. Of the three NRC licensee events, two occurred at medical facilities and the other occurred at a fuel cycle facility.

The 11 AOs are within the statistical variation of the average of 14 ± 6 AOs for each of the previous FYs since FY 2006. Three of the 11 AO events reported this year occurred in the previous FY, but the NRC completed its evaluation of these events for potential AO reporting in FY 2016. The eight medical event AOs are approximately 0.007 percent of the estimated number of nuclear medicine and radiation therapy procedures involving radioactive material performed in the United States annually. Neither AO caused permanent damage to an organ or resulted in physiological impairment.

The AO numbers in the FY 2016 NMED Annual Report and FY 2016 AO Report differ slightly since the two reports cover different time periods and data sets. The FY 2016 NMED Annual Report covers those AOs that were identified in FY 2016 (this includes events that occurred in FY 2016 where a final AO determination has been made, events that occurred in FY 2016 where a final AO determination has not been made, and events that occurred in FY 2015 but were not identified until FY 2016). Whereas, the FY 2016 AO Report covers all AOs that were determined to be AOs in FY 2016 (this includes events that occurred in FY 2016 where a final AO determination has been made, and events that were reported prior to FY 2016 but a final AO determination was not made until FY 2016). This data is summarized in Table 1 below.

<i>Table 1. Number of AO's and Potential Abnormal Occurrences (PAO) reported in the FY16 AO Report and FY16 NMED Report</i>			
	Number of AO/PAO's occurring in FY16	Number of AO/PAO's occurring prior to FY16, but determination made or identified in FY16	Total Number of AO's reported
FY16 AO Report	8	3	11
FY16 NMED Annual Report	8	2	10

Based on its analysis, the staff has not identified any trends or significant safety concerns among medical licensees. The staff continues to monitor licensee performance diligently and to provide prompt follow-up response when warranted.

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 2016, 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 2016, the NRC issued 67 escalated enforcement actions involving NRC materials licensees (including fuel cycle facilities). The escalated enforcement actions issued in FY 2016 include: 1 Severity Level II Problem and 16 Severity Level III NOV/Problems with proposed civil penalties totaling \$192,500; 44 Severity Level III NOV with no civil penalty, and 6 Orders. One of the six Orders involved the imposition of civil penalties totaling \$21,000, and the other five were Confirmatory Orders issued to confirm commitments associated with Alternative Dispute Resolution agreements.

For FY 2016, the number of escalated enforcement actions for the Materials and Waste Programs increased by 32 (91 percent) from the total number of actions issued in FY 2015 (35). While this represents a significant increase over the prior FY, the 67 escalated enforcement actions issued in FY 2016 is comparable to the average number of escalated actions issued to materials licensees and fuel cycle facilities in FYs 2011 and 2012.

As in previous years, the number of actions issued in FY 2016 were largely influenced by cases involving gauge users and radiographers. Gauge user cases rose from 12 to 17 (an increase of 42 percent) in large part due to an increase in the number of cited violations of 10 CFR 30.34, "Security requirements for portable gauges." Additionally, the number of escalated actions involving radiographers increased from 3 to 8 in FY 2016; however, this number is comparable to the average number of actions issued to radiographers in the 4 previous FYs prior to FY 2016. Materials distributor (14 actions) and individual wrongdoing (6 actions) cases also significantly influenced the 1-year increase in the number of escalated enforcement actions issued in FY 2016. Materials distributors and individual actors contributed to only 4 of the 35 escalated actions that were issued in FY 2015.

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 2016, one nuclear materials licensee was identified that met Criteria II in SECY-11-0132 for discussion at the AARM, Westinghouse Columbia Fuel Fabrication Facility. The staff's analysis regarding this licensee may be found in Enclosure 3. The staff's analysis outlines the issues and describes the regulatory actions being taken to improve licensee performance.

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 using the original 2002 criteria for identifying nuclear materials licensees that warrant discussion at the AARM and subsequent revisions in 2008 and 2011, the staff has

concluded that the current criteria are effective and valid, and appear to be working efficiently. For FY 2016, 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 one nuclear materials licensee that met the criteria, as described in SECY-11-0132, for discussion at the AARM.

COORDINATION:

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

/RA/

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Enclosure:

1. Nuclear Material Events Database
Annual Report FY 2016
2. Westinghouse Columbia Fuel
Fabrication Facility Write up Summary
3. Fuel Cycle Operating Experience
Report 2016

MEMO FROM M. DAPAS: ANNUAL REPORT TO THE COMMISSION ON LICENSEE PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS FISCAL YEAR 2016, March 27, 2017

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OFFICE	NMSS/MSTR	NMSS/MSTR	NMSS/MSTR	RGN I	RGN II
NAME	SEasson	DBollock	PHenderson for DCollins via email	JTrapp via email for DDorman	MLesser for Chaney via email
DATE	2/06/2017	2/06/2017	3/02/2017	2/15/2017	2/27/2017
OFFICE	RGN III	RGN IV	NSIR	OI	OE
NAME	JGiessner for CPederson via email	MShaffer for KKennedy via email	BHolian via email	KHowell via email	PHolahan via email
DATE	2/21/2017	2/23/2017	2/17/2017	2/13/2017	2/15/2017
OFFICE	OGC (NLO)	Tech Ed	NMSS		
NAME	MSimon for MDoane via email	WMoore	MDapas		
DATE	3/13/2017	3/14/17	3/27/17		

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