

POLICY ISSUE **(Information)**

April 5, 2013

SECY-13-0036

FOR: The Commissioners

FROM: Mark A. Satorius, Director */RA/*
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 2012

PURPOSE:

This paper provides the eleventh 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) 2012. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2012, 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 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 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 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 are 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; 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.

Typically generic and/or special event study results are included in this aggregated information; however, after review and analysis of the event data, it was determined that an event study was not warranted for FY 2012.

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, as reported in NRC's "Fiscal Year 2012 Performance and Accountability Report," related to nuclear materials events. 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 2012. Also, the safety and security performance measure targets were met in FY 2012.

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). It should also be noted that for the FY 2012 NMED Annual Report, Transportation (TRS) events involving fuel cycle process facilities are also coded as Fuel Cycle Process (FCP) events. A copy of the FY 2012 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 covering October 1, 2002, through September 30, 2012 (i.e., FY 2003 through FY 2012), a total of 5,802 events (1,959 NRC and 3,843 Agreement State events) associated with materials licensees were reported to NRC, compared to 5,938 events that were reported for the previous 10 consecutive year period, covering October 1, 2001, through September 30, 2011 (i.e., FY 2002 through FY 2011).

For the current 10 year period, the review of the data did not indicate any significant performance trends. The NMED annual report indicated 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 NRC reportable events, NRC lost/abandoned/stolen materials events, and NRC medical events indicated statistically significant decreasing trends. Also shown in the summary table, there was one statistically significant increasing trend and that was 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 for the FY 2012 NMED Annual Report that the transfer of licensees from NRC to Agreement State authority could result in increasing numbers of

Agreement State events and decreasing numbers of NRC events.

For FY 2012, 45 of the 513 reportable events were considered to be of higher significance and are described in the FY 2012 NMED Annual Report. The breakdown of these significant events by category was as follows:

- 10 lost/abandoned/stolen material events;
- 12 medical events;
- 6 radiation overexposure events;
- 2 release of material or contamination events;
- 2 leaking sealed source events;
- 8 equipment failure events;
- 1 transportation event;
- 2 fuel cycle process events; and
- 2 events (i.e., embryo/fetus dose event) that met the “Other” event category.

For the ten significant lost/abandoned/stolen material events, it should be noted that there were no nuclear material sources that were classified under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004) as Category 1 sources. There were three Category 2 sources, and seven Category 3 sources that were lost, all of which were subsequently recovered with the exception of one Category 3 source. A summary of the significant events that took place in FY 2012 may be found 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 may be found in the main body of the report for the specific event categories.

AO Data

The staff determined that 22 events were identified as AOs involving nuclear materials during FY 2012. These AOs include 4 events at NRC licensed facilities and 18 events at Agreement State licensed facilities. One of the AOs at an NRC-licensed facility involved an electrical equipment fire at a commercial nuclear power plant that impacted safety-related equipment. One of the Agreement State identified AOs involved radiation exposure to an embryo fetus, and another involved an exposure to the extremities of a radiographer. The remaining 19 AOs were medical events as defined in 10 CFR Part 35, “Medical Use of Byproduct Material.” Given that these medical-related AOs are a small number of events in contrast to the significantly large number of medical procedures performed annually, the staff does not believe that these events represent a generic concern. Based on the results of last year’s special event study (SECY-12-0052, Enclosure 2), staff also determined that comparing the numbers of AO’s when they are reported versus when they actually occurred also affected the presence and/or appearance of statistically significant trends within the data. The results of that 10 year study indicated that there were no statistically significant trends or generic concerns in the data.

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 these 22 events include: poor maintenance practices; inability of the pregnancy test to provide positive determination so close to conception; corrosion of the drive cable and improper maintenance; failure to properly visualize, identify and/or verify the treatment site; failure to administer the correct dosage; failure to

properly review and/or verify the written directive; and failure to follow procedure.

In addition to these 22 AOs that were identified in the FY 2012 AO report, the staff has identified an additional 4 events (1 NRC, 3 Agreement State) that took place in FY 2007– FY 2012 that are potential AOs for which additional information is required. Reasons for not providing additional information include ongoing pre-decisional enforcement actions that must be resolved and the additional time needed for follow-up of certain events. The staff is working with the Agreement States and NRC licensees to obtain the necessary information; the events will be included in a future report.

Data Derived Through Escalated Enforcement Actions

For the 2012 calendar year (CY) period (January 1, 2012, through December 31, 2012), NRC issued 59 escalated enforcement actions involving NRC materials licensees (i.e., including fuel cycle licensees). Escalated enforcement actions in the Materials and Waste Programs includes civil penalties and Notices of Violation (NOV) for Severity Levels I, II, and III violations (some of these actions involved multiple violations that were grouped together and issued as one problem), as well as Orders and Demands for Information (DFI). The escalated enforcement actions issued in CY 2012 for the Materials and Waste Programs include one Severity Level II NOV, 49 Severity Level III NOVs, and 9 Orders. The nine Orders consisted of one Confirmatory Order that was issued to confirm a commitment, four Confirmatory Orders that were issued to confirm commitments associated with Alternative Dispute Resolution (ADR) agreements, and four individual action Orders. Also, for these 59 escalated enforcement actions, 12 of them involved issuance of a civil penalty.

For CY 2012, the number of escalated enforcement actions for the Materials and Waste Programs decreased by 7 actions from what was issued in CY 2011 (i.e. 66 escalated actions in CY 2011). The number of escalated enforcement actions issued in the last five years shows a decreasing trend (e.g., 118 actions to 59 actions). This is mainly due to a decrease in enforcement actions issued to gauge user licensees and appears to indicate that materials licensees have improved their compliance with the security and control requirements imposed in 2008. No significant performance trends were identified after review of the escalated enforcement action data.

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 2012, there are two nuclear materials licensees that met or will likely meet the criteria due to significant issues regarding information security. Due to the classified nature of the information related to these licensees, the details regarding these licensees will not be provided in this report. Additional information will be provided to the Commission in a separate and secure meeting.

NRC Final Safety Culture Policy Statement

On June 14, 2011, the NRC Final Safety Culture Policy Statement was published in the *Federal Register*. Since its publication, NRC staff has developed educational tools, such as case

studies, brochures, and posters to further communicate the Commission's expectations. In addition, the staff interacted directly with stakeholders, including domestic and foreign industry representatives and organizations, national trade groups, and international nuclear organizations to engage them on safety culture issues and implementation strategies.

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 is effective and valid, and appear to be working efficiently. The staff identified two nuclear materials licensees that met or will likely meet 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.

/RA/

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Enclosures:

1. Nuclear Material Events Database
Annual Report FY 2012
2. Summary of Severity Level I and II
Enforcement Actions for CY 2012

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