POLICY ISSUE
INFORMATION

April 6, 2010 SECY-10-0040

FOR: The Commissioners

FROM: Charles L. Miller, 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 2009

PURPOSE:

This paper provides the eighth annual report on significant nuclear materials issues and adverse 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) 2009. This paper does not address any new commitments or resource implications.

SUMMARY:

The staff evaluated significant nuclear materials issues and performance trends based on aggregated information obtained from operating experience associated with reportable events and generic issues 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 discernable performance trends or generic issues. For FY 2009, there were two

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nuclear material licensees, Nuclear Fuel Services, Inc. and the Department of Veteran Affairs Philadelphia VA Medical Center, who met the criteria 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 nuclear materials licensees that will 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 approving 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' performances 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.

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 issues 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: (1) Abnormal Occurrence (AO) data; (2) strategic outcomes and performance measures data; (3) data derived through escalated enforcement actions; (4) annual report data based on assessment of events reported to the Nuclear Material Events Database (NMED); (5) generic and special event study results; and (6) significant licensee performance issues that were identified based on the criteria described in SECY-08-0135.

The following sections represent an evaluation of the nuclear material events data and significant licensee performance issues followed by overall conclusions of performance in the Materials and Waste Programs.

(1) Abnormal Occurrence Data:

The staff determined that nine of the events reported to NRC in FY 2009, involving the Materials and Waste Programs, met the criteria for AO events. These AO events include three events at NRC-licensed facilities and six events at facilities licensed in Agreement States. Seven of the nine AO events were medical events and the remaining two events involved radiation exposure to an embryo/fetus. A breakdown of the AO events by type of events and jurisdiction of the event (NRC vs. Agreement State) may be found in Enclosure 1 of this paper. No significant performance trends or generic concerns were identified when analyzing the FY 2000 through FY 2009 data.

The staff's analysis and evaluation resulted in the finding that human error was a main contributor to the root causes of these AO events. The causes for these nine events include (1) misidentification of the target organs listed in the written directive; (2) errors in programming the equipment software; (3) malfunction of the medical equipment; (4) lack of training and procedures, (5) failure to recognize a potential issue with the method of treatment and (6) receiving false negative pregnancy tests.

Given the small number of AO events reported versus the very large number of total medical treatments and diagnostic procedures performed by medical-use licensees per year (e.g., more than 20 million procedures), the staff does not believe that these events represent a generic concern.

(2) 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 2009 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero, and there were no events reported during FY 2009 that met any of the strategic outcomes. Also, the safety and security goals for the performance measures were not exceeded in FY 2009.

(3) Data Derived Through Escalated Enforcement Actions:

For the 2009 calendar year (CY) period (January 1, 2009, through December 31, 2009), NRC issued 89 escalated enforcement actions involving NRC materials licensees (some of these actions involved multiple violations grouped together and issued as a problem). 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, as well as Orders and Demands for Information (DFI). The escalated enforcement actions issued in CY 2009 for the Materials and Waste Programs include 66 Severity Level III NOVs and 23 Orders, which include 19 confirmatory orders that were issued to confirm commitments associated with Alternative Dispute Resolution (ADR) settlement agreements, 3 orders imposing civil penalties, and 1 individual action order. Also, for these 89 escalated enforcement actions, 20 civil penalties and 2 DFIs were issued.

In CY 2009 there was a decrease in the number of escalated enforcement actions compared to CY 2008, which resulted in 118 escalated enforcement actions for the Materials and Waste Programs. Also, in CY 2009 there were no cases involving Severity Level I or II violations compared to an average of approximately three per year for previous years. The decrease in escalated enforcement actions may be due, in part, because of the improved performance observed by material licensees in complying with the increased control orders issued in CY 2005. In addition, the total number of NRC material licensees decreased due to the States of Pennsylvania, Virginia, and New Jersey becoming Agreement States by the end of CY 2009.

(4) Assessment of Data Reported to NMED:

The NMED contains records of events involving nuclear material reported to NRC by its licensees, Agreement States, and non-licensees. These reported events are sorted by event-reporting requirements 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 and is presented in an annual summary report, in which historical data is aggregated for evaluation of potential trends. A copy of the FY 2009 NMED Annual Report is available in Enclosure 2 of this paper. Copies of previous NMED Annual Reports may be found at http://nmed.inl.gov/.

In order to eliminate the random fluctuations in the event data from year to year and to assess an average trend of the data, the last 10 FY of data is reviewed. For the 10 year period covering October 1, 1999, through September 30, 2009, a total of 5,261 events (1,742 NRC and 3,519 Agreement State events) associated with materials licensees were reported to NRC, compared to last year's total of 5,227 events that were reported for the 10 year period, covering October 1, 1998, through September 30, 2008. It should be noted for the purposes of the NMED Annual Report 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). For the data in the NMED Annual Report and in this section, the term "event" is used to describe an individual event category and not a single occurrence/event report.

For the current 10 year period, the NMED annual report indicated a downward statistical trend for the number of reported NRC regulated events. There could be several possible reasons for this trend, including changes in NRC regulations or NRC's change to a performance based inspection program, which results in improved licensee programs. However, a specific reason could not be determined for this and other statistical trends found in this report, although NMED, enforcement, event coordination and performance metrics data were evaluated.

For FY 2009, 38 of the 456 total reportable events were considered safety significant events as described in the FY 2009 NMED Annual Report. There were 3 lost/abandoned/stolen radioactive material events, 12 medical events, 1 radiation overexposure event, 14 release of material or contamination events, 2 leaking sealed source events, 1 equipment failure event, 3 transportation events, and 2 events that met the "Other" event category. For the 3 significant lost/abandoned/stolen radioactive material events, it should be noted that there were 2 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 2 sources and 1 source, which included an aggregate of a 100 small Am-241 sources, was classified as a Category 3

source. All of the IAEA classified Category 2 and 3 sources were recovered. A summary of the significant events that took place in FY 2009 may be found on Page ix of the enclosed NMED Annual Report, 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.

(5) Generic and Special Event Study Results:

In 2008, the staff performed a special study to evaluate portable gauge losses and thefts. The staff reviewed event data from 10 years prior (CY 1998 thru CY 2007) to determine any trends in the area of portable gauge losses and thefts in general as well as any measurable results from the 10 CFR 30.34(i) rulemaking that became effective in July 2005. The study at that time did not show a clear trend or provide an indication of the effectiveness of the 10 CFR 30.34(i) rulemaking.

This year, since 2 additional years of portable gauge event data was available, the staff decided to re-evaluate the portable gauge losses and thefts to determine if there are any trends or measurable results from the 10 CFR 30.34(i) rulemaking. The results of this year's portable gauge study are described below.

Many portable gauge designs contain Americium-241/Beryllium (Am/Be) and Cesium-137 (Cs-137) sources. Generally each portable gauge contains only 10 milliCuries (mCi) of Cs-137 and 40 mCi of Am-241. Based on portable gauge event data from the last 10 years (CY 2000 thru CY 2009), the total amount of unrecovered Am/Be reported lost or stolen was 13.3 Ci, which would be rated as IAEA Category 3 amount of material. In addition there were 3.17 Ci of unrecovered Cs-137, which would also be rated as IAEA Category 3 amount of material.

Analysis of the portable gauge event data for the last 10 years also determined the following:

- Theft of gauges from a vehicle occurs more often when at a residence or other location than at a hotel;
- More gauges are stolen (72 percent) than missing (28 percent), and a missing gauge is more likely to be recovered than a stolen gauge; and
- More gauges appear likely to be recovered if stolen from a residence (54 percent) than from other locations including the jobsite (Average ~ 44 percent).

From examining the data described above, the data does indicate a statistically significant decreasing trend in the number of portable gauge lost and theft events in the last 10 years. The data also indicates that there has been a significant decrease in the amount of portable gauge events since 2005, which would indicate that the 10 CFR 30.34(i) rulemaking appears to have an effect on the number of portable gauge lost and theft events. A graph of this data may be found in Enclosure 3.

It should be noted that a study is also being performed regarding the effectiveness of the new fuel cycle regulations (i.e., Subpart H of 10 CFR Part 70). This study is scheduled to be completed by November 2010, and the results from this study will be provided in next year's annual report on licensee performance in the materials and waste programs.

(6) Licensees Identified with Significant Performance Issues:

SECY-08-0135 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: (1) very serious events (those triggering NRC's strategic level measures); (2) significant licensee issues or events; or (3) licensee performance trends. For FY 2009, there were two nuclear material licensees that met the criteria.

The nuclear material licensees that met the criteria as described in SECY-08-0135 were Nuclear Fuel Services, Inc. and the Department of Veteran Affairs Philadelphia VA Medical Center. The staff's analysis regarding these licensees may be found in Enclosure 4. 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 events 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 the significant-issues criteria, two licensees were identified as having significant performance issues during FY 2009. NRC staff is addressing the issues surrounding these licensees.

COORDINATION:

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

/RA Cynthia Carpenter for/

Charles L. Miller, Director
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Enclosures:
1. Annual Trend in Abnormal Occurrence Events from FY 2000 - 2009
2. Nuclear Material Events Database Annual Report FY 2009
3. Portable Gauge Trend Analysis for January 1, 2000, to December 31, 2009
4. Licensees Identified with Significant Performance Issues

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