POLICY ISSUE
(Notation Vote)

April 4, 2007 SECY-07-0066

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS - FISCAL YEAR 2006

PURPOSE:

This paper provides the fifth 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) 2006. This paper does not address any new commitments or resource implications.

SUMMARY:

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 trends or generic issues. The staff identified one nuclear material licensee that met the criteria as described in Table 1 of SECY-02-0216 (ML022410435).

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When separated from Enclosure 5, this document may be released to the public.

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, on December 11, 2002, the staff issued SECY-02-0216, providing criteria for determining nuclear materials licensees that will be discussed at the AARM. 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.

This paper is the fifth annual report developed to keep the Commission informed of the overall performance trends, as well as significant issues among NRC and Agreement State licensees in the Materials and Waste Programs.

DISCUSSION:

The evaluation of significant adverse performance issues and performance trends is based on aggregated information on operating experience associated with reportable events and generic issues affecting the industry. As committed to in SECY-02-0216, 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 Occurrences (AO) data; (2) strategic outcomes and performance measures data; (3) data derived through escalated enforcement actions; (4) quarterly 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 issues that were identified based on significant issues criteria.

The following sections represent an evaluation of the significant adverse performance issues and performance trends followed by overall conclusions of performance in Materials and Waste Programs.

(1) Abnormal Occurrences Data:

The staff determined that nine of the events reported to NRC in FY 2006, involving the Materials and Waste Programs, met the criteria for Abnormal Occurrences (AO). The FY 2006 AO Report is scheduled to be published in April 2007. The AO events include three events at NRC-licensed facilities and six events at facilities licensed in Agreement States. The three events at NRC licensed facilities consist of one event at a fuel fabrication facility and the other two events were medical events (including one involving a dose to an embryo/fetus). The

six Agreement State-licensee events included five medical events (including one involving a dose to an embryo/fetus), and one industrial event. There is no discernable trend in the number of AO events when data from FYs 1999 through 2006 are compared (Enclosure 1). An analysis of the AO events between Agreement States and NRC was performed in a special study, which may be found in Section 5 of this paper.

The staff's analysis and evaluation of these events resulted in the common finding that human error, including failure to adhere to procedures, was a contributor to the root cause for every event reported as a FY 2006 AO. For eight of the nine AO events reported, human error was the primary cause. Five events involved not verifying the correct dosages (activity), not performing a pregnancy test to women of childbearing age, and not performing radiation surveys. Three events were medical events that involved incorrect input to computer software and failure to verify that the sources were placed in the correct position. For one of the nine AO events reported, human error was a contributing factor. This event was at a fuel facility, and involved failure to maintain configuration control and compliance with procedures.

However, given the small number of events reported versus the very large number of total medical treatments, diagnostic procedures, industrial jobs and fuel fabrication processes performed by all licensees per year, the staff does not believe that these events represent a generic issue.

Also, no significant performance trends or generic concerns were identified when FYs 1999 through 2006 data was analyzed.

(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 2006 Performance and Accountability Report," related to materials events. The metrics for the strategic outcomes are zero, and there were no events reported during FY 2006 that met any of the strategic outcomes. Also, the number of events for each performance measure did not exceed 80 percent of the metric.

Thirty-one medical events occurred during FY 2006. There were 31 medical events in FY 2005 and 40 medical events in FY 2004. Based on the "Fourth Quarter FY 2006 NMED Quarterly Report," a statistical trend analysis performed on data from FYs 1997 through 2006 determined that the data does not indicate a statistically significant trend. No generic issues were identified after an evaluation of these events was conducted.

NRC met its strategic outcomes and performance measures for the Materials and Waste Programs for FY 2006. An analysis of the strategic and performance events data between Agreement States and NRC was performed in the special study, which may be found in Section 5 of this paper.

(3) Data Derived Through Escalated Enforcement Actions:

During FY 2006, NRC issued 51 escalated enforcement actions involving NRC materials licensees. Escalated enforcement in the Materials and Waste Programs includes civil penalties, orders, and Notices of Violation for Severity Levels I, II, and III violations. In FY 2006, there were two enforcement actions that resulted in Severity Level II violations. In the past 5 years, the average for Severity Level I or II violations is about four per year. There were three in FY 2002, five in FY 2003, five in FY 2004, four in FY 2005, and two in FY 2006. Summaries of Severity Level I or II violations for FYs 2002 through 2006 are described in Enclosure 2. The "Enforcement Program Annual Report FY 2006," issued by the Office of Enforcement, describes the Agency's enforcement activities, including several other cases resolved through the Alternate Dispute Resolution (ADR) process, during the FY, and includes various tables and figures. The Annual Report does not identify any significant trends.

(4) Assessment of Data Reported to NMED:

The Nuclear Materials Event Database (NMED) contains records of events involving nuclear material reported to NRC by its licensees, Agreement States, and non-licensees. These reported events are classified based on event-reporting requirements defined in NRC regulations. The event reports are evaluated to identify any safety-significant events and their causes. NMED data are analyzed for the main event types, and are presented in a quarterly report, in which 16 quarters of historical data are aggregated for evaluation of potential trends. The NMED Quarterly Report is posted on the NMED web site at https://NMED.inl.gov and is directly available to NRC and Agreement State staffs. Using event analysis and reviews published in the NMED Quarterly Report, performance trends can be identified. Fourth-quarter reports include an annual summary of data.

A copy of the "Fourth Quarter FY 2006 NMED Quarterly Report" may be found in Enclosure 3. For the 16-quarter period covering October 1, 2002, through September 30, 2006, a total of 1,972 events associated with materials licensees were reported to NRC, versus a total of 2,038 events that were reported for the previous 16-quarter period, covering October 1, 2001, through September 30, 2005.

For the 16-quarter period ending September 30, 2006, 48 percent of the events were classified as "Lost/Abandoned/Stolen Material." The remaining 52 percent were divided among "Equipment" (24 percent); "Leaking Sealed Source" (7 percent); "Transportation" (6.5 percent); "Medical Events" (8 percent); "Radiation Overexposure" (2.5 percent); "Release of Material or Contamination" (3 percent); and "Other" (1 percent). This represents no significant change from the percentages for the previous 16-quarter period. An analysis of the strategic and performance event data between Agreement States and NRC was performed in the special study, which may be found in Section 5 of this paper.

(5) Generic and Special Event Study Results:

The special study presented in this annual report is an evaluation of total event performance for FY 2006, to determine if there are any significant differences in performance between Agreement States and NRC.

In comparing the data, the assumption was made that the distribution of licensee types and uses was the same between the Agreement States and NRC. This was considered a valid assumption given the data in each category included multiple States, and that the States were fairly uniformly distributed across the U.S. As a result, the composition of Agreement States licensee population and the NRC licensee population would be very much the same, and differ only in magnitude (number of licensees).

Enclosure 4 contains the details of the analysis. In summary, there were no significant differences identified after comparison of the Agreement State and NRC data. There was no indication of significant difference in the frequency of event occurrence/licensee. The magnitude of Agreement State and NRC events was low considering the number of Agreement State and NRC licensees, and was consistent with the number of events reported for previous years.

(6) Significant Issues Identified Based on Significant Issues Criteria:

SECY 02-0216 defines the criteria to identify those issues and licensees that rise to the level of needing the highest level management attention and awareness. The criteria targets the most critical issues involving: (1) very serious events (those triggering the strategic level measures); (2) significant licensee performance or program issues; or (3) NRC program gaps or failures that have been identified.

There is one nuclear material licensee that met the significant issues criteria as described in SECY-02-0216. The staff's analysis regarding this licensee may be found in Enclosure 5. The staff's analysis outlines the issues and describes the regulatory actions being taken to improve licensee performance. Due to the threat environment that exists in the United States since September 11 terrorist attacks, it has been determined that certain security information concerning this nuclear material licensee, which was previously available to the public, is considered sensitive unclassified information and is no longer publicly available.

OVERALL PERFORMANCE CONCLUSIONS:

Based on review of numerical 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, there was one nuclear material licensee that was identified through event evaluations, or other follow-up reviews, as having significant performance issues, during FY 2006. NRC staff is addressing the issues surrounding this licensee.

COORDINATION:

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

/RA Martin J. Virgilio Acting for/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Annual Trend in AO Events from FYs 1999-2006
2. Summary of Severity Level I and II Enforcement Actions for FYs 2002-2006
3. Fourth Quarter FY 2006 NMED Quarterly Report
4. Review of Breakdown of Agreement State and NRC Event Data
5. Significant Issues and Incident Investigations

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OFFICE	RGN II	RGN III	RGN IV	NMSS/DHLWRS	NSIR	OGC	OE
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