POLICY ISSUE
(Information)

April 7, 2008 SECY-08-0048

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS (FISCAL YEAR 2007)

PURPOSE:

The purpose of this paper is to provide the sixth 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), and SRM SECY-07-0066, "Annual Report to the Commission on Licensee Performance in the Materials and Waste Programs – Fiscal Year 2006," dated June 20, 2007 (ML071710239). This report covers Fiscal Year (FY) 2007. 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 trends or generic issues. For FY 2007, there were no nuclear material licensees that met the criteria of significant nuclear materials issues and adverse licensee performance.

CONTACT: Duane E. White, FSME/DMSSA
(301)415-6272

However, an update on the status of Nuclear Fuel Services (NFS), which met the criteria last FY, is provided to discuss ongoing corrective actions.

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 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.

In addition, this paper addresses the Commission's SRM of June 20, 2007, concerning the FY 2006 materials and waste programs annual licensee performance report (SECY-07-0066). The SRM directed staff to eliminate direct comparison of high and low risk-significant events, and to specifically make the International Atomic Energy Agency (IAEA) Code of Conduct the central focus on matters of lost, abandoned, and stolen material in future Nuclear Materials Events Database (NMED) quarterly reports and annual licensee performance reports. In response to this SRM, the staff created a new NMED annual report that replaces the NMED fourth quarter report, which was used for previous materials and waste programs annual licensee performance reports. In comparison to the previous NMED fourth quarter report, the new NMED annual report provides the following features:

- Revised the executive summary and individual sections to provide a summary of the risk-significant events;
- Removed performance metrics to eliminate confusion with metrics presented elsewhere in the SECY paper;
- Removed the pie charts for all events to eliminate direct comparison of high and low risk-significant events;
- Resorted the order of the sections within the report to present event types of more interest first;
- Provided a new format for the charts to improve readability and to show comparison between NRC and Agreement State events;
- Removed short-term quarterly data to focus on long-term and annual summary data to better support the annual licensee performance report; and
- Added the IAEA Categorization of Sources to focus the definition of risk-significant lost source data to the IAEA definitions.

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 (ML022410435), 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) annual report data based on assessment of events reported to the 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 11 of the events reported to the NRC in FY 2007, involving the Materials and Waste Programs, met the criteria for AO. The FY 2007 AO Report is scheduled to be published in April 2008. The AO events included five events at NRC-licensed facilities and six events at facilities licensed in Agreement States. All of the five events at NRC-licensed facilities were medical events (including one involving a dose to an embryo fetus). Also, the six Agreement State licensee events were medical events. There is no discernable trend in the number of AO events when data from FYs 1998 through 2007 are compared. 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.

The staff's analysis and evaluation of these events resulted in the finding that human error, including failure to adhere to procedures, was a contributor to the root cause for every event reported as a FY 2007 AO. For 10 of the 11 AO events reported, human error was the primary cause. For these 10 medical events, five of the events involved incorrect input into computer treatment planning software, three of the events involved failure to verify that the sources were placed in the correct position, and two of the 10 events involved not verifying the prescribed dosages (activity). The event that was not primarily due to human error involved a dose to an embryo fetus because of a false negative pregnancy test.

However, given the small number of events reported versus the very large number of total medical treatments and diagnostic procedures performed by medical-use licensees per year, the staff does not believe that these events represent a generic concern.

Also, no significant performance trends or generic concerns were identified when the data for FYs 1998 through 2007 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 2007 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero, and there were no events reported during FY 2007 that met any of the strategic outcomes. Also, the number of events for each performance measure did not exceed 80 percent of the metric.

(3) Data Derived Through Escalated Enforcement Actions:

In past annual materials and waste licensee performance reports, escalated enforcement data was provided by NRC's Office of Enforcement (OE) for a given FY. In 2005, OE began tracking and reporting the agency's enforcement activities by calendar year (CY). In an effort to be consistent with OE current reporting methods, this report will begin providing enforcement information on a CY basis. The current report will cover a 15 month period covering October 1, 2006, through December 31, 2007.

For the period October 1, 2006, through December 31, 2007, NRC issued 84 escalated enforcement actions involving NRC materials licensees, with 74 of these actions in CY 2007. Escalated enforcement in the Materials and Waste Programs includes civil penalties, Orders, and Notices of Violation for Severity Levels I, II, and III violations. Also in this period, there was one enforcement action that resulted in a Severity Level II violation. In the past 6 years, the average for Severity Level I or II violations was about three per year.

There were three in FY 2002, five in FY 2003, five in FY 2004, four in FY 2005, two in FY 2006, and one in FY/CY 2007. Summaries of Severity Level I or II violations for FY/CY 2007 are described in Enclosure 2. No significant performance trends were identified.

(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 are analyzed for the main event types, and are presented in an annual summary report, in which historical data are aggregated for evaluation of potential trends. The NMED Annual Report is posted on the NMED Web site at https://nmed.inl.gov and is directly available to NRC and Agreement State staff. Using event analysis and reviews published in the NMED Annual Reports, performance trends can be identified.

A copy of the FY 2007 NMED Annual Report may be found in Enclosure 3. For the 10 year period covering October 1, 1997, through September 30, 2007, a total of 5,053 events (1,903 NRC and 3,150 Agreement State) associated with materials licensees were reported to the NRC, versus a total of 5,260 events that were reported for the previous 10-year period, covering October 1, 1996, through September 30, 2006. For the current 10-year period, the NMED annual report indicated a slight downward trend for all NMED events.

There could be several possible reasons for this trend including, change in technology, change in regulations, and NRC's change to a performance based inspection program, which results in improved licensee programs. However, a specific reason could not be determined for the trend. Also, after evaluating the NMED, enforcement, and performance metrics data, the staff did not identify any performance issues that were associated with the trend. For several of the individual event types, the NMED annual report also indicated downward trends for NRC events while Agreement State events showed no trend or an upward trend. These trends are believed to be due to the shifting of licensees from NRC jurisdiction to Agreement State jurisdiction.

For FY 2007, 15 of the 393 total reportable events were considered safety significant events. There were three lost radioactive source events, 11 medical events, and one radiation overexposure event. The three radioactive sources that were lost are rated under the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (2004) as Category 2 and 3 sources; two of the sources were Category 2 sources and the other source was a Category 3 source. All three of the sources, however, were recovered. No Category 1 sources were lost in FY 2007. For the 11 medical events, all of the events were abnormal occurrences, and approximately half of these events did not result in significant adverse effects to the patient. One radiation overexposure resulted in a member of the public receiving a calculated dose between 5,000 and 10,000 mrem, which exceeds the public dose limit of 100 mrem and the occupational dose limit of 5,000 mrem.

(5) Generic and Special Event Study Results:

The staff performed a special study to evaluate portable gauge losses and thefts. The data was reviewed to determine any trends in the area of portable gauge losses and thefts in general, and any measurable results from the 10 CFR 30.34(i) rulemaking that became effective in July 2005.

Portable gauges generally contain Americium-241/Berrilyium (Am/Be) or Cesium 137 (Cs-137) sources. Based on portable gauge event data from 2002 thru 2007, the total amount of unrecovered Am/Be reported lost or stolen was 7.38 Curies (Ci), which would be rated as IAEA Category 3 amount of material. And, there was 1.81 Ci of unrecovered Cs-137, which would be rated as IAEA Category 4 amount of material.

Analysis of the portable gauge event data 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 (69%) than missing (31%), 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 vehicle (average ~ 50%) than from a jobsite (44%).

From examining the data described above, the data does not show a clear trend or indication of the effectiveness of the 10 CFR 30.34(i) rulemaking. The long term data for the period 1998 through 2007 show no trend, but the data after 2005 show a possible drop in portable gauge losses and thefts.

Since there is some indication of a possible drop in the data after 2005, staff will continue to watch the data to see if a definite trend develops over the next 2 to 3 years.

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

Table 1 of SECY-02-0216 defines the criteria to identify those 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 the strategic level measures); (2) significant licensee performance or program issues; or (3) NRC program gaps or failures that have been identified. For FY 2007, there were no nuclear material licensees that met the criteria.

In FY 2006, NFS met the significant-issues criteria, and an update is being provided 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, there were no licensees that were identified through event evaluations, or other follow-up reviews, as having significant performance issues, during FY 2007. Corrective actions are ongoing for significant issues identified last year.

COORDINATION:

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

/RA/

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Executive Director
for Operations

Enclosures:
1. Annual Trend in AO Events from FYs 1999-2007
2. Summary of Severity Level I and II Enforcement Actions for FYs 2002-2007
3. FY 2007 Nuclear Material Events Database Annual Report
4. Update of Nuclear Fuel Services, Inc.

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DATE	02/15/08	03/03/08	02/29/08	02/29/08	02/27/08	02/15/08	02/27/08
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DATE	03/03/08	02/29/08	02/27/08	03/04/08	02/27/08	03/03/08	03/04/08
OFFICE	FSME/DMSSA	NMSS	TechEditor	FSME	EDO		
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