

# POLICY ISSUE INFORMATION

April 14, 2011

SECY-11-0056

FOR: The Commissioners

FROM: Scott W. Moore, Acting 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 2010

## PURPOSE:

This paper provides the ninth 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) 2010. This paper does not address any new commitments or resource implications.

## SUMMARY:

For FY 2010, 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 and that health and safety was protected. For FY 2010, there were two nuclear material

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licensees, Nuclear Fuel Services, Inc. and the U.S. Department of Veteran Affairs, who met the criteria 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 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.

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: Abnormal Occurrence (AO) data; strategic outcomes and performance measures data; data derived through escalated enforcement actions; annual report data based on assessment of events reported to the Nuclear Material Events Database (NMED); generic and/or special event study results; and 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.

### AO Data

The staff determined that 15 events were identified as AOs during FY 2010. These AOs include eight events at NRC-licensed or regulated facilities and seven events at Agreement State-licensed facilities. Twelve of the 15 AO events were medical events as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, and the remaining 3 events involved radiation exposure to an embryo/fetus. It should also be noted that of the 15 AO events, only 6 of the events occurred in FY 2010. The remaining nine AOs occurred previously and the NRC's evaluation was completed in FY 2010. In addition to these 15 AOs that were identified during FY 2010, the staff has identified an additional 15 events in FY 2006 - FY 2010 that are potentially AOs for which additional information about the event is required. Reasons for the missing information include ongoing, pre-decisional enforcement actions that must be resolved. In other cases, additional time is needed for event follow-up. The staff is working with the Agreement States and licensees to obtain the necessary information, and the events will be included in a future report. 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 last 10 years of data.

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

The staff's analysis and evaluation found that human error was a main contributor to the root causes of these AO events. The causes for these 15 events include: failure to properly visualize, identify and/or verify the treatment site; malfunction of the medical equipment; errors in set-up of medical equipment; failure to perform a pregnancy test; and receiving false negative pregnancy tests.

### 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 2010 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero occurrences, and there were no occurrences reported during FY 2010 that met any of the strategic outcomes. Also, the safety and security performance measure targets were met in FY 2010.

### Data Derived Through Escalated Enforcement Actions

For the 2010 calendar year (CY) period (January 1, 2010, through December 31, 2010), NRC issued 88 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 violation), as well as Orders and Demands for Information (DFI). The escalated enforcement actions issued in CY 2010 for the Materials and Waste Programs include 4 Severity Level II

NOVs, which are described in Enclosure 2 of this paper, 71 Severity Level III NOVs, 11 Orders, and 2 DFIs. The 11 Orders consisted of 6 Confirmatory Orders that were issued to confirm commitments associated with Alternative Dispute Resolution (ADR) agreements, 1 Order revoking a license, 1 Order approving a settlement agreement, and 3 individual action Orders (i.e., one of the individual Orders resulted from ADR). Also, for these 88 escalated enforcement actions, 23 of them involved a civil penalty.

For CY 2010, the number of escalated enforcement actions for the Materials and Waste Programs was approximately equivalent to the number of actions issued in CY 2009 (i.e. 89 escalated actions in CY 2009). The number of escalated enforcement actions issued in CY 2010 is consistent with the distribution of escalated enforcement actions in past years. No significant performance trends were identified after review of the escalated enforcement action data.

#### 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 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 and is presented in an annual summary report, and in this report historical data is aggregated for evaluation of potential trends. It should be noted that for the FY 2010 NMED Annual Report, events related to the fuel cycle process have been added to the report. A copy of the FY 2010 NMED Annual Report is available in Enclosure 3. Copies of previous NMED Annual Reports may be found at <http://nmed.inl.gov/>.

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). 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.

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, 2000, through September 30, 2010, a total of 5,592 events (2,014 NRC and 3,578 Agreement State events) associated with materials licensees were reported to NRC, compared to 5,261 events that were reported for the previous 10 consecutive year period, covering October 1, 1999, through September 30, 2009. It should be noted that due to the addition of the fuel cycle process events, an additional 386 events were added to the number of total events for the 10 year per period covering FY 2001 through FY 2010. Without the addition of the fuel cycle process events, the total number of events would have been 5,206 events for the latest period.

For the current 10 year period, the review of the overall current and prior event 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 3, page 4, Table 1, for a summary of trending analysis). For example, the radiation overexposure ten-year data trend analysis determined that NRC-regulated and Agreement State-regulated events represented statistically significant decreasing trends. However, based on the current analysis

of NMED, enforcement, event coordination and performance metrics, a specific reason was not identified for the statistical trends found in the report.

For FY 2010, 32 of the 421 reportable events were considered more significant and are described in the FY 2010 NMED Annual Report. The breakdown of these significant events was as follows:

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

For the four significant lost/abandoned/stolen radioactive material events, it should be noted that there were four sources (i.e., one source per event) that were classified under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004) as Category 3 sources. All but one of the IAEA classified Category 3 sources were recovered. There were no IAEA Category 1 or 2 sources that were reported lost, abandoned or stolen in FY 2010. A summary of the significant events that took place in FY 2010 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.

#### Generic and Special Event Study Results

In CY 2010, the staff performed a study to evaluate fuel cycle events related to Subpart H in 10 CFR Part 70. Subpart H was added to Part 70 in 2000 to impose performance requirements on fuel cycle licensees who process enriched uranium and plutonium, and the regulations require enhanced safety programs and an integrated safety analysis (ISA), and impose new reporting requirements. The purpose of the study was to evaluate operating experience related to the new requirements.

NMED contained records of 70 events reported by these licensees between FY 2005 and 2010. The NMED data indicates that the number of events reported each year has increased slightly in recent years but, a trend analysis of the data determined that the data does not represent a statistically significant trend. A breakdown of these events by number and event cause may be found in Enclosure 4. Based on the information in the NMED records, the study found that the events reported had the following causes:

- Human error was the direct cause of 56 percent of the events,
- Equipment failure was the direct cause of 24 percent of the events,
- Procedure problems were the direct cause of 10 percent of the events, and

- For the remaining 10 percent of the events, the cause of the event was not reported (i.e., 9 percent of events) or the event was caused by an external condition that was outside the control of the licensee (i.e., 1 percent of events).

A majority of the human errors (64 percent) were associated with management deficiencies such as deficient policies, administrative controls, work planning, resource allocation, or supervision.

Appendix A of Part 70 contains the new reporting requirements imposed in 2000. Most of the events related to Subpart H were reported under only 2 of the 10 requirements in Appendix A.

- 44 percent were reported under Part 70, Appendix A, Section (b)(2) – Loss or degradation of an item relied on for safety (IROFS) that results in failure to meet the performance requirements in 70.61.
- 43 percent were reported under Part 70, Appendix A, Section (b)(1) – Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the ISA, and which results in failure to meet the performance requirements in 70.61.

After evaluating the NMED records, which include investigation results and corrective actions, the staff concludes that licensees are using the ISAs and the IROFS to evaluate the safety significance of identified events and new accident scenarios. The conclusions from the evaluations have resulted in improved ISAs and IROFS. Licensees are making corrections to ISAs that fail to analyze, or improperly analyze accident scenarios. The staff believes that the ISAs will continue to improve as more experience is gained. In addition, the staff concludes that efforts to reduce human error and improve management oversight should lead to improved performance. The staff intends to discuss the study results in upcoming meetings with the industry. The staff will continue to focus inspection resources on management oversight, and support industry initiatives to improve human performance, such as recent efforts to improve safety culture.

#### 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: very serious events (those triggering NRC's strategic level measures); significant licensee issues or events; or licensee performance trends. For FY 2010, 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 U.S. Department of Veteran Affairs. The staff's analysis regarding these licensees is contained in Enclosure 5. 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 2010. 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.

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Enclosures:

1. Annual Trend in Abnormal Occurrence  
Events from FY 2001-2010
2. Summary of Severity Level I and II  
Enforcement Actions for CY 2010
3. Nuclear Material Events Database  
Annual Report FY 2010
4. Fuel Cycle Event Study Breakdown
5. Licensees Identified with Significant  
Performance Issues

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WITS200200096/EDATS: SECY-2010-0191

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