

POLICY ISSUE INFORMATION

April 3, 2009

SECY-09-0052

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE
PERFORMANCE IN THE MATERIALS AND WASTE PROGRAMS
FISCAL YEAR 2008

PURPOSE:

This paper provides the seventh 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) 2008. 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 2008, there was one nuclear material licensee, Nuclear Fuel Services, Inc., who met the criteria for identifying nuclear materials licensees for discussion at the Agency Action Review Meeting (AARM).

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

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 (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 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 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 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 Occurrence Data:

The staff determined that 10 of the events reported to NRC in FY 2008, involving the Materials and Waste Programs, met the criteria for AO events. These AO events include 5 events at NRC-licensed facilities and 5 events at facilities licensed in Agreement States. All of the AO events were medical events (including 2 involving a dose 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 1998 through FY 2008 data. The "Report to Congress on Abnormal Occurrences - FY 2008" is scheduled to be published in April 2009.

The staff's analysis and evaluation of these AO events resulted in the finding that human error was a main contributor to the root causes of these AO events. For these 11 medical events; (1) 4 of the events involved not following or lack of procedures; (2) 3 of the events involved improper setup of equipment; (3) 2 of the events involved providing the incorrect radioactive material or dose to a patient; and, (4) 1 event involved misidentification of the organ to be treated.

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., 17 to 19 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 2008 Performance and Accountability Report," related to materials events. The metric for the strategic outcomes is zero, and there were no events reported during FY 2008 that met any of the strategic outcomes. Also, the safety and security goals for the performance measures were not exceeded in FY 2008.

(3) Data Derived Through Escalated Enforcement Actions:

For the 2008 calendar year (CY) period (January 1, 2008, through December 31, 2008), NRC issued 118 escalated enforcement actions involving NRC materials licensees (some of these actions involved multiple violations grouped together and issued as a problem). Escalated enforcement 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 2008 include 94 Severity Level II and III actions, 23 Orders, and one DFI.

In the past, the average for Severity Level I or II NOVs have been about three per year. In CY 2008, there were two cases involving Severity Level II violations, as described in the summaries provided 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. A copy of the FY 2008 NMED Annual Report is available in Enclosure 3 of this paper.

In order to eliminate the random fluctuations in the event data from year to year and to assess an average trend of the data, we look at the last 10 years of data. For the 10 year period covering October 1, 1999, through September 30, 2008, a total of 5227 events (1867 NRC and 3360 Agreement State) associated with materials licensees were reported to NRC, versus a total of 5,053 events that were reported for the previous 10 year period, covering October 1, 1998, through September 30, 2007. 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, change in NRC 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 this and other statistical trends found in this report, although NMED, enforcement, event coordination and performance metrics data were evaluated.

For FY 2008, 31 of the 640 total reportable events were considered safety significant events as described in the FY 2008 NMED Annual Report. There were 5 lost/abandoned/stolen radioactive material (LAS) events, 10 medical (MED) events, 3 radiation overexposure (EXP) events, 9 release of material or contamination (RLM) events, 2 leaking sealed source (LKS) events, 1 equipment failure (EQP) event, 2 transportation (TRS) events, and 2 "other" (OTH) events. For the 5 significant LAS events, there were 11 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 was classified as a Category 3 source. All of these sources were recovered. For the 10 MED events, 8 of these events were considered abnormal occurrences for FY 2008. One of the significant MED events involving prostate brachytherapy procedures was actually a compilation of 92 medical procedures at the same facility. All of the significant EXP events involved radiographers and, 1 of these events resulted in a 236 rem extremity dose. For the 9 RLM events, 2 of the events involved sources that were breached during removal from gauges and, 2 events involved the transportation of

contaminated individuals from a nuclear power plant to offsite medical facilities. The other 5 RLM significant events involved the cremation of a body containing brachytherapy seeds, 2 spill/release incidents at laboratories, a contaminated waste package at a gaseous diffusion plant, and an event at a uranium hexafluoride production facility. The 2 significant LKS events involved sources that were breached during removal from a gauge. These 2 events were also considered significant RLM events. There was 1 significant EQP event that involved a radiography equipment failure that resulted in an occupational radiation overexposure. This EQP event was also considered a significant EXP event. The 2 TRS significant events involved sources becoming unshielded during shipment. The OTH significant events involved 2 fetal doses resulting from treatments administered to pregnant patients. These 2 fetal dose events were classified as AO for FY 2008.

(5) Generic and Special Event Study Results:

General licenses (GLs) are established by the regulations¹ and grant authority to a person for a certain named activity or product involving licensed material. A GL is provided by regulation and is effective without the filing of an application with the regulatory authority (e.g., NRC or Agreement State) or the issuance of a licensing document to a person. NRC developed a General License Tracking System (GLTS) in 2001 to implement an annual registration program for certain 10 CFR Part 31 general licensed devices (GLDs) with the goal of improving the tracking and accountability of the GLs and GLDs containing radioactive sealed sources. The GLTS contains information from approximately 40,350 GLs, possessing approximately 513,000 devices. Of these, approximately 90 percent of GLDs in the GLTS are tritium exit signs that do not require an annual registration. Approximately 1,100 NRC-authorized GLs require annual registration and, these licenses cover approximately 7,600 GLDs.

In 2009, the staff evaluated events involving GLDs, which contain byproduct material. The data was reviewed to determine the type of general licensed events that have been reported to NMED and, to determine if there are any trends. Data was taken from NMED for the period covering January 1, 1998, to December 31, 2008. The data was downloaded from NMED on February 3, 2009. The data indicated that there were 546 events that involved GLDs during this time period. There were 7,776 GLDs involved in the 546 events. Tritium exit signs accounted for 93 percent (7,267 devices) of the total number of GLDs involved in these events, which is in line with the fact that approximately 90 percent of the devices in GLTS are tritium exit signs. Static eliminators were the next largest type of device involved in the GLD events. Static eliminators accounted for three percent (251 devices) of the total number of GLDs involved in these events. A breakdown of the type of GLDs and the number of GLDs by event type that have been involved in events for this time period may be found in Enclosure 4.

¹ Title 10, Part 31, "General Domestic Licenses for Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 31) describes GLs for byproduct materials. The regulations for GLs for source material appear in 10 CFR Part 40, "Domestic Licensing of Source Material," Sections 40.2 through 40.28, and those for GLs for special nuclear material are in Subpart C, "General Licenses," of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

We also looked at the isotopes and the activity that was involved in the GL events for the period January 1, 1998, to December 31, 2008. The study indicated that approximately 99 percent of the activity involved in these general licensed events was from Tritium (approximately 111,572 Ci). The majority of this tritium has been lost due to the large number of tritium exit signs and other GL devices containing tritium that have been lost or damaged. The activity of tritium is also higher than the other isotopes because 10 to 20 curies (Ci) of tritium is generally present in each exit sign while the activity of isotopes in other GLDs tend to be in the millicurie range. A breakdown of the type of isotopes and the amount of activity by event type that was involved in these GL events may also be found in Enclosure 4.

After analyzing the GL event data, the staff found that for the three most numerous devices (e.g., tritium exit signs, static eliminators, and gauges) that were involved in the GL events for this time period, the tritium exit sign events involved the least amount of general licensees. For the 250 events that involved 7,267 tritium exit signs there were only 74 general licensees involved in these events. For the 127 static eliminator and 119 gauge events there were 113 and 115 general licensees, respectively, involved in these events. The NRC is investigating the cause for the large number of tritium exit signs involved in these events. No other trends were found during this study.

The NRC is currently working on several actions that relate to GLDs. The staff has developed a proposed rulemaking for "Limiting the Quantity of Radioactive Materials in a Generally Licensed Device," which is currently being reviewed by the Commission. This rule would limit the quantity of byproduct material allowed in a GLD to below one-tenth (1/10) of the IAEA Category 3 threshold levels. Also, in regards to general licensed tritium exit signs, in January 2009, the NRC released a DFI request to general licensees that possess at least 500 tritium exit signs. This DFI was developed after a general licensee indicated that they may have a large number of lost or unaccounted for exit signs. The DFI will allow NRC to evaluate whether other general licensees with tritium exit signs have the same issue and to determine if additional actions will be required.

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

SECY-08-0135 defines the criteria used 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 NRC's strategic level measures); (2) significant licensee issues or events; or (3) licensee performance trends. For FY 2008, there was one nuclear material licensee that met the criteria.

The nuclear material licensee that met the significant issues criteria as described in SECY-08-0135 was Nuclear Fuel Services, Inc. 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.

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 was one licensee that was identified as having significant performance issues during FY 2008. 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/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. Annual Trend in AO Events from FYs
1998-2008
2. Summary of Severity Level I and II
Enforcement Actions for CY 2008
3. FY 2008 Nuclear Material Events
Database Annual Report
4. General License Event Summary for
January 1, 1998, to December 31, 2008
5. Nuclear Fuel Services, Inc.

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