

POLICY ISSUE INFORMATION

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SECY-06-0087

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 2005

PURPOSE:

This paper provides the fourth annual report on significant nuclear materials issues, as well as 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) 2005.

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 includes 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 indicating adverse licensee performance. The staff identified no nuclear materials licensees that met the criteria as described in Table 1 of SECY-02-0216 (ML022410435) for discussion in this paper, as well as for discussion at the Agency Action Review Meeting (AARM). A discussion on performance trends will also be presented at the AARM. This paper does not address any new commitments or resource implications.

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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, 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 fourth 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 Occurrence (AO) data; (2) strategic, goal and performance goal data; (3) data derived through escalated enforcement actions; (4) generic and special event study results; (5) quarterly report data based on assessment of events reported to the Nuclear Material Events Database (NMED); 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) AO Data:

The staff determined that nine of the events reported to NRC in FY 2005, involving the Materials and Waste Programs, met the criteria for AOs. The FY 2005 AO Report is scheduled to be published around April 2006. The AO events include seven therapeutic medical events/misadministrations (including one involving a dose to an embryo/fetus) and two

diagnostic medical events/misadministrations (including one involving an infant). Although the nine AO events for FY 2005 represent a decrease from the 17 events reported for FY 2004, there is no discernable trend in the number of AO events when data from 1999-2005 are compared (Enclosure 1).

The staff's analysis and evaluation of these events resulted in the common finding that human error was the primary contributor to the root cause for all the events reported as FY 2005 AOs. In addition, four of the nine events reported involved incorrect input to computer software. These input errors, combined with other errors, such as failure to verify that the sources were in the correct position, resulted in medical events/misadministrations. However, given the small number of events reported versus the very large number of total medical treatments and diagnostic procedures performed by all licensees per year, the staff does not believe that this represents a generic issue for all treatments and procedures. Other examples of human errors that contributed to the root cause included: 1) failure to verify correct dosages (activity); (2) use of sources incompatible with the applicator; and 3) improper positioning of equipment and sources and failure to verify correct placement.

No significant performance trends or generic concerns were identified when FYs 1999-2005 data was analyzed.

(2) Strategic Goal and Performance Goal Data:

NRC staff focused on verification and validation of data generated by NRC, as well as by the industry and other external sources, to determine the impact on performance measures. Performance measure data highlighted in this report are those with values exceeding a performance goal or likely to exceed a performance goal within 80 percent of the maximum value, as described in SECY-02-0216, Table 1 (ML022410435). For FY 2005, all Strategic Goals were met. The metrics for the strategic goals are zero, and there were no events reported during FY 2005 that met any of the strategic measures. All performance and precursor goals were met in FY 2005. No measured values for the performance or precursor goals exceeded 80 percent of the metric.

The number of medical events and misadministrations reported in FY 2005 has decreased from the number of events reported for previous years. Thirty-one medical events and misadministrations occurred during FY 2005 (versus 40 in FY 2004 and 39 in FY 2003). However, based on the "Fourth Quarter FY 2004 NMED Quarterly Report," a statistical trend analysis performed on data from 1995 through 2005 determined that the data do not indicate a statistically significant trend. No generic issues were identified after an evaluation of these events was conducted.

NRC met its strategic, performance, and precursor goals in the Materials and Waste Programs for FY 2005.

(3) Data Derived Through Escalated Enforcement Actions:

During FY 2005, NRC issued 40 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 2005, there were four enforcement actions that resulted in Severity Level I or II violations. In the past 4 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, and four in FY 2005. Summaries of Severity Level I or II violations for FYs 2002, 2003, 2004, and 2005 are described in Enclosure 2. The Office of Enforcement's (OE) "Enforcement Program Annual Report" describes the agency's enforcement activities during a given fiscal year, and includes various tables and figures. OE's "Enforcement Program Annual Report - FY 2004" does not identify any significant trends.

(4) Generic and Special Event Study Results:

This annual report presents studies in two areas: high-risk lost and stolen sources, and overexposure events.

High-risk Lost and Stolen Sources:

Given the continued level of focus on high-risk lost and stolen sources, an update to last year's analysis was performed on the number of lost and stolen radioactive sources exceeding the threshold for quantities of concern, which is found in Enclosure 3. This special review of lost and stolen radioactive sources of greatest concern uses a risk-informed approach to data analysis. The radioactive sources of greatest concern are those sources that may pose a significant risk to individuals, society, and the environment. The threshold quantities used for this analysis are the Category 2 quantities in Table I of International Atomic Energy Agency's "Code of Conduct on the Safety and Security of Radioactive Sources." Staff reviewed the number of events involving lost and stolen sources of greatest concern from calendar years 1994 - 2005 (Enclosure 3).

Between 1994 and 2005, there were 60 events involving loss or theft of risk-significant sources (70 percent were lost sources and 30 percent were stolen). This is an average of about 5 per year. In approximately 80 percent of the events for the 12-year period, the sources were recovered. This results in an average of about one unrecovered source per year. In FY 2005, a new Performance Goal, Goal 2: Security-Performance Measure #1, was established under the Security Area to monitor the number of unrecovered, risk-significant sources that pose a safety or security threat (NSIR determination).

In FY 2005, one source was lost and not recovered. The event involved the loss of a radiography source in about 27 meters (90 feet) of water in the Gulf of Mexico, as it was being transferred from an offshore platform to a transport boat. This event does not meet the criteria

of Goal 2: Security-Performance Measure #1, based on a determination, by NRC's Office of Nuclear Security and Incident Response (NSIR), that the risk-significance of this source is low, based on the location (i.e., water depth) of the source.

The analysis provided this year represents no significant change to the averages from the period from calendar years 1994 - 2004. The data analysis does not reveal a discernable trend in the number of lost and stolen events for radioactive material exceeding the threshold quantities. There is no evidence of theft for malevolent use.

Although the number of high-risk lost and stolen sources is very low, NRC takes each of these events very seriously. The NRC, in partnership with Agreement State regulators, have enhanced the security and control measures for these sources, as a means of further reducing the number of lost and stolen sources. These measures have been put in place for all licensees throughout the U.S. The NRC and the Agreement States are inspecting those licensees to verify compliance with these requirements.

Overexposure Events:

Given the significant potential consequences of overexposures, staff performed a special study of the overexposure events that have occurred in the 4-year period from FYs 2002-2005. Details are found in Enclosure 4.

Analysis of the data showed that only a small percentage of the total events each year are overexposures. There were 56 overexposure events in the 4-year period analyzed. This is only about 3 percent of the total 2038 events for the 4-year period. In addition, few of these overexposure events meet AO criteria (i.e., significant events). There were 6 overexposures that were AOs in the 4-year period. This is less than 0.3 percent of total events, or less than 10 percent of the overexposure events. There were zero AO overexposures in FY 2005.

To put this in perspective, it must be compared to the total number of opportunities for an overexposure to occur. Per NUREG-0713, vol. 26, it is estimated that there are over 13,000 monitored occupational workers at over 120 materials licensees. Also, per NUREG-1350, vol. 17, there are over 21,000 materials licensees. In addition, some types of activities involving radioactive sources are conducted in environments where members of the public are nearby, such as in hospitals, in radiography or portable gauge field work, or during transportation. This is a normal part of the nature of these activities. Although the material and areas are controlled, the proximity of the public presents the possibility of inadvertent opportunities for members of the public to be in close proximity to sources (e.g., medical, radiography, well logging, portable gauges, transportation). Given the large number of individuals either working with sources, or in the area where sources might be used, there are a large number of opportunities each day for an inadvertent overexposure to occur. Considering this, it is significant that the number of overexposures recorded each year is so low.

The analysis also showed that overexposure events primarily involved three type of licensees. Approximately 88 percent involved radiography, well logging, and radiopharmaceuticals (49 out of 56). The remaining 12 percent involved a brachytherapy source, two fixed gauges, and three events involving unsealed material (7 out of 56). In evaluating the specific events, we found certain patterns within the three primary types of licensees involved.

Radiography overexposure events typically involve whole body doses less than 10 rem to occupational workers and only involve one person. Of the 6 events where doses exceeded 10 rem, the highest was 152 rem, and the next highest was 31.4 rem. One event involved a dose to the public (doses to 2 FedEx package handlers from handling a damaged shipping package containing Ir-192 wafers for radiography sources).

Well logging overexposure events typically involve non-radiation rig workers in the area and involve more than one person.

Events involving radiopharmaceuticals typically involve extremity doses to occupational workers. The exception to this was 2 events that involved whole body doses to family caring for or visiting patients that were receiving therapeutic radiopharmaceutical doses, and where the family member did not adhere to directions/controls provided by the hospital to minimize dose received (e.g., moved lead shield out of the way to be closer to the patient).

These patterns are not unexpected given the types of work being performed in these areas, and the typical environments in which they are conducted.

Lastly, the analysis showed that human error was the cause in approximately 80 percent of the events (45 out of 56). Awareness of workers regarding the need for attention to procedures and detail is important in reducing the potential for overexposures.

In summary, no regulatory changes are recommended. The NRC is already engaged in raising awareness of the potential for overexposure. Some examples are: issuance of Information Notices to make licensees aware of potential problems or weaknesses; sharing of examples of overexposures in the NMSS Quarterly Newsletter (which goes to all licensees); communicating the importance that NRC places on avoiding overexposure by issuing enforcement (which also provides incentive for other licensees to avoid actions which could cause them to receive enforcement); and conducting inspections (to allow NRC to identify pre-cursor issues that may lead to overexposures). In addition, human reliability studies have been started with RES to explore whether there are ways to further reduce potential for human errors.

(5) Assessment of Data Reported to NMED:

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.

Enclosure 5 is a copy of the "Fourth Quarter FY 2005 NMED Quarterly Report." For the 16-quarter period covering October 1, 2001, through September 30, 2005, a total of 2038 events associated with materials licensees were reported to NRC, versus a total of 2060 that were reported for the previous 16-quarter period, covering October 1, 2000, through September 30, 2004.

For the 16-quarter period ending September 30, 2005, 47 percent of the events were classified as "Lost/Abandoned/Stolen Material." The remaining 53 percent were divided among "Equipment" (24 percent); "Leaking Sealed Source" (8 percent); "Transportation" (7 percent); "Medical Events (or Misadministrations)" (7 percent); "Radiation Overexposure" (3 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.

Although some of the graphs in the Quarterly Report indicate slight increasing or decreasing patterns, ongoing routine assessment of events did not reveal any significant adverse performance trends.

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

There are no nuclear materials licensees that met the significant issues criteria as described in SECY-02-0216. This indicates that there were no critical failures in licensee performance, and that there were no issues that were not able to be addressed in the normal inspection and enforcement processes.

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. These 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. In FY 2005, there were no licensees identified for discussion according to these criteria. NMSS, STP and the Regions used this as an opportunity to review the threshold criteria to ensure that it was still appropriate. It was determined that the criteria continue to appropriately identify those issues that need to be raised for discussion at the

AARM. This does not imply that events, issues, and licensee performance below these criteria are not of importance. The staff determined however, that those items were being appropriately dealt with at lower levels or in other venues, and did not warrant discussion at the AARM. We are confident that our processes would allow us to identify licensees or candidates meeting the SECY-02-0216 criteria.

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 were no nuclear materials licensees that were identified through event evaluations, or other follow-up reviews, as having significant performance issues, during FY 2005. Moreover, it is important to recognize that the degree of NRC oversight applied to different licensees, or regarding NRC followup of trends or issues, is not driven solely by the AARM process. Heightened oversight of licensees, or followup and action taken relative to trends seen in events, may be in effect even if that licensee's performance does not rise to the level of the AARM criteria in a given year.

COORDINATION:

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

/RA by William F. Kane Acting For/

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Enclosures:

1. Annual Trend in AO Events from FYs 1999-2005
2. Summary of Severity Level I and II Enforcement Actions for FYs 2002-2005
3. Annual Trend in Lost and Stolen Source Events Exceeding the Threshold Quantities for Radioactive Sources of Concern
4. Review of Overexposure Events
5. Fourth Quarter FY 2005 NMED Quarterly Report (ML060310600)

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