



POLICY ISSUE **(Information)**

May 10, 2019

SECY-19-0050

FOR: The Commissioners

FROM: John W. Lubinski, Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE
PERFORMANCE IN THE NUCLEAR MATERIALS AND WASTE SAFETY
PROGRAM FISCAL YEAR 2018

PURPOSE:

This paper provides the annual report for fiscal year (FY) 2018 on significant nuclear materials issues and licensee performance trends in the Nuclear Materials and Waste Safety Program. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2018, the staff evaluated significant nuclear materials issues and licensee performance trends based on reportable events and operating experience associated with Nuclear Materials and Waste Safety Program licensees. With the exception of the review of escalated enforcement actions, this evaluation included both the U.S. Nuclear Regulatory Commission (NRC) and Agreement State licensees. The staff concluded that there are no significant nuclear materials issues or discernible adverse licensee performance trends and that public health and safety was maintained. The staff identified one nuclear materials licensee that met the criteria for discussion at the Agency Action Review Meeting (AARM).

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BACKGROUND:

On June 28, 2002, the Commission issued SRM M020501, "Briefing on Results of Agency Action Review Meeting – Reactors, 9:00 A.M., Wednesday, May 1, 2002, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)." 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, and lost or stolen sources) and on adverse licensee performance.

In response to SRM M020501, the staff developed SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated December 11, 2002 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML022410435). On February 25, 2003, the Commission issued SRM-SECY-02-0216 (ADAMS Accession No. ML030560328), which approved the staff's proposed criteria and process and directed the staff to provide the report on an annual basis. Subsequently, in SECY-08-0135, "Revision of the Criteria for Identifying Nuclear Materials Licensees for Discussion at the Agency Action Review Meeting," dated September 16, 2008 (ADAMS Accession No. ML082480564) the staff updated the criteria to provide additional clarity and incorporate the NRC's current policies and procedures. The Commission approved the revised criteria and directed the staff to include an additional criterion pertaining to licensees who previously were discussed at the AARM, but whose corrective actions were ineffective in correcting the underlying performance issues. The revision to the criteria for identifying nuclear materials licensees for discussion at the AARM was provided to the Commission in SECY-11-0132, "Revision of the Criteria for Identifying Nuclear Material Licensees for Discussion at the Agency Action Review Meeting," dated September 20, 2011 (ADAMS Accession No. ML112280111).

DISCUSSION:

The information used to evaluate significant issues and licensee performance trends includes: (1) strategic outcomes and performance measure data; (2) annual assessment of events reported to the Nuclear Material Events Database (NMED); (3) fuel cycle operating experience; (4) Abnormal Occurrence (AO) data; (5) generic and/or special event study results; (6) data derived through escalated enforcement actions; and (7) significant licensee performance issues. The following sections present the results of the staff's evaluation with respect to this information, followed by overall conclusions regarding significant issues and licensee performance in the Nuclear Materials and Waste Safety Program.

Strategic Outcomes and Performance Measure Data

In the FY 2018 Agency Financial Report (AFR), dated November 8, 2018 (ADAMS Accession No. ML18317A204), the agency reported it met all performance goals. The AFR included one AO from the Nuclear Materials Users Business Line that met or exceeded the performance indicator for "Number of radiation exposures that meet or exceed AO criteria I.A.1 (unintended radiation exposure to an adult), I.A.2 (unintended radiation exposure to a minor), or I.A.3 (radiation exposure that has resulted in unintended permanent functional damage to an organ or physiological system)." The occurrence involved radiation exposure to a radiographer exceeding the annual limit. The licensee attributed the overexposure to not following company operating and safety procedures. Several actions were taken by the licensee to prevent recurrence including sending an alert to personnel notifying them of the event and meetings with all staff to restate operating and safety requirements. The licensee does not expect any

adverse health effects to the radiographer from this event. This one event did not exceed the performance goal which is less than or equal to three AOs. Additionally, the AFR reported no instances in FY 2018 in which the performance indicator for "Prevent sabotage, theft, diversion, or loss of risk significant quantities of radioactive material that meet or exceed AO criteria I.C.1 (stolen, abandoned, or unrecovered lost), I.C.2 (substantiated case of actual theft or diversion), and the portion of I.C.3 (substantiated loss of a formula quantity) concerning theft or diversion of special nuclear material" was not met. The performance goal is zero occurrences. However, an event was later identified as having met AO criteria I.C.1 involving the theft and recovery of a truck transporting an industrial radiography camera. The occurrence was not included in the FY 2018 AFR due to late identification of the AO. The NRC staff concluded that this event was not an indication of a significant issue or licensee performance trend. Rather it was an isolated occurrence due to miscommunication between the radiographers that was unlikely to be repeated. Several actions were taken by the licensee to prevent recurrence including retraining of all radiographers on security requirements, and the development of more specific procedures associated with truck locking and alarms. There was no radiological impact to the public or employees due to the event. The FY 2019 AFR will include an update and explanation of the initial result reported. Additional details on these events are provided in SECY-19-0024, "Report to Congress on Abnormal Occurrences: Fiscal Year 2018," dated February 27, 2019 (ADAMS Accession No. ML18340A008). There were no occurrences in the other safety and security strategic goal performance indicators for the materials program. Copies of the FY 2018 AFR may be found at: <https://www.nrc.gov/docs/ML1831/ML18317A204.pdf>.

Assessment of Data Reported to Nuclear Material Events Database

The NMED contains records of events involving nuclear materials reported to the NRC by its licensees, the Agreement States, and non-licensees. The event reports are evaluated to identify events that are considered to be safety significant and their associated causes. The NMED data is analyzed for the main event types, aggregated for evaluation of potential trends, and presented in an annual summary report (NMED Annual Report, ADAMS Accession No. ML19065A232). Copies of previous NMED Annual Reports may be found at: <http://nmed.inl.gov/>.

To account for random fluctuations in the event data from year to year and to assess any trends, the data from the last 10 FYs are reviewed. For the 10-year period from FY 2009 through FY 2018, a total of 4,577 events (780 NRC and 3,797 Agreement State) associated with materials licensees were reported to the NRC, compared to 4,938 events that were reported for the 10-year period from FY 2008 through FY 2017. The numbers of events are a very small proportion of the total number of activities carried out. For the current 10-year period, the data indicates that the total number of events per year is relatively stable.

Several statistically significant decreasing trends were identified in the following specific focused areas: 1) overall number of NRC-regulated events, 2) number of NRC-regulated Release of Licensed Material or Contamination (RLM) events, and 3) total (NRC-regulated and AS-regulated) number of RLM events. These trends are consistent with identical trends observed during the FY 2017 event review and do not represent new trends.

For FY 2018, 18 of the 394 NMED events were considered to be of higher significance and are described in the FY 2018 NMED Annual Report. These significant events are categorized as follows:

- 6 lost/abandoned/stolen material events;
- 8 medical events classified as AOs or potential AOs;
- 3 radiation overexposure events requiring reporting within 24 hours; and
- 1 release of licensed material or contamination events.

A detailed description of each event is provided in the FY 2018 NMED Annual report.

Based on analysis of the data reported to NMED, the staff did not identify any significant issues that warrant specific action or policy changes. A discussion of the AOs is included below.

Fuel Cycle Operating Experience

The Fuel Cycle Operating Experience (FC OpE) Program provides technical and licensing staff, inspectors, and management key insights that can inform inspection planning, licensing reviews, and program changes. As part of the FC OpE Program, the staff evaluated the numbers and types of events since calendar year (CY) 2007 and used statistical analyses to identify trends in performance, determine contributing factors, and evaluate the safety significance of those events. Based on an analyses of CY 2018 events, the staff concluded that: (1) the most common areas for reported events continue to be criticality and operational safety; (2) some of the contributing factors associated with the events in CY 2018 were failures or degradation in management measures (e.g., configuration management and maintenance), and (3) given the analysis of the data and the low safety significance of reported events in CY 2018, the staff did not identify the need for any additional changes to the fuel cycle inspection or licensing programs.

Abnormal Occurrence Data

The FY 2018 Report to Congress on Abnormal Occurrences contained 11 FY 2018 events involving nuclear materials as AOs. Eight events involved Agreement State licensees, and three events involved NRC licensees. Two events were the radiography operations and stolen radiography camera events already discussed. The remaining nine AOs were medical events.

The nine medical event AOs are a very small percentage, approximately 0.007 percent, of the estimated number of nuclear medicine and radiation therapy procedures involving radioactive material performed in the United States annually (based on data in the IMV Benchmark Report Radiation Therapy October 2010, IMV Medical Division, Inc.).

Based on its analysis of the events, the staff did not identify any trends or significant safety concerns among medical licensees.

Special Event Study Results

The NRC staff requested that Idaho National Laboratory (INL) staff perform a review (ADAMS Accession No. ML19065A234) of medical event records contained in NMED. The objective of the review was to determine the number of medical events caused by inadequate training of medical staff.

The review focused on reportable medical events that occurred in FY 2017 and 2018 (86 events total). Of the 86 events reviewed, 14 were regulated by NRC and 72 by Agreement States. Only one event identified inadequate training as the cause, while in three others, inadequate training was inferred. The specific cause of inadequate training was difficult to identify from the reference documents, since they typically identify that events result from human error, but do not identify why the human error occurred. As a result, INL determined that the records/references do not contain enough detailed information to identify how many medical events are caused by inadequate training of medical staff. The staff agreed with the INL determination that the study was inconclusive in identifying whether there is a trend with regard to medical events caused by inadequate training of medical staff. In addition, given the inconsistent details provided in the reference documents, NRC staff are evaluating the need for clarifying guidance on event reporting and inspection report documentation.

A separate medical event review was performed by the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Medical Events Subcommittee. During the fall 2018 ACMUI meeting and the April 4, 2019, ACMUI Commission meeting, the ACMUI subcommittee presented its evaluation of medical events (MEs) reported between FY 2014 and FY 2017 (ADAMS Accession No. ML19065A236).

The ACMUI subcommittee identified two overarching themes. First, the performance of a time out immediately prior to administration of radioactive materials, could have prevented some MEs. Second, infrequent performance of administrations appears to be a contributing factor in a number of MEs. From FY14-FY17, the subcommittee identified a total of 225 reported MEs. Of the 225 MEs, 45 (20 percent) could have been prevented by a "time out," and 27 (12 percent) by more recent/frequent performance of the administration(s). The presentation concluded with a recommendation that the NRC issue an Information Notice to alert authorized users of the identified themes. The NRC staff accepted the subcommittee's recommendation and will issue an Information Notice on the best practices to prevent medical events by October 31, 2019.

Data Derived Through Escalated Enforcement Actions

The following escalated enforcement actions in the Nuclear Materials and Waste Safety Program involved civil penalties and Notices of Violation (NOV) for Severity Level I, II, and III violations, Orders, Demands for Information, and enforcement action of any Severity Level against an Individual. In FY 2018, the NRC issued 32 such escalated enforcement actions involving NRC materials licensees (including fuel cycle facilities). These escalated enforcement actions include:

- 1 Severity Level II Problem¹ with a proposed civil penalty;
- 6 Severity Level III NOVs/Problems with proposed civil penalties;
- 22 Severity Level III NOVs/Problems with no proposed civil penalty;
- 1 Severity Level IV NOV with no proposed civil penalty (Individual)²; and
- 2 Confirmatory Orders³.

¹ The NRC may also collectively characterize related violations as a single "problem" in lieu of citing multiple NOVs.

² SL-IV NOVs to individual Actions are considered escalated enforcement actions.

³ One of the two Confirmatory Orders was issued to confirm commitments associated with an Alternative Dispute Resolution agreement.

The 32 total escalated enforcement actions for the Materials and Waste Programs in FY 2018 is a decrease of 27 from the total number of actions issued in FY 2017 (59). This represents a fairly significant reduction from FY 2017. Gauge user, radiography, and medical cases made up the majority of the FY 2018 cases (7, 7, and 5, respectively). Gauge user cases dropped from 20 in FY 2017 to 7 in FY 2018. The decrease of 13 actions for gauge users accounts for more than 48 percent of the total decrease in the number of escalated enforcement actions issued in FY 2018 for the Nuclear Materials and Waste Safety Program. This may be due to the new enforcement guidance memorandum (EGM-18-002, "Interim Guidance for Dispositioning Violations for Failure to Control and Maintain Constant Surveillance for Portable Gauges,") dated August 1, 2018. The number of radiographer cases stayed the same (7) from FY 2017 to FY 2018. Medical cases dropped from 9 in FY 2017 to 5 in FY 2018. In general escalated enforcement actions for all categories under nuclear material users have decreased in FY 2018 compared to FY 2017 indicating that there are no significant licensee performance trends.

Licensees Identified with Significant Performance Issues

For FY 2018, there is one nuclear materials licensee that resulted in the NRC implementing strategic level measures to address a significant licensee issue. Specifically, Southern California Edison (SCE) San Onofre Nuclear Generating Station (SONGS) Independent Spent Fuel Storage Installation (ISFSI) met criteria II.2, having been issued a Severity Level II violation, and having unique or unusual performance aspects that warrant additional NRC oversight.

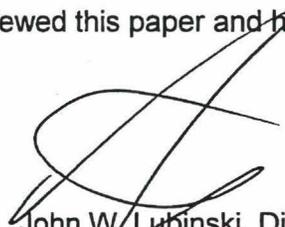
The staff convened a special inspection team and has had extensive interactions with both the licensee and the public regarding these issues. Further background and details regarding this event and the resulting inspections can be found on the staff public webpage: <https://www.nrc.gov/reactors/operating/ops-experience/songs-spec-insp-activities-cask-loading-misalignment.html?>

OVERALL CONCLUSIONS:

Based on the review of event data and assessment of key events, the staff concludes that the Nuclear Materials and Waste Safety Program is functioning effectively to protect public health and safety. The staff concluded that there are no discernible adverse licensee performance trends or significant nuclear materials issues. However, there was one licensee that the staff identified as meeting the AARM licensee discussion criteria with a significant performance issue.

COORDINATION:

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



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THE NUCLEAR MATERIALS AND WASTE SAFETY PROGRAM FISCAL YEAR
2018

ML19065A225 (Package)

WITS TICKET NO. 200200096/NMSS-2019-00088

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NAME	LDudes for CHaney	JGiessner for DRoberts	AVegel for SMorris	FPeduzzi for GWilson	SKirkwood for: MZobler
DATE	4/ 24 /2019	4/ 24 /2019	4/ 24 /2019	4/ 23 /2019	4/30/2019
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