

**POLICY ISSUE**  
**(Information)**

April 17, 2018

SECY-18-0048

FOR: The Commissioners

FROM: Marc L. Dapas, 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 2017

PURPOSE:

This paper provides the 16th annual report on significant nuclear materials issues and licensee performance trends in the Nuclear Materials and Waste Safety Program 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 following revised criteria identified 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 (ML082480564), as well as SECY-11-0132, "Revision of the Criteria for Identifying Nuclear Material Licensees for Discussion at the Agency Action Review Meeting," dated September 20, 2011 (ML112280111). This report covers fiscal year (FY) 2017. This paper does not address any new commitments or resource implications.

CONTACT: Robert Sun, NMSS/MSST  
301-415-3421

SUMMARY:

For FY 2017, the staff evaluated significant nuclear materials issues and licensee performance trends based on aggregated information obtained from operating experience associated with reportable events and generic concerns affecting these categories of 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, from the assessment of the overall performance data, that there are no discernible adverse licensee performance trends or generic concerns and that public health and safety was maintained. The staff identified no nuclear materials licensees that met the criteria, as described in SECY-11-0132, for discussion at the Agency Action Review Meeting (AARM).

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)," 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, 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, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," (ML022410435) 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 SRM-SECY-02-0216 (ML030560328), which approved the staff's proposed process for evaluating materials licensees with performance issues for discussion at the AARM, and providing the Commission with information on the Nuclear Materials and Waste Safety Program 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 the NRC's current policies and procedures. In response to the associated SRM, the staff again revised the criteria for identifying nuclear material licensees for discussion at the AARM 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 information regarding that 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.

## DISCUSSION:

The evaluation of significant issues and licensee performance trends is based on aggregated information that includes operating experience associated with reportable events and generic concerns affecting categories of nuclear materials licensees. As committed to in SECY-02-0216, the staff has developed a process for providing the Commission with annual updates on significant issues and licensee performance trends that builds on existing processes and information and has minimal impact on staff resources.

The aggregated information used to evaluate significant issues and licensee performance trends was obtained through existing processes and systems and includes the following information: strategic outcomes and performance measure data; annual assessment of events reported to the Nuclear Material Events Database (NMED); Abnormal Occurrence (AO) data; generic and/or special event study results; data derived through escalated enforcement actions; and significant licensee performance issues that were identified based on the criteria described in SECY-11-0132. The following sections present the results of the staff's evaluation with respect to this information, followed by overall conclusions about licensee performance in the Nuclear Materials and Waste Safety Program.

### Strategic Outcomes and Performance Measure Data

The staff focused on verification and validation of data generated by the NRC and the Agreement States to determine the impact on strategic outcomes and performance measures related to nuclear materials events, as reported in the NRC's FY 2019 Congressional Budget Justification (CBJ). In the FY 2019 CBJ, the agency reported no AOs 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 performance goal is less than or equal to three AOs. There were two events pending inspections and evaluation of results included in the FY 2019 CBJ, which have subsequently been determined to not be AOs. There were no occurrences in the other safety and security strategic goal performance indicators for the materials program. Therefore, the FY 2017 target is met. Copies of the FY 2019 CBJ may be found at: <https://www.nrc.gov/docs/ML1802/ML18023B460.pdf>.

### Assessment of Data Reported to NMED

The NMED contains records of events involving nuclear materials reported to the NRC by its licensees, the Agreement States, and non-licensees. These reported events are sorted by the event reporting requirements as defined in the NRC's regulations. The event reports are evaluated to identify those 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). For the purposes of the NMED Annual Report, 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). A copy of the FY 2017 NMED Annual Report is provided as Enclosure 1. 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 2008 through FY 2017, a total of 4,938 events (929 NRC and 4,009 Agreement State) associated with materials licensees were reported to the NRC, compared to 4,949 events that were reported for the previous 10-year period from FY 2007 through FY 2016. For the current 10-year period, the data indicates that the total number of events per year is relatively stable.

Although the data for “All NMED Events” indicated no statistically significant performance trends, there were some statistically significant trends related to more focused aspects of the data (See Enclosure 1, page 4, Table 1, Summary of Trending Analysis). For example, the trend analysis determined that the NRC-regulated events represent a statistically significant decreasing trend. Additionally, the total number of events and Agreement State events involving lost/abandoned/stolen material, along with the total and NRC-regulated events related to the release of licensed material or contamination, all reflected statistically significant decreasing trends. However, based on the analysis of the events, enforcement, and performance metrics data for the current 10-year period, the staff did not identify a specific reason for these observed trends. The staff did note that as a result of the transfer of authority from the NRC to four Agreement States during this 10-year period, the percentage of NRC events decreased as Agreement State events increased, though the total number of events stayed roughly the same. In addition, the NRC has performed outreach, communication, and rule change activities in the past 10 years such as: outreach efforts with Agreement States on event reportability criteria, issuance of Information Notice 2014-06, “Damage of Industrial Radiographic Equipment Due to Falling Equipment and Improper Mounting,” and issuance and implementation of Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” which may contribute to the number of reportable events.

For FY 2017, 33 of the 410 NMED events were considered to be of higher significance and are described in the FY 2017 NMED Annual Report. Note that a single event may be listed in more than one event type category. The breakdown of these significant events by category was as follows:

- 7 lost/abandoned/stolen material events;
- 11 medical events classified as AOs or potential AOs;
- 3 radiation overexposure events requiring reporting within 24 hours;
- 3 release of licensed material or contamination events;
- 6 equipment-related events;
- 1 leaking sealed source event;
- 2 transportation-related events; and
- 0 events classified as “other.”

For the 7 significant lost/abandoned/stolen material events, none of the nuclear material sources were classified as Category 1, and 6 were classified as Category 2 under the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (2004). Five of the lost Category 2 sources were subsequently recovered. The remaining unrecovered source sank on a barge in the Bering Sea. One event involved a Category 3 source, which was subsequently recovered. A summary of the significant events that occurred in FY 2017 is provided in the Executive Summary of the enclosed NMED Annual Report (Pages ix – x), and a detailed description of each event is provided in the main body of the report.

Based on analysis of the data reported to NMED, as shown in the FY 2017 NMED Annual Report, the staff did not identify any significant issues that warrant specific action or policy changes.

### Fuel Cycle Operating Experience

The Fuel Cycle Operating Experience Program (FC OpE) supports technical and licensing staff, inspectors, and management by providing insights that can inform inspection planning, licensing reviews, and program changes. The purpose of the FC OpE annual report is to provide an analysis of reported events at fuel cycle facilities that identify trends and to make recommendations to improve fuel cycle programs. A copy of the Fuel Cycle Annual Operating Experience Report 2017 is provided as Enclosure 2. Using event data from 2007 to 2017, the staff concluded: (1) a time series plot proves to be a reasonable model that shows a time series trend on the total number of events; (2) a more detailed analysis of events identified a cycle of similar events that re-appear at fuel cycle facilities every 3 to 7 years; (3) over the course of the 11-year period, the most recurring causal factors were configuration management, failure to adhere to procedures, and inadequate maintenance; and (4) a performance area analysis identified the predominant themes of reported events for facilities licensed under 10 CFR Part 70 as unexpected accumulation of special nuclear material, unanalyzed conditions or invalid assumptions in the facility Integrated Safety Analysis, and failures in Criticality Warning or Criticality Accidents Alarm Systems. For facilities licensed under 10 CFR Part 40, chemical releases are the most commonly reported event.

Based on an analysis of the FC OpE, as shown in Enclosure 2, the staff did not identify any issues that warrant significant actions or policy changes.

### AO Data

The FY 2017 Report to Congress on Abnormal Occurrences (AO Report) identifies 11 events involving nuclear materials as AOs during FY 2017. Six events involved Agreement State licensees and five events involved NRC licensees. All 11 AOs were medical events, as defined in Title 10 of the *Code of Federal Regulations* Part 35, "Medical Use of Byproduct Material."

The 11 AOs are within the statistical variation of the average of  $13 \pm 6$  AOs for each of the previous FYs since FY 2008. Two of the 11 AO events reported this year occurred in previous FYs, but the NRC completed its evaluation of these events for potential AO reporting in FY 2017. The 11 medical event AOs are approximately 0.009 percent of the estimated number of nuclear medicine and radiation therapy procedures involving radioactive material performed in the United States annually. None of the AOs caused permanent damage to an organ or resulted in physiological impairment.

The AO numbers in the FY 2017 NMED Annual Report and the FY 2017 AO Report differ slightly since the two reports cover different time periods and data sets. The FY 2017 NMED Annual Report covers those AOs that were identified in FY 2017 (this includes events that occurred in FY 2017 where a final AO determination has been made, events that occurred in FY 2017 where a final AO determination has not been made, and events that occurred in FY 2016 but were not identified until FY 2017). In comparison, the FY 2017 AO Report covers all AOs that were determined to be AOs in FY 2017 (this includes events that occurred in FY 2017

where a final AO determination has been made, and events that were reported prior to FY 2017 but a final AO determination was not made until FY 2017). This data is summarized in Table 1 below.

<i>Table 1. Number of AO's and Potential Abnormal Occurrences (PAO) reported in the FY 2017 AO Report and FY 2017 NMED Report</i>			
	Number of AO/PAO's occurring in FY17	Number of AO/PAO's occurring prior to FY17, but determination made or identified in FY17	<b>Total Number of AO's reported</b>
FY17 AO Report	9	2	<b>11</b>
FY17 NMED Annual Report	11	2	<b>13</b>

Based on its analysis (except for Y-90 microsphere medical events addressed below in a special study), the staff has not identified any trends or significant safety concerns among medical licensees. The staff continues to monitor licensee performance diligently and to provide prompt follow-up response when warranted.

#### Special Event Study Results

Pursuant to SRM-SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated December 11, 2002, the staff conducted a special event study to further analyze any observed trends during the FY.

As a result of routine inspections and the event reporting review process, the staff noted an increase in Y-90 microsphere brachytherapy medical events, which raised questions and warranted additional attention. The staff evaluated the following three areas to better understand the possible cause for the observed increase: the regulatory requirements for Y-90 microspheres; the use of post-treatment imaging to determine dose delivered to the intended site; and potential licensee performance trends. Specific license conditions for the use of Y-90 microspheres, which derive from NRC's standard license conditions, require pre-treatment imaging to verify proper catheter placement. The license conditions for the use of Y-90 microspheres give high confidence that each treatment is in accordance with the physician's (authorized user's) written directive. Post-treatment imaging to verify the dose delivered to the intended site is not required by NRC regulations or license conditions.

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) reviewed NRC's licensing guidance in 2014. As part of its review, the ACMUI examined some of the challenges in administering Y-90 microsphere treatments. Specifically, once Y-90 microspheres are injected into the vascular pathway to the treatment target, flow of the microspheres and their sites of final implantation are entirely dependent on the patient's unique vascular anatomy and blood flow dynamics. The ACMUI agreed that pre-treatment lung shunt evaluation (which is performed as an elective procedure by some licensees) and pre-treatment imaging to verify proper catheter placement is within the licensee's control in administering Y-90 microsphere treatments. The ACMUI considered both the benefits and challenges of conducting post-treatment imaging, including the lack of accuracy for dosimetry determinations given the available post-treatment

imaging technologies. Based on current post-treatment imaging capabilities, the ACMUI made no recommendation to include post-treatment imaging in the licensing guidance.

The recent medical events and AOs that raised some concerns with the NRC staff were identified during post-treatment imaging and likely would not have been identified by the licensees, nor reported to the NRC, had it not been for the post-treatment imaging. The staff suspected that a potential for increased medical event reports involving Y-90 microspheres could be related to an increase in the number of procedures performed using Y-90 microspheres as well as technological advancement in post-treatment imaging. To help inform any potential future actions, the staff took a deeper look at Y-90 microsphere medical events.

The staff asked Idaho National Laboratory (INL) to perform a case study on Y-90 microsphere medical events and AOs found in the NMED. Since Y-90 microsphere treatments began in the United States 15 years ago, the numbers of medical events reported have increased over time. A followup by the NMSS staff using Y-90 usage data from manufacturers showed that the increase in reported medical events over 15 years is commensurate with the increase of Y-90 microsphere procedures. The NMSS staff's normalized data shows that the rate of incidence of Y-90 medical events has remained steady over 15 years.

Based on the staff review of the INL case study report and analysis of trending data from NMED, negative performance trends or regulatory gaps were not found. Although the staff did not identify negative performance trends, the special event study of Y-90 microsphere medical events was helpful in examining whether NRC's regulatory framework is adequate with respect to evolving medical technologies. The staff concluded that the current requirements continue to provide reasonable assurance of adequate protection and that there is not a need to update licensing guidance to provide additional information on post-treatment imaging.

#### Data Derived Through Escalated Enforcement Actions

The following escalated enforcement actions in the Nuclear Materials and Waste Safety Program include civil penalties and Notices of Violation (NOV) for Severity Level I, II, and III violations, as well as Orders and Demands for Information. In FY 2017, the NRC issued 51 escalated enforcement actions involving NRC materials licensees (including fuel cycle facilities). The escalated enforcement actions issued in FY 2017 include:

- 1 Severity Level II Problem with no proposed civil penalty;
- 7 Severity Level III NOVs/Problems<sup>1</sup> with proposed civil penalties;
- 36 Severity Level III NOVs/Problems with no proposed civil penalty; and
- 7 Orders.

Four of the seven Orders involved Confirmatory Orders that were issued to confirm commitments associated with Alternative Dispute Resolution agreements, and two Orders involved the imposition of civil penalties. In addition, one Order prohibiting involvement in NRC-regulated activities was issued to an individual for deliberately violating the NRC's industrial radiography requirements. Nine of the 51 escalated enforcement actions involved issuance of proposed civil penalties totaling \$94,500, two of these nine actions involved Orders imposing civil penalties.

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

For FY 2017, the number of escalated enforcement actions for the Nuclear Materials and Waste Safety Program decreased by 17 (25 percent) from the total number of actions issued in FY 2016 (68). While this represents a significant decrease from the prior FY, the 51 escalated enforcement actions issued in FY 2017 are comparable to the average number of escalated actions issued to materials licensees and fuel cycle facilities for the prior 5-year period between FY 2012 and FY 2016 (50).

As in previous years, the total number of actions issued in FY 2017 were largely influenced by cases involving gauge users and radiographers. This year, the number of escalated enforcement actions issued to gauge users and radiographers remained nearly the same as in FY 2016; 17 and 9 actions respectively. Additionally, there were no escalated actions taken against materials distributors during FY 2017. This represents a sharp decrease in the number of actions taken in this licensee category when compared to FY 2016, when 14 actions were issued. The decrease of 14 actions for materials distributors accounts for more than 87 percent of the total decrease in the number of escalated enforcement actions issued in FY 2017 for the Nuclear Materials and Waste Safety Program.

#### Licensees Identified with Significant Performance Issues

SECY-11-0132 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 licensee performance trends. For FY 2017, no nuclear materials licensees were identified that met Criteria II in SECY-11-0132 for discussion at the AARM.

#### OVERALL PERFORMANCE CONCLUSIONS:

Based on the review of event data and assessment of key events, the staff concludes that the Nuclear Materials and Waste Safety Program are functioning effectively to protect public health and safety. Based on staff review using the original 2002 criteria for identifying nuclear materials licensees that warrant discussion at the AARM and subsequent revisions in 2008 and 2011, the staff has concluded that the current criteria are effective and valid, and appear to be working efficiently. For FY 2017, all lost or stolen nuclear materials sources classified as Category 1 through 3 in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (2004), were recovered, except for a single Category 2 event that was lost at sea, and was not recovered. The staff identified no nuclear materials licensees that met the criteria, as described in SECY-11-0132, for discussion at the AARM.

COORDINATION:

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

***/RA Scott Moore for/***

Marc L. Dapas, Director  
Office of Nuclear Material Safety  
and Safeguards

Enclosures:

1. Nuclear Material Events Database  
Annual Report FY 2017
2. Fuel Cycle Operating Experience  
Report 2017
3. MED Events Involving Y-90 Microsphere  
Brachytherapy FY 2008-2017

SUBJECT: ANNUAL REPORT TO THE COMMISSION ON LICENSEE PERFORMANCE IN  
THE MATERIALS AND WASTE PROGRAMS FISCAL YEAR 2017

**ML18047A733 (P)**

<b>OFFICE</b>	NMSS/MSTR	NMSS/MSTR	NMSS/MSTR	RGN I	RGN II
<b>NAME</b>	SEasson	DBollock	CEinburg for KWilliams	DLew	CHaney
<b>DATE</b>	2/16/2018	2/16/2018	2/26/2018	3/6/2018	3/7/2018
<b>OFFICE</b>	RGN III	RGN IV	NSIR	OI	OE
<b>NAME</b>	SWest	ATannenbaum for KKennedy	BMcDermott	TSolomon for S.Langan	ABoland
<b>DATE</b>	3/13/2018	3/6/2018	3/7/2018	3/6/2018	3/7/2018
<b>OFFICE</b>	OGC (NLO)	Tech Ed	NMSS		
<b>NAME</b>	MDoane	LMoorin	MDapas		
<b>DATE</b>	3/14/2018	3/15/2018	4/17/2018		

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