



POLICY ISSUE

(Information)

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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 2019

PURPOSE:

This paper provides the annual report for fiscal year (FY) 2019 on significant nuclear materials issues and licensee performance trends in the Nuclear Materials and Waste Safety Program¹. This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2019, 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 did not identify any Nuclear Materials and Waste Safety Program licensees that met the criteria for discussion at the Agency Action Review Meeting (AARM).

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

¹ Independent Spent Fuel Storage Installation and Decommissioning licensee trends are not specifically tracked as a part of this paper. The FY2019 Decommissioning Program annual report is available at <https://www.nrc.gov/docs/ML1928/ML19282A391.html>

BACKGROUND:

On June 28, 2002, the Commission issued Staff Requirements Memorandum (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 revised 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 following information is used to evaluate significant issues and licensee performance trends: (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) Integrated Materials Performance Evaluation Program (IMPEP) significant actions; (6) programmatic self-assessment results and improvements; (7) data derived through escalated enforcement actions; and (8) 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 2021 Congressional Budget Justification (ADAMS Accession No. ML20024D764), the agency reported its FY 2019 performance results. While the agency met its performance goals, there were two areas to highlight with respect to safety and security. For the safety category, there was only one occurrence reported. The one occurrence did not exceed the specific indicator's target of ≤ 3 . For the security category, there was only one occurrence reported as well. However, this one occurrence did exceed the specific indicator's target of 0.

The one safety related occurrence involved an internal radiation overexposure to a licensee employee who was trying to clean up a small area of contamination. The employee used a

high-efficiency particulate air (HEPA) vacuum however, this vacuum had previously been used to clean up americium-241 metal. The employee turned on the vacuum and noticed it was blowing out debris. As a result, the employee received an internal exposure of 2,990 mSv (299 rem) to the maximally exposed organ (bone). The primary root cause was determined to be the failure of a HEPA vacuum. Additional factors contributing to this event were improper use of a HEPA vacuum (use of the vacuum in an area for which it was not designed), inadequate procedures, and poor emergency training. Several actions were taken by the licensee to prevent recurrence including revising its radiation protection procedures to prohibit the use of potentially contaminated equipment in areas where contamination is not expected and to clearly define the procedures to follow during an emergency, and training for the licensee's staff. The licensee does not expect any adverse health effects to the employee from this event.

The one security related occurrence involved the unauthorized removal of three industrial radiography cameras by a licensee employee without authorization. The devices were recovered, and the licensee upgraded its access security measures to prevent a single authorized individual from removing the devices.

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. ML20044D670). Previous NMED Annual Reports, which include a detailed description of individual events, are available 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 2010 through FY 2019, a total of 4,569 events (738 NRC and 3,831 Agreement State) associated with materials licensees were reported to the NRC, compared to 4,577 events that were reported for the 10-year period from FY 2009 through FY 2018. The ratio of NRC events to Agreement State events (16 percent NRC events; 84 percent Agreement State events from FY 2010 through FY 2019) is consistent with the ratio of NRC licensees to Agreement State licensees (13 percent NRC licensees; 87 percent Agreement State licensees in FY 2019). 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.

A statistically significant decreasing trend over the 10-year period was identified in the overall number of NRC-regulated events. However, the decreasing number of NRC-regulated events is consistent with the decreasing number of NRC licensees over the 10-year period as more NRC-regulated states shift into Agreement States. The NRC staff concluded that this trend was not an indication of a significant issue or performance trend.

Based on analysis of the data reported to NMED, the staff determined that events reported in FY 2019 reflect healthy and consistent event reporting across both NRC and Agreement State licensees and did not identify any significant issues that warrant specific action or policy changes.

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 analysis of CY 2019 events (ADAMS Accession No. ML20010E852), the staff concluded that: (1) the most common areas for reported events continue to be criticality and operational safety, involving unanalyzed conditions and failures in Criticality Warning or Criticality Accidents Alarm Systems; and (2) the most common contributing factors continue to be failures or degradation in management measures (e.g., configuration management, maintenance, adherence to procedures).

Abnormal Occurrence Data

The FY 2019 Report to Congress on AO contained nine FY 2019 events involving nuclear materials as AOs. All nine events involved Agreement State licensees. Two events were the internal radiation overexposure and the unauthorized removal of three industrial radiography cameras already discussed. The remaining seven AOs were medical events. The seven medical event AOs are a very small percentage, approximately 0.006 percent, of the estimated number of nuclear medicine and radiation therapy procedures involving radioactive material performed in the United States annually².

Based on its analysis of the events, the staff did not identify any safety significant trends or significant safety concerns among medical licensees. However, the staff has issued several generic communications to alert the medical community on topics including: Yttrium-90 medical events, Strontium-82/Rubidium-82 generator elution events and issues, methods to prevent medical events, and patient skin contamination events associated with I-131 Metaiodobenzylguanidine during neuroblastoma treatments. These information notices can be found at: <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2019/>

Integrated Materials Performance Evaluation Program

The IMPEP continues to be effective in fulfilling its objective of evaluating adequacy and compatibility of Agreement State and NRC materials activities. Agreement State and NRC Programs continue to adequately protect public health and safety. During FY 2019, NRC and Agreement State staff conducted 11 IMPEP reviews. The IMPEP teams did not identify major performance issues regarding the protection of health and safety compatibility of Agreement State or NRC regional materials programs. Additional details can be found in the "Annual Report on Agreement States and U.S. Nuclear Regulatory Commission's Radioactive Materials Programs for Calendar Year 2019," (ADAMS Accession No. ML20066H908).

² Based on data in the IMV Benchmark Report Radiation Therapy October 2010, IMV Medical Division, Inc.

Programmatic Self-Assessments and Improvements

In 2019, the staff became aware of on-site contamination at some fuel facilities, revealed through licensee submitted concurrent reports to state environmental agencies. Although the issues were not safety significant, licensing and inspection staff, using a questioning attitude, collaborated to explore the ability of our inspection and licensing programs to appropriately identify and assess licensees' compliance with the decommissioning planning rule in Title 10 of the *Code of Federal Regulations* 20.1406. This rule requires that licensees, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface. The staff identified an opportunity to enhance inspection procedures and licensing guidance in this area.

Recognizing the need to identify potential program enhancements and to continue to make fuel cycle licensing and oversight programs more risk-informed, the staff initiated the "Building a Smarter Fuel Cycle Program" effort in April 2019. As part of this effort, a working group (WG) was formed to conduct a holistic assessment of the fuel cycle inspection program to improve the effectiveness and efficiency of the program. The staff evaluated operating experience, risk insights, inspection data, and lessons learned from previous events to develop recommendations for enhancement. Additionally, the staff solicited input from internal and external stakeholders and incorporated feedback into the recommendations, as appropriate. The recommended enhancements include: 1) modifications to inspection frequencies and resource estimates associated with completion of inspection procedures; 2) modifications to inspection procedures to reduce overlaps; and 3) modifications to inspection frequencies of inspection procedures for facilities with an NRC approved corrective action program (See working group report at ADAMS Accession No. ML20073G659). These enhancements will ensure that appropriate focus is applied to inspection areas that provide the greatest safety benefit in determining that a facility is operating safely and in accordance with regulatory requirements.

In June 2019, the NRC staff formed a WG to evaluate and enhance the Independent Spent Fuel Storage Installation (ISFSI) inspection program. The WG used an objective process that considered probabilistic risk analyses, byproduct material radiation exposure studies, subject matter expertise, operating experience, and lessons learned from 30 years of ISFSI inspection experience to inform recommended enhancements to the program. The WG also solicited and considered input from internal and external stakeholders in the development of the recommendations. The recommendations would result in a more risk-informed inspection program that includes: 1) a triennial inspection frequency for routine inspections; 2) adding a cross qualification program for existing inspectors to facilitate full or partial ISFSI inspector qualification; 3) a revised level of effort for each applicable inspection procedure; and 4) consolidating funding for ISFSI inspections into one business line. The working group also recommended follow-on efforts to further assess areas for enhancement that were not covered by this effort (see working group report at ADAMS Accession No. ML20078P093). These enhancements provide for a more risk-informed inspection program that focuses on areas most important to safety and provide a comprehensive and consistent approach to oversight of spent fuel storage across NRC regional offices.

Escalated Enforcement Action Review

Escalated enforcement actions include Severity Level I, II, and III Notices of Violation (NOVs); civil penalties; NOVs to individuals; Orders to modify, suspend, or revoke NRC licenses or the authority to engage in NRC-licensed activities; and Orders issued to impose civil penalties. In

FY 2019, the NRC issued 40 escalated enforcement actions involving NRC materials licensees (including fuel cycle facilities).

For FY 2019, the number of escalated enforcement actions for the Nuclear Materials and Waste Program increased by three (8 percent) from the total number of actions issued in FY 2018 (37). While this represents an increase over the prior FY, the 40 escalated enforcement actions issued in FY 2019 are approximately 18 percent less than the average annual number of escalated actions issued to materials licensees and fuel cycle facilities for the prior five-year period, between FY 2014 and FY 2018 (49).

Licensees Identified with Significant Performance Issues

For FY 2019, no nuclear materials licensees were identified that met Criteria II in SECY-11-0132 for discussion at the AARM.

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 is no discernible adverse licensee performance trends or significant nuclear materials issues.

COORDINATION:

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

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

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