



POLICY ISSUE

(Information)

DATE: May 3, 2022 **SECY-22-0041**

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 FOR FISCAL YEAR 2021

PURPOSE:

This paper provides the annual report for fiscal year (FY) 2021 on significant nuclear materials issues and licensee performance trends in the Nuclear Materials and Waste Safety Program.¹ This paper does not address any new commitments or resource implications.

SUMMARY:

For FY 2021, 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. This evaluation included both the U.S. Nuclear Regulatory Commission (NRC) and Agreement State licensees, except for the review of escalated enforcement actions, which is focused on NRC licensees since Agreement States conduct their own enforcement programs. The staff concluded that there are no significant nuclear materials issues or discernible adverse trends in licensee performance and that public health and safety were 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) that will be held on May 5, 2022.

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¹ Consistent with previous years' reports, this paper does not specifically track independent spent fuel storage installation trends. Fuel facility licensee trends are also not specifically tracked in this report. Decommissioning licensee trends are discussed in the FY 2021 Decommissioning Program annual report (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21280A400), which is available at <https://www.nrc.gov/docs/ML2128/ML21280A400.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)" (ADAMS Accession No. ML021820604). 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 (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 that were discussed at a previous AARM, but their corrective actions were ineffective in correcting the underlying performance issues. The Commission received the revised criteria for identifying nuclear materials licensees for discussion at the AARM 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 NRC staff evaluated significant issues and licensee performance trends for FY 2021 using strategic outcomes and performance measure data, assessment of data reported to the Nuclear Material Events Database (NMED), abnormal occurrence (AO) data, Integrated Materials Performance Evaluation Program (IMPEP) significant actions, input related to the Coronavirus Disease 2019 (COVID-19) Pandemic, programmatic self-assessment results and improvements, data derived from escalated enforcement actions, and significant licensee performance issues. The sections below present the results of the staff's evaluation with respect to this information, followed by overall conclusions on significant issues and licensee performance in the Nuclear Materials and Waste Safety Program.

Strategic Outcomes and Performance Measure Data

In the FY 2021 Agency Financial Report (AFR) (ADAMS Accession No. ML21348A037), the agency reported its FY 2021 performance results. The agency met its performance goals for both safety and security, with no occurrences of events that met the reporting criteria. The FY 2021 AFR is available at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2220/v5/index.html#abs>.

Annual Assessment of Event Data

The staff reviews materials events to ensure timely responsiveness and a level of management involvement appropriate to the event's significance. The Headquarters Operations Officer immediately reviews events requiring formal reports to the NRC Operations Center to determine whether they are significant enough to warrant immediate agency management awareness and possible action. Regional coordinators in the Office of Nuclear Material Safety and Safeguards (NMSS) review all materials events reported to the Operations Center and evaluate them against AO and International Nuclear Event Scale reporting criteria. Agency management is briefed when necessary, depending on the significance and severity of the event. Response to significant events is managed with the appropriate level of agency resources, ranging from review by Analysis and Trending Groups (ATGs) to reactive inspections and orders issued to licensees.

Throughout the year, the ATGs identify possible issues or trends that may require additional agency action. Regional coordinators also review significant international events. For FY 2021, no significant generic implications or trends were identified.

The staff did issue an Information Notice to alert licensees of recent issues associated with monitoring occupational exposure to radiation from licensed and unlicensed radiation sources. The Information Notice resulted from NRC-identified issues at medical-use licensees with compliance issues associated with interventional radiology physicians who conducted licensed activities under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000, "Other medical uses of byproduct material or radiation from byproduct material." This Information Notice can be found at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2021/index.html>. While useful to share with licensees in a generic communication, the seven occurrences identified over a two-year period represent a very small percentage of nuclear medicine and radiation therapy procedures and do not represent a significant trend. As part of the ATG review, the staff and the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) also conduct a medical event review each year. The review includes the causes of those events, if known, as well as any recommendations for action. For FY 2021, the ACMUI Subcommittee on Medical Events concluded that the number of medical events for the prior year was low, consistent with previous years (ADAMS Accession No. ML21288A127). The Committee also recommended an ACMUI subcommittee be formed to focus on yttrium-90 events, which make up a significant portion of all medical events, and for the subcommittee to propose, in consultation with the vendors, methods to decrease the number of these events.

The staff also reviews reports in NMED from NRC licensees, the Agreement States, and non-licensees, to identify safety-significant trends and common causes. The staff analyzes the NMED data for the main event types, aggregated for the evaluation of potential trends, and presented in an annual summary report that includes a detailed description of individual events. The FY 2021 report can be found at ADAMS Accession No. ML22049B538, and previous reports are available at <https://nmed.inl.gov/>.

To account for random fluctuations in the event data from year to year and to assess any trends, the staff reviews the data from the last 10 FYs. For the 10-year period from FY 2012 through FY 2021, a total of 4,476 events (670 NRC and 3,806 Agreement State) associated with materials licensees were reported to the NRC, compared to 4,512 events that were reported for the 10-year period from FY 2011 through FY 2020. The ratio of NRC events to Agreement

State events (15 percent NRC events; 85 percent Agreement State events, from FY 2012 through FY 2021) is consistent with the ratio of NRC licensees to Agreement State licensees (13 percent NRC licensees; 87 percent Agreement State licensees, in FY 2021). These events represent a very small proportion of the total number of activities carried out. For the current 10-year period, the data indicate that the total number of events per year is stable.

A statistically significant decreasing trend over the 10-year period was identified in the number of events in NRC jurisdiction (total number, combining all event types). However, the decreasing number of NRC-regulated events is consistent with the decreasing number of NRC licensees over the 10-year period as additional Agreement States began regulation. The NRC staff concluded that this trend was not an indication of a significant issue or performance trend.

Based on an analysis of the data reported to NMED, the staff determined that events reported in FY 2021 reflect consistent event reporting across both NRC and Agreement State licensees.

Abnormal Occurrence Data

The staff identified seven potential AOs related to the medical use of byproduct materials, which is comparable to the number of AOs in prior years. This number of potential AOs is a very small percentage of the estimated number of nuclear medicine and radiation therapy procedures performed in the United States annually. Based on its analysis of the events, the staff did not identify any safety-significant trends or safety concerns.

Integrated Materials Performance Evaluation Program

The IMPEP continues to be effective in fulfilling its objective of evaluating the adequacy and compatibility of Agreement State and NRC materials programs. Agreement State and NRC programs continue to adequately protect public health and safety, despite challenges presented by the COVID-19 pandemic. During FY 2021, the NRC and Agreement State staffs conducted nine IMPEP reviews. All nine programs were found adequate to protect public health and safety and the eight Agreement State programs were found compatible with the NRC's regulatory program. Additional details appear in the "Annual Report on Agreement States and the NRC's Radioactive Materials Programs for Calendar Year 2021," issued on April 13, 2022 (ADAMS Accession No. ML22080A218).

Escalated Enforcement Action Review

Escalated enforcement actions include Severity Level I, II, and III notices of violation; civil penalties; notices of violation to individuals; and orders to modify, suspend, or revoke NRC licenses or the authority to engage in NRC-licensed activities. In FY 2021, the NRC issued 32 escalated enforcement actions involving Nuclear Materials and Waste Safety Program licensees. The total number of actions increased by two from FY 2020 but remained consistent with the average of 33 actions per year over the last four years. The staff did not identify generic trends that warrant detailed analysis.

Licensees with Significant Performance Issues

For FY 2021, the staff identified no nuclear materials licensees that met the criteria in SECY-11-0132 for significant performance issues warranting discussion at the AARM.

Nuclear Materials and Waste Safety Oversight During the COVID-19 Pandemic

Nuclear materials and waste oversight activities include programmatic oversight and inspection activities of decommissioning facilities; uranium recovery; low-level waste facilities; fuel cycle facilities; spent fuel storage and transportation; and academic, industrial, and medical uses of nuclear materials. NRC inspection activities verify licensee compliance with the Commission's regulations and thus provide reasonable assurance of adequate protection of public health and safety. As a response to the COVID-19 pandemic, NRC allowed for flexibilities in accomplishing the inspection program. Inspections have been conducted onsite, remotely, or in a hybrid approach with onsite and remote inspection. Inspectors and license reviewers from across the NRC regional offices and headquarters have cooperated to accomplish the highest-priority mission work. The staff continues to coordinate with licensees to ensure the safety of both NRC staff and site personnel. When delays or deviations from the applicable inspection manual chapter were necessary due to COVID-19 considerations, the delays or deviations were tracked, and the NRC staff worked with the affected licensee to put plans in place for completing the inspection as soon as practicable.

NMSS has coordinated with the Office of Nuclear Reactor Regulation on issuing parallel guidance regarding the implementation of the inspection programs upon the staff's reentry from maximum telework to a hybrid work environment. On November 2, 2021, NMSS issued a memorandum (ADAMS Accession No. ML21294A278) providing updated guidance for the implementation of the inspection programs during this transition. This memorandum indicates that inspection programs should be implemented in accordance with the respective Nuclear Materials and Waste Safety Program inspection manual and procedures. It provides certain flexibilities and specifies when to interact with business line leads.

Audit of NMSS COVID-19 Pandemic Oversight Processes

The Office of the Inspector General (OIG) evaluated the NRC's nuclear materials and waste oversight processes during the COVID-19 pandemic and documented their findings in report "Audit of COVID-19's Impact on Nuclear Materials and Waste Oversight (OIG-21-A-15)," dated September 23, 2021 (ADAMS Accession No. ML21266A130). The audit found the NRC's nuclear materials and waste oversight processes during the COVID-19 pandemic have generally been effective in helping the NRC accomplish its mission; however, OIG identified opportunities for strengthening the process during prolonged work disruptions. The OIG made five recommendations to strengthen the agency's approach to conducting its mission during prolonged work disruptions that involve improvements to agency guidance to address inspections during prolonged work disruptions, and enhancements to the Web-Based Licensing (WBL) systems, and guidance to manage recordation of inspection data.

The WBL system was originally deployed for the Nuclear Materials Users business line and has since evolved to include data management and dashboards for licensing and oversight, as appropriate, across all Nuclear Materials and Waste Safety business lines. The NRC staff continues to enhance WBL to expand its usage to meet the needs of the agency, including recommendations from the OIG.

NMSS COVID-19 Pandemic Oversight Activities Assessment

A staff working group evaluated the various practices, adjustments, processes, and inspection techniques used to implement the Nuclear Materials and Waste Safety Program during the COVID-19 pandemic. To accomplish this, the working group conducted outreach to staff via a series of surveys and interviews, held a government-to-government meeting with the Agreement States, and held two public meetings in July and August 2021. External stakeholders: (1) were appreciative of the communication and coordination efforts by the staff to conduct inspections during the pandemic; (2) regarded the use of electronic reading rooms, remote exit meetings, and virtual interviews as very effective and expressed these should continue to be leveraged; and (3) observed the flexibility and responsiveness of the staff during the pandemic.

On November 24, 2021, the working group issued its report (ADAMS Accession No. ML21294A368). The group concluded that the Nuclear Materials and Waste Safety oversight programs remained effective during the COVID-19 pandemic and that the staff continued to demonstrate creativity, innovation, flexibility, and resiliency to best accomplish the objectives of the inspection programs. The working group provided eight recommendations to enhance the implementation of these programs during the COVID-19 pandemic (or any future pandemics or public health emergencies) and to enhance aspects of the current framework for the oversight programs.

The staff is holistically evaluating the working group recommendations for adoption in concert with other ongoing activities to update inspection manual chapters across the Nuclear Materials and Waste Safety Program. Of note, the staff is developing specific guidance for future pandemics that can be included in relevant manual chapters, consistent with a recent recommendation by the NRC Inspector General in OIG-21-A-15, "Audit of COVID-19's Impact on Nuclear Materials and Waste Oversight," dated September 23, 2021 (ADAMS Accession No. ML21266A130).

A Coordinated, "OneNMSS" Approach to Nuclear Materials and Waste Safety

In NMSS, the four main business lines (Nuclear Materials Users, Spent Fuel Storage and Transportation, Fuel Facilities, and Decommissioning and Low-Level Waste) have discrete functions across a wide variety of licensees and technologies. In addition, NMSS has integrated reactor-related functions as the Centers of Expertise in rulemaking, environmental reviews, and financial assurance reviews are housed in the office. The office continues to seek ways to harmonize and streamline approaches across this variety of work and programs, adopting a "OneNMSS" approach wherever possible and explaining differences if necessary.

For example, multiple program areas are taking similar approaches to modernize and risk-inform their inspection programs. In FY 2021, the reactor decommissioning, fuel cycle, uranium recovery, and spent fuel and transportation inspection manual chapters were updated and published. The staff is currently working on materials decommissioning and nuclear materials manual chapters and associated inspection procedures. These updates have incorporated risk insights to focus inspection effort to areas providing the greatest safety benefit. In addition, NMSS embarked on a coordinated approach to periodically review and update its inspection documents, as well as to fully document "program adjustments" when approaches different from those documented in inspection guidance are necessary. The office issued interim guidance on inspection activities in a memorandum dated February 19, 2021 (ADAMS Accession

No. ML21048A030 [non-public]). The business line managers are taking the necessary steps to align and implement the expectations provided in this memorandum.

The office is also updating and centralizing its procedures for operating experience programs. In the past, the different business lines have assessed operating experience in different ways. NMSS is now seeking a coordinated program to systematically review operating experience, assess its significance, provide timely and effective communication to stakeholders, and apply the lessons learned to regulatory decisions and programs. The new coordinated program will have a shared template, consistent due dates, and established responsibilities. The changes to the program will create consistency in the operating experience program framework but will not limit the flexibility needed for each program area to perform a meaningful assessment of data. The procedural revisions will be complete and incorporated into the program by next year's AARM.

Finally, NMSS is taking a single approach to make greater use of technology and data-driven decision-making. NMSS launched the Data Foundation to increase the use of data-driven decision-making and dashboards, leveraging program-wide enhancements and expansion to the use of the WBL system. In coordination with the Office of the Chief Financial Officer and Embark Venture Studios in the Office of Nuclear Reactor Regulation (NRR), the staff has deployed a total of 14 dashboards as a part of the Data Foundation to date covering a range of uses, such as: monitoring sources, providing key metric data, inspection planning and timeliness, and facilitating licensing actions.

Programmatic Self-Assessment and Improvement

Self-assessment of the Waste Incidental to Reprocessing Program

In 2021, NMSS completed a self-assessment of the Waste Incidental to Reprocessing (WIR) program (ADAMS Accession No. ML21168A265 [non-public]). The scope of the WIR program includes required consultation and monitoring activities for Department of Energy (DOE) sites in the states of South Carolina and Idaho, as directed in the FY 2005 National Defense Authorization Act, as well as consultation activities performed at DOE's request for sites located in other states. The staff conducted the self-assessment to evaluate the performance of the WIR program and identify potential improvements to make the program more effective, efficient, and risk-informed. One driver for the self-assessment was a potential increase in workload given DOE's plans to accelerate certain WIR-related activities, such as closure of legacy underground storage tanks.

The self-assessment provided an opportunity to communicate best practices, promote knowledge management, consider the effectiveness of internal and external communications, and identify any needed improvements to guidance. The assessment methodology included a review of relevant documentation as well as interviews with cognizant staff to obtain their perspectives on program strengths, challenges, and opportunities for improvement. The self-assessment found that the WIR program has been effective in meeting its objectives through a risk-informed, performance-based approach. The program consistently generates high-quality products that provide a sound technical basis to support NRC's WIR consultation and monitoring roles. The self-assessment also identified two recommendations that could improve program effectiveness and efficiency: (1) improvements to guidance and (2) enhanced communications. The results of the self-assessment appear in a report dated June 24, 2021 (ADAMS Accession No. ML21168A265 [non-public]).

The staff has begun implementing activities under each recommendation. Periodic WIR program meetings have been reinstated on a quarterly basis to discuss lessons learned, best practices, and items of interest across the WIR program. Staff developed a “WIR Hub” using Microsoft Teams and has continued to add features and content to facilitate communication and knowledge sharing across the program. In the area of guidance development, staff performed an initial scoping assessment for the revision of NUREG-1854, *NRC Staff Guidance for Activities Related to U.S. Department of Energy Waste Determinations* and compiled other WIR guidance materials that could serve as useful examples. In FY 2022, staff is developing a delegation of authority memorandum to clarify roles and responsibilities and is performing an assessment of site-specific communication plans to determine whether a generic WIR communication plan would be beneficial.

Very Low Safety Significance Issue Resolution Process for Nuclear Materials

In 2021, an NMSS working group drafted screening criteria for assessing and dispositioning issues of low safety significance arising during inspections, where there is uncertainty regarding the licensing basis for these issues (known as very low safety significance issue resolution or VLSSIR). Consistent language on this topic is being added to all relevant inspection manual chapters as part of the update described above. In addition, the working group conducted a series of tabletop exercises that applied the screening criteria to oversight issues across the Nuclear Materials and Waste Safety Program. Leveraging progress in NRR on VLSSIR, NMSS staff is evaluating the use of this approach on a case specific basis to assess risk to independent spent fuel storage installation handling operations during extreme weather events. The working group also began exploring ways to incorporate principals of VLSSIR in licensing reviews, similar to NRR’s concept of Risk Informed Process Evaluations.

CONCLUSION:

Based on the review of event data and self-assessments documented in this paper, the staff concluded 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. The staff is implementing a variety of enhancements to incorporate risk insights, use technology, and apply lessons learned from the COVID-19 pandemic.

COORDINATION:

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



Signed by Lubinski, John
on 05/03/22

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