



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 FOR FISCAL YEAR 2022

PURPOSE:

This paper provides the annual report for fiscal year (FY) 2022 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 2022, 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 U.S. Nuclear Regulatory Commission (NRC) and Agreement State licensees. The review of escalated enforcement actions is focused on NRC licensees because data are readily available only for enforcement

CONTACT: Jennifer Fisher, NMSS/MSST
301-415-1456

¹ The Nuclear Materials and Waste Safety Program is implemented through the Nuclear Materials Users, Fuel Facilities, Spent Fuel Storage and Transportation, and Decommissioning and Low-Level Waste business lines. The High-level Waste (HLW) business line was not included in this annual report. There were limited Nuclear Waste Policy Act activities which occurred in FY 2022, as part of the HLW business line. The NRC continued to provide a monthly update to Congress on the status of its remaining Nuclear Waste Fund appropriations, completed knowledge management activities, and provided support and advice in NRC proceedings. No significant nuclear materials issues and licensee performance trends were applicable.

actions taken by the NRC.² The staff concluded that there were 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 10, 2023.

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)" (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 "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance," dated December 11, 2002 (SECY-02-0216; ML022410435). On February 25, 2003, the Commission issued SRM-SECY-02-0216 (ML030560328), which approved the staff's proposed criteria and process and directed the staff to provide the report on an annual basis. Subsequently, in "Revision of the Criteria for Identifying Nuclear Materials Licensees for Discussion at the Agency Action Review Meeting," dated September 16, 2008 (SECY-08-0135; 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 revised criteria for identifying nuclear materials licensees for discussion at the AARM were included in "Revision of the Criteria for Identifying Nuclear Material Licensees for Discussion at the Agency Action Review Meeting," dated September 20, 2011 (SECY-11-0132; ML112280111). Annually, the staff evaluates the Nuclear Materials and Waste Safety Program licensees per the process described in Management Directive 8.14, "Agency Action Review Meeting" (ML18073A211).

DISCUSSION:

The staff evaluated significant issues and licensee performance trends for FY 2022 using strategic goals and performance measure data, significant licensee performance issues, data derived from escalated enforcement actions, operating experience reports, assessment of data reported to the Nuclear Material Events Database (NMED), abnormal occurrence (AO) data, Integrated Materials Performance Evaluation Program (IMPEP) significant actions, and programmatic self-assessment results and improvements. The sections below present the results of the staff's evaluation.

At the 2023 AARM, a representative from the Organization of Agreement States will participate in the Nuclear Materials and Waste Safety Program portions of the meeting virtually. This

² The NRC Enforcement Policy is not a matter of compatibility for Agreement States to implement.

involvement recognizes the increasing contribution of the Agreement States to the execution of the National Materials Program.³

Licensees with Significant Performance Issues

For FY 2022, the staff did not identify any licensees that met the criteria in SECY-11-0132 for significant performance issues warranting discussion at the AARM.

Strategic Goals and Performance Measure Data

In the Annual Performance Plan and Report (ML23038A113), the agency reported its FY 2022 performance results. The staff's performance relative to Strategic Goal 1, "Ensure the Safe and Secure Use of Radioactive Materials," is directly relevant to the assessment in this paper. All four business lines met the Agencywide Performance Indicators established for licensing, inspection, enforcement, and allegations. The Fuel Facilities, Decommissioning and Low-level Waste, and Spent Fuel Storage and Transportation business lines met all performance goals and indicators associated with the safe and secure use of radioactive materials.

The Nuclear Materials Users business line met all but one of its strategic goal performance indicators for the safe and secure use of radioactive materials. In FY 2022, two (Mississippi and Washington) of the thirteen reviewed Agreement State programs had more than one unsatisfactory IMPEP performance indicator. A Management Review Board (MRB), comprised of NRC senior managers and an Agreement State representative, reviewed IMPEP results for Mississippi and Washington Agreement State radiation control programs and found their performance adequate, but needing improvement. Neither program was found to be compatible with the NRC's nuclear materials program.^{4,5} Because of the significance of IMPEP findings in the Mississippi Agreement State Program, the Commission acted on an MRB recommendation to place that program on probation on October 4, 2022.⁶ The MRB Chair determined that the Washington Agreement State Program should enter a period of heightened oversight, based on the results of its IMPEP review. The NRC is actively engaging with these programs to provide support consistent with their respective performance improvement plans.

The NRC increases its early engagement with all Agreement States when challenges are raised informally. To address broader contributing issues, the Office of Nuclear Material Safety and Safeguards (NMSS) formed a joint working group with the Agreement States to assess the National Materials Program and identify if potential enhancements are necessary to provide for the effective and proactive assessment of performance across the program.

³ The National Materials Program is a broad and collective effort within which the NRC and the Agreement States function in carrying out their respective regulatory programs for radioactive material. The goal of the National Materials Program is the protection of public health, safety, security, and the environment associated with the hazards of radioactive material while effectively using regulatory resources.

⁴ In a July 21, 2022, letter to the Mississippi State Department of Health (ML22178A114), the NRC shared the results from the MRB review of the IMPEP results. The IMPEP was held on February 7 - 11, 2022.

⁵ In an August 12, 2022, letter to the Secretary of Health of Washington State (ML22206A205), the NRC shared the results from the MRB review of the IMPEP results. The IMPEP was held on March 28, 2022 to April 1, 2022.

⁶ "Placement of the Mississippi Agreement State Program on Probation," dated October 4, 2022 in the *Federal Register* (FR) (87 FR 60212).

Escalated Enforcement Action Review

Escalated enforcement actions include notices of violation (NOVs) for Severity Level I, II, and III violations; civil penalties; NOVs to individuals; and orders to modify, suspend, or revoke NRC licenses or the authority to engage in NRC-licensed activities. In FY 2022, the NRC issued 52 escalated enforcement actions involving Nuclear Materials and Waste Safety Program licensees. The 13-year average for the Nuclear Materials and Waste Safety Program is 55 escalated enforcement actions per year, which is consistent with this year's total.⁷

In FY 2022, the Fuel Facilities,⁸ Decommissioning and Low-Level Waste, and Spent Fuel Storage and Transportation business lines issued one, three, and zero escalated enforcement actions, respectively.

In FY 2022, the Nuclear Materials Users business line issued 48 escalated enforcement actions to NRC licensees. The NRC regulated 2,120 material licensees in FY 2022.⁹ Approximately 2 percent of NRC licensees within the Nuclear Materials Users business line received an escalated enforcement action. The 13-year average for escalated enforcement within the Nuclear Materials Users business line is 49 escalated enforcement actions per year. When the escalated enforcement actions were normalized by the number of licensees regulated within that year, the trend did not demonstrate a significant increase or decrease over time. Instead, the 13-year dataset demonstrated variability between 1 and 3 percent.

Operating Experience

Fuel Facilities

The FY 2022 Fuel Cycle Operating Experience Report (ML23026A291) described a review of fuel cycle facility event reports from FY 2022 and part of calendar year 2021. Twenty total events were reported at fuel facilities in FY 2022; however, concurrent reports and trips/falls were screened out to focus on the 11 remaining event notifications. Of these 11, three were radiation protection performance area events, four were criticality safety performance area events, three were construction performance area events, and one was an operational safety fire performance area event. The safety significance of two apparent violations continued to be evaluated. The remaining events either resulted in no enforcement action, or were dispositioned as minor, noncited violations or as NOVs for Severity Level IV violations. There was an increase in FY 2022 events compared to the previous year, but the number of events was not significantly higher than the 10-year average. Failure and/or degradation of management measures continued to be the most common contributing factor to events and should continue to be an area of inspection focus.

⁷ The agency's reliable dataset of escalated enforcement actions is from 2009 onward. The NRC Office of Enforcement dashboards were used to collect and assess this information.

⁸ The staff notes that an assessment of enforcement actions pertaining to security inspections is underway. If a trend is identified, the staff will notify the Commission through the calendar year 2022 "Report to Congress on the Security Inspection Program for Operating Commercial Power Reactors and Category I Fuel Cycle Facilities: Results and Status Update."

⁹ STC-22-073, "Annual Count of Active Radioactive Material Licenses in the National Materials Program," dated December 7, 2022 (ML22340A465).

Spent Fuel Storage and Transportation

The FY 2022 Independent Spent Fuel Storage Installations (ISFSI) Operating Experience Report (ML23030B924) described a review of spent fuel storage inspection findings from FY 2022. This included inspection findings from both Certificate of Compliance holders and licensees. The assessment noted that violations of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 72.48, “Changes, tests, and experiments,” were the most frequently issued violation. In next year’s operating experience assessment, the staff will consider inspection findings over a 3-year period and re-evaluate 72.48 violations with a larger sample size to determine if a trend exists.

On April 15, 2022, the staff issued Enforcement Guidance Memorandum (EGM) 22-001, “Enforcement Discretion for Noncompliance of Tornado Hazards Protection Requirements at Independent Spent Fuel Storage Installations” (ML22087A496) to provide guidance on how to exercise enforcement discretion when a specific or general license of an ISFSI does not comply with its design or licensing basis for protection against environmental conditions and natural phenomena as required by 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Great Than Class C Waste.” On March 3, 2023, the staff issued EGM 22-001 Revision 1, to include applicability for storage of Greater than Class C Waste at an ISFSI (ML23061A183). Additionally, the staff is reviewing industry guidance for endorsement with clarifications and exceptions through a regulatory guide that would provide methods that the NRC staff considers acceptable to comply with protection against environmental conditions and natural phenomena. The staff expects to issue this regulatory guide prior to the expiration of EGM 22-001 in April 2024.

Decommissioning and Low-Level Waste

The FY 2022 Decommissioning and Low-Level Waste Operating Experience Report (ML22333B090) described a review of operating experience data and stated the need for external stakeholder communication by issuing information notices on fire protection at decommissioning reactors and on industrial safety at decommissioning reactors. The report recommended the development of a generic communication to clarify the requirements for the contents of 10 CFR 50.75(g), “Reporting and recordkeeping for decommissioning planning,” files that include information important to the safe and effective decommissioning of a facility.

The FY 2022 Decommissioning Program annual report (ML22286A047) summarized decommissioning activities at nuclear facilities in the United States. This report discussed the current progress and accomplishments of the NRC’s Decommissioning Program and identified key Decommissioning Program activities that the staff will undertake in the next year.

Nuclear Materials Users

The NMED Annual Report for FY 2022 (ML23023A080) provided an assessment of nuclear material events reported by NRC licensees, Agreement States, and non-licensees. The NMED data were analyzed for the main event types, aggregated for the evaluation of potential trends, and presented in an annual summary report that included a detailed description of individual events.

The annual report included an assessment of nuclear material event reports to identify statistically significant trends and significant events. To account for random fluctuations in the event data from year to year and to assess any trends, the assessment included data from the last 10 FYs. A trend analysis was performed on each event category to identify the existence or absence of a statistically significant trend. A statistically significant trend was observed if the analysis indicated that the computed fit and slope of a least squares linear model was valid at a 95 percent confidence level.

The assessment displayed plots of the annual number and trend of NMED events that occurred during the 10-year period. These trends were established for events in NRC jurisdiction, for events in Agreement States, and for the total. The trend analysis determined that the events for NRC licensees for all categories of events represented a statistically significant decreasing trend over the past 10 years. However, a statistically significant trend was not observed for all events involving Agreement State licensees, nor was there a statistically significant trend when all the event data was combined (NRC and Agreement State licensees). The staff considered whether yearly fluctuations in the number of NRC and Agreement State licensees may have influenced this trend. The staff normalized the event data by number of licensees regulated for each year. The normalized data showed a slightly decreasing trend for NRC licensees and no observed trend for Agreement State licensees. Therefore, the staff concluded that the statistically significant decreasing trend in events for NRC licensees identified in the annual NMED report was a valid observation. Based on evaluation of this data, the staff did not identify any regulatory action and will continue to monitor this trend.

The assessment showed a statistically significant decreasing trend with transportation events for both NRC and Agreement State licensees over the 10-year period. The number of transportation events was stable over the last four years. The staff will continue to monitor this trend in the operating experience program.

The assessment included a 10-year plot of all medical events for both NRC and Agreement State licensees. A statistically significant trend was not present. An additional assessment titled, "Medical Events Involving Radiopharmaceuticals (Fiscal Year 2013-2022)," (ML23054A176) emphasized medical events involving radiopharmaceuticals that had been recently approved by the U.S. Food and Drug Administration and licensed by the NRC. With the emergence of several new radiopharmaceuticals over the past decade, the staff found it prudent to conduct this more focused review of medical events. This assessment identified 76 medical events involving the administration of radiopharmaceuticals between 2013 and 2022. The evaluation showed no statistically significant change in the number of events per year. As part of the evaluation of medical events, it was identified that most of the reported events (74 percent) involved human error. Equipment failures and procedural problems caused less than 10 percent of events. The staff will continue to monitor radiopharmaceutical medical events as additional radiopharmaceuticals are in clinical trials and are expected to receive U.S. Food and Drug Administration approval in the next few years.

Abnormal Occurrence Data

The FY 2022 Report to Congress on AOs contained nine FY 2022 events involving nuclear materials as AOs. One event involved an NRC licensee, and the remaining eight events involved Agreement State licensees. Seven AOs were medical events, and the remaining two events involved human overexposures. The nine AOs were included in the more extensive analysis of the nuclear material events provided in the NMED Annual Report for FY 2022. Only 2 percent of the events from the Nuclear Materials Users business line met the AO criteria. The other business lines did not have any events or incidents that met the AO criteria. No other events of interest were included in the Report to Congress.

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 radiation control programs. Overall, Agreement State and NRC programs continue to adequately protect public health and safety. During FY 2022, the NRC and Agreement State staff conducted 13 IMPEP reviews. 9 of the 13 Agreement State programs were found adequate to protect public health and safety and 4 of the Agreement State programs were found adequate to protect public health and safety but need improvement. Nine programs were found compatible with the NRC's regulatory program, and four programs were found not compatible. As discussed above, the Mississippi Program was placed on probation and the Washington State Program entered a period of heightened oversight. In addition, the MRB Chair placed the Rhode Island Agreement State Program on a period of heightened oversight on February 16, 2022.¹⁰ The MRB Chair also placed the New York Agreement State Program on a period of heightened oversight on January 11, 2023.¹¹ Additional details appear in the "Annual Report on Agreement States and the NRC's Radioactive Materials Programs for Calendar Year 2022" (ML23055B049).

A Coordinated Approach to the Nuclear Materials and Waste Safety Program

The Nuclear Materials and Waste Safety Program business lines have discrete functions across a wide variety of licensees and technologies. Staff and management continued to seek ways to harmonize and streamline approaches across this variety of work, adopted a consistent approach wherever possible, and explained differences as necessary.

A new operating experience program procedure was issued that provided the framework for a consistent evaluation, while also allowing flexibility to ensure that each business line maintained the ability to perform a meaningful assessment of data. In the past, the business lines assessed operating experience in different ways. Moving forward, the new coordinated program will help to systematically review operating experience, assess its significance, and provide timely and effective communication to stakeholders. The results of several of these assessments are discussed above.

Multiple program areas took similar approaches to modernize and risk-inform their inspection programs. Inspection Manual Chapter (IMC) 2602, "Decommissioning Fuel Cycle, Uranium Recovery, and Materials Inspection Program," (ML22010A141) was revised in its entirety to

¹⁰ In a February 16, 2022, letter to the Rhode Island Department of Health (ML22032A318), the MRB Chair determined that the Rhode Island Agreement State Program be placed on a period of heightened oversight. The IMPEP was conducted on October 19 - 22, 2021.

¹¹ In a January 11, 2023, letter to the State of New York (ML22353A062), the MRB Chair determined that the New York Agreement State Program be placed on a period of heightened oversight. The IMPEP was conducted on July 18 - 29, 2022.

incorporate a more risk-informed and performance-based approach to the Decommissioning Program. In a related and coordinated effort, IMC 2800, "Materials Inspection Program," was also revised and issued for comment to the regions and Agreement States. The IMC 2800 effort also included updates to 10 inspection procedures that were issued in April 2022. The revised procedures incorporated additional risk and performance insights that will help inspectors focus on the most safety-significant aspects of licensed activities. In addition, both the IMC 2602 and IMC 2800 updates included guidance on how to implement the program during pandemics, as well as how to address items of very low safety significance. The IMC 2800 update also addressed how to transition inspection program elements for materials licensees undergoing decommissioning.

Improvements to qualification and training programs are important to our continued ability to onboard and cross-qualify staff. A qualifications working group was formed and is reviewing the Fuel Facilities and Spent Fuel Storage and Transportation qualification programs, specifically IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," to develop recommendations. Another working group, with NRC and Agreement State staff, was formed to revise the materials licensing and inspection qualification programs in IMC 1248, "Qualifications Programs for Federal and State Materials and Environmental Management Programs." The working group leads will share improvements and efficiencies with each other.

Programmatic Improvements

Data-Driven Decision Making

In FY 2022, the Nuclear Materials Users business line implemented improved data analytics tools to improve the planning of licensing and oversight work, automate data processing, and enhance data accuracy and consistency to support data driven decision making. These tools allow staff to monitor the licensing and oversight programs more efficiently and support continuous coordination among the regional offices implementing the materials program. For example, data analytics related to materials licensing were used by regional branch chiefs and license reviewers to improve the workload management of the approximately 1,500 materials licensing actions that are processed every year. These new tools significantly reduced the time spent processing data to manage the workload distribution among staff, determine which licensing actions are at risk of becoming overdue, and ensure consistency in reporting Congressionally mandated timeliness metrics. Licensing staff is now able to shift their focus from processing data to visualizing trends and identifying risks. Development of similar data analytics tools is ongoing for the other NMSS business lines.

Enhancing Source Security

The 2022 Radiation Source Protection and Security Task Force Report (ML22213A157) concluded that there were no significant gaps in radioactive source protection and security that were not already being addressed through interagency cooperation and actions. The Task Force on Radiation Source Protection and Security (Task Force) evaluated and provided recommendations to the President and Congress relating to the security of radioactive sources in the United States from potential terrorist threats, including acts of sabotage, theft, or use of a radioactive source in a radiological dispersal device or radiation exposure device. The Task Force agencies completed significant initiatives for preventing and mitigating cybersecurity vulnerabilities related to Category 1 and 2 radioactive sources and were able to address a

recommendation from a previous report.¹² Task Force agencies will continue to coordinate cybersecurity strategies and actions as threats continue to evolve. Actions for six of the remaining Task Force recommendations are ongoing.

The staff provided the Commission with a draft proposed rule on radioactive source security and accountability (SECY-22-0112; ML22277A809) that would require licensees transferring category 3 quantities of radioactive material to verify licenses through the NRC License Verification System or by contacting the license-issuing authority to confirm that the recipient licensee is authorized to receive the type, form, and quantity of radioactive material to be transferred. In addition, the draft proposed rule would require that generally licensed devices containing category 3 quantities of byproduct material could only be transferred to licensees possessing a specific NRC or Agreement State license. The staff accelerated the development of this proposed rule because the scope and objectives were clearly defined and did not require additional research to develop the regulatory basis. The staff also used collaborative approaches for stakeholder engagement to gain efficiencies.

The NRC also issued Information Notice 2022-01, "Information Regarding the U.S. Government Accountability Office Investigation of the Transfer of Byproduct Material other than category 1 and 2," to remind licensees to ensure, before transferring any radioactive material, that license verification meets the requirements set forth in NRC regulations or other equivalent Agreement State requirements. This information notice emphasized the importance of vigilance regarding radioactive source security following an U.S. Government Accountability Office (GAO) investigation and report (GAO-22-103441).

Standing Committee for Reviewing Emerging Medical Technologies

In the past, NRC and Agreement State staff formed separate working groups to develop licensing guidance for each emerging medical technology. The time it took to form these working groups contributed to lengthy review times. In some situations, inconsistencies in the National Materials Program occurred when some Agreement States issued licenses for the use of new technologies prior to the completion of technology-specific licensing guidance.

The NRC reorganized its process for reviewing emerging medical technologies and developing associated licensing guidance. The NRC and Agreement States established a Standing Committee for Reviewing Emerging Medical Technologies in December 2020, which included both NRC and Agreement State staff. Through this approach, the NRC staff gained efficiencies by engaging and collaborating earlier with regional staff, Agreement States, and the Advisory Committee on the Medical Uses of Isotopes. Through the Standing Committee, the NRC staff received early feedback on 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," determinations, as well as on draft licensing guidance documents. This programmatic improvement maintained the opportunity for Agreement States to have early and substantive involvement in the development of new guidance documents.

¹² The Task Force agencies, as required by Energy Policy Act of 2005, include U.S. Nuclear Regulatory Commission, U.S. Department of Homeland Security, U.S. Department of Defense, U.S. Department of Energy, U.S. Department of Transportation, U.S. Department of Justice, U.S. Department of State, Office of the Director of National Intelligence, Central Intelligence Agency, Federal Emergency Management Agency, Federal Bureau of Investigation, U.S. Environmental Protection Agency. In addition, U.S. Department of Health and Human Services, Office of Science and Technology Policy, and Organization of Agreement States (nonvoting member) were also invited to participate.

The NRC staff issued its first licensing guidance under this new approach in March 2022 for Alpha Tau Medical's Alpha DaRT™ manual brachytherapy. This emerging medical technology uses alpha particles from radon-220 to treat localized tumors.

CONCLUSION:

Based on the review of licensee performance trends, operating experience reports, and identified improvements 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 and no significant nuclear materials issues.

COORDINATION:

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



Signed by Lubinski, John
on 05/02/23

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 2022. DATED: May 2, 2023.

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NFields, NRR

Keisha.Cornelius@deq.ok.gov

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