

# Nuclear Materials User Operating Experience Report FY2023

## 1. Introduction

The objective of the Nuclear Materials User Operating Experience (OpE) report is to provide an analysis that identifies trends in operational data and to make recommendations to improve our regulatory programs. By systematically reviewing operational data and assessing its significance, the Office of Nuclear Material Safety and Safeguards (NMSS)/ Division of Material Safety, Security, State, and Tribal Programs (MSST) is aiming to provide insights that can inform future inspections and licensing reviews, provide timely and effective communication to stakeholders, and apply the lessons learned to regulatory decisions and programs. The scope of the assessment is the 2023 fiscal year (FY).

## 2. Data Assessment

### Reported Events

The reported events within the scope of this assessment includes Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," as well as reporting requirements that are dependent on the type of license issued. These reporting requirements include:

- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."
- 10 CFR Part 31, "General Domestic Licenses for Byproduct Material."
- 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations."
- 10 CFR Part 35, "Medical Use of Byproduct Material."
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators."
- 10 CFR Part 37, "Physical Protection of Category 1 and 2 Quantities of Radioactive Material."
- 10 CFR Part 39, "Licenses & Radiation Safety Requirements for Well Logging."
- 10 CFR Part 40, "Domestic Licensing of Source Material."
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

The OpE review group reviewed the "NMED Annual Report for FY2022 (ML23023A080)," dated January 31, 2023. The reported events were classified into the following categories: (1) Lost/Abandoned/Stolen Material, (2) Medical, (3) Radiation Overexposure, (4) Release of Licensed Material or Contamination, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, and (8) Other. The group reviewed the significant events and the statistically significant trends identified in the annual report. To account for random fluctuations in the event data from year to year, the assessment included data trends for the last ten years.

Throughout the year, the NMSS Analysis and Trending Groups (ATGs) reviewed the event notifications reported to the NRC headquarters operation center (HOC). The ATG considered whether the cause of the event could be generic for other licensees and sought to identify

trends that may indicate the need for regulatory action. The OpE review group worked with the following ATGs—Medical Radiation Safety, Sealed Sources and Devices, Transportation, and Part 37 Security—to determine whether trends and/or observations had been identified. In addition, the OpE review group reviewed the “Medical Events Involving Radiopharmaceuticals; Fiscal Year 2013-2022 (ML23054A176),” dated February 28, 2023. This assessment assessed 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.

In addition to the review of domestic events, the OpE review group incorporated the international events posted by the International Atomic Energy Agency (IAEA), which met the International Nuclear and Radiological Event Scale (INES) reporting levels 2 through 7 into the OpE review group discussions (ML23264A059).

When the Office of Nuclear Reactor Regulation (NRR) identifies safety or regulatory concerns that may be applicable to NMSS, the outreach is through NRR’s Technical Review Group process. In the last fiscal year, the NMSS OpE Coordinator did not forward any concerns that were relevant to the Nuclear Materials User business line.

#### Part 21 Reports: Reporting Defects and Non-compliance

The OpE review group reviewed Part 21 reports received during FY2023, including Counterfeit, Fraudulent, and Suspect Items (CFSI), to determine whether any were relevant to the Nuclear Materials User business line. None were identified.

#### Enforcement

The OpE review group focused on enforcement of NRC licensees because data is readily available only for enforcement actions taken by the NRC. The NRC Enforcement Policy is not a matter of compatibility for Agreement States to implement. Enforcement issued by the Agreement States was outside the scope of this assessment.

The OpE review group searched the Agencywide Documents Access and Management System (ADAMS) for escalated enforcement and reviewed the NRC public website<sup>1</sup> to determine if any significant enforcement actions (including Notices of Violation, Orders and Confirmatory Action Letters) were issued in the past FY. Minor violations, inspector follow up items, and unresolved items were not included in the assessment as they were outside the scope. The OpE review group also generated reports from the Web-based Licensing (WBL) database on the non-escalated enforcement issued in FY2023.

The OpE review group binned the non-escalated and escalated enforcement, as well as the orders and confirmatory action letters, into five categories; (1) Radiation Protection; (2) Material Security, Control and Accountability; (3) Regulatory and Administrative Matters; (4) Transportation; and (5) Medical. The OpE review group focused the discussion of these

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<sup>1</sup> The NRC maintains a list of Significant Enforcement Actions (<https://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>) on its public website.

categories on the number of enforcement items, significance, and the prevalence of common threads within the categories. The OpE review group used this preliminary assessment, as well as event data and observations from the ATGs, to select areas for further analysis within the Trending and Review section.

Table 1. Enforcement Actions Against Nuclear Materials Users.

Category	Significant Enforcement Actions	Non-Escalated Enforcement	Total
Radiation Protection	8	98	<b>106</b>
Material Security, Control and Accountability	13	75	<b>88</b>
Regulatory and Administrative Matters	11	21	<b>32</b>
Transportation	0	32	<b>32</b>
Medical	8	23	<b>31</b>
<b>TOTAL</b>	<b>40</b>	<b>249</b>	<b>289</b>

Within each category, the OpE review group created subgroups of enforcement actions to further enhance discussions.

*Radiation Protection*: Administrative Controls and Oversight (45), Additional Commitments (24), Surveys & Instrumentation (22), Radiation Safety Training (7), Dose Limits & Personnel Monitoring (6), Posting & Labeling (2)

*Material Security, Control and Accountability*: Physical Inventories & Leak Testing (34), Security – Category 3 or Less (29), Transfer & Disposal (11), Security – Category 1 or 2 (9), Device-Specific Requirements (5)

*Regulatory and Administrative Matters*: Unauthorized Activities (19), Notifications & Reporting (11), Falsification of Records (1), Failure to Pay Debts (1)

*Transportation*: Hazmat Training (18), Shipping Papers (8), Package Requirements (6)

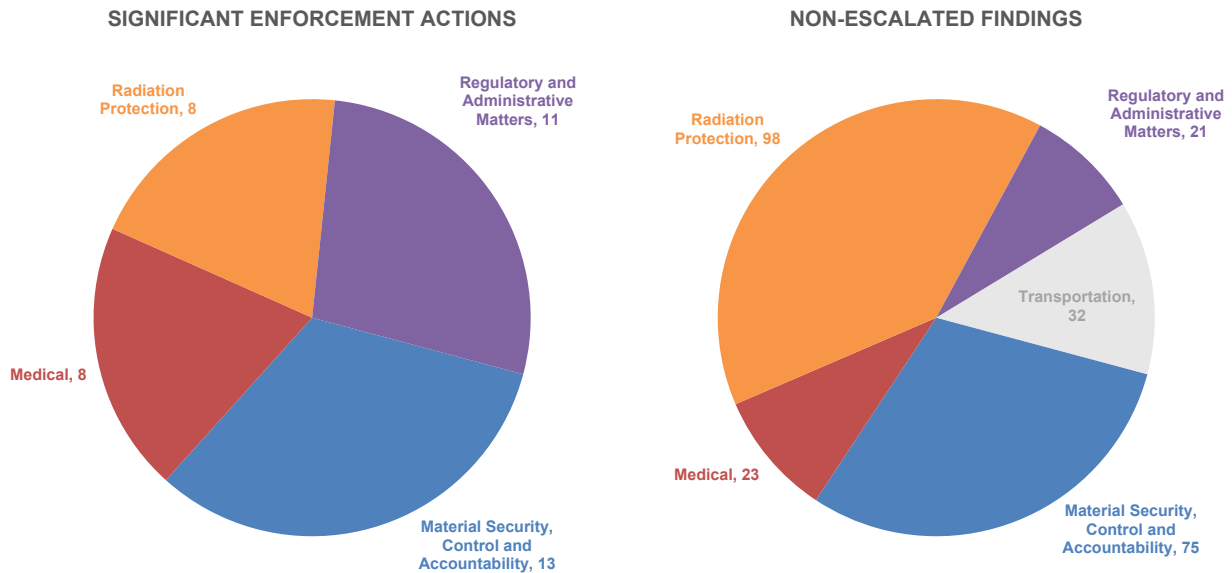
*Medical*: Written Directives & Associated Procedures (24), Diagnostic Administration Requirements (7)

### 3. Trending and Review

#### Enforcement Overview

The NRC issued 33 Severity Level (SL) III violations and four Orders (including one that addressed four significant findings<sup>2</sup>) to materials users in FY2023. Seven included civil penalties. No SLI or SLII violations were issued this year.

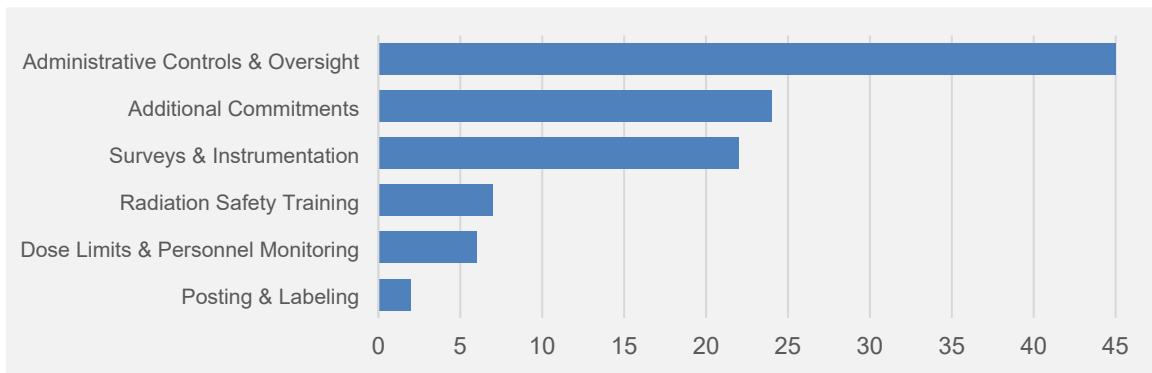
Significant enforcement actions were roughly balanced across all categories excluding transportation. In contrast, of the 247 non-escalated findings (i.e., SL IV violations) this year, nearly 80% were from just two categories: *Radiation Protection* and *Material Security, Control & Accountability*.



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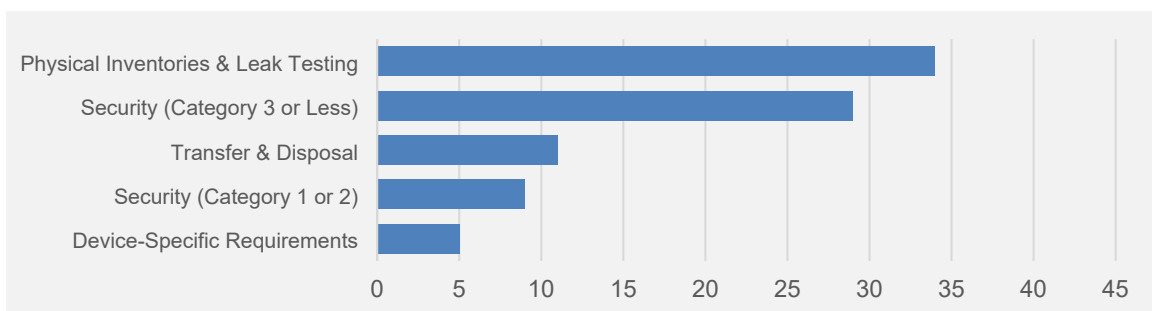
<sup>2</sup> Cabell Huntington Hospital (EA-22-003), Confirmatory Order Related to NRC Inspection Report No. 03003370/2021001 and NRC Office of Investigations Report No. 1-2021-015, dated November 10, 2022. <https://www.nrc.gov/docs/ML2231/ML22313A116.pdf>

Radiation Protection (Administrative Controls and Oversight)



During the review of enforcement actions, the OpE review group focused on the category of Radiation Protection because it contained the most findings, overall. The Administrative Controls and Oversight subgroup contained 45 findings. 23 violations were cited against 10 CFR 20.1101, “Radiation Protection Programs,” section (c), which required a review of the content and implementation of the radiation safety program, at least annually. This was the most frequently cited requirement in FY2023. Recent findings were due to elevated turnover, particularly at the Radiation Safety Officer (RSO) position and suggested a need for continued inspector emphasis on awareness of and accountability for radiation safety and regulatory compliance at the highest levels of a licensee’s organization. The prevalence of this and other findings related to program oversight reveals an opportunity for licensees to strengthen the continuity of oversight and compliance within Radiation Protection. The OpE review group did not identify any weakness within the NRC regulations or regulatory framework. No generic communications were proposed. The OpE review group recommends that this observation be communicated to the inspectors within the Division of Radiological Safety and Security (DRSS), as well as the Agreement States, for awareness.

Material Security, Control and Accountability



The OpE review group considered the enforcement within the Material Security, Control and Accountability category. Physical inventory and leak testing issues were a notable contributor to the category with 34 findings. Although no sources were subsequently found to be lost or leaking, the prevalence of these and other security, control, and accountability issues suggests a need for continued inspector emphasis.

The Security (Category 3 or Less) subgroup contained 29 findings. Nearly half of the security findings involving Category 3 material or less involved a portable gauge. Fortunately, only one was for the actual loss of a gauge. Inspectors should continue to focus on consistent and continuous compliance with security requirements for portable gauge licensees.

The Part 37 ATG reviewed events from January 1, 2021 to September 31, 2023 which included the reported loss and/or theft of Category 2 quantities of radioactive materials. No Category 1 nuclear material was lost or stolen during this time period. The eight events identified in this review included 4 incidents involving international shipping.<sup>3</sup> The other four events included a device that fell out of a truck during transport, a device stolen from a truck, a truck stolen with a device inside, and a source that was delivered but not secured.<sup>4</sup> All of the Category 2 nuclear material was recovered. The Part 37 ATG concluded that the theft and loss of radioactive materials was generally infrequent in nature and generally occurred as the result of inadequate implementation of existing requirements. The ATG did not identify a gap in regulatory requirements.

The OpE review group noted that the Security (Category 1 and 2) subgroup included 9 findings, issued during the last FY, which corresponded to NRC licensees. The Agreement State enforcement actions were not included in this analysis. The OpE review group reviewed four SLIV violations, a SLIV problem (3 SLIV violations), and a SLIII problem (2 violations). No trends were identified. The enforcement data did not overlap with the event data in a meaningful way.

The OpE review group recommends that the NRC issue generic communication to alert industrial radiography licensees about the FY 2023 security events involving Category 2 sources. With MSST management alignment, staff are already working towards implementation.

#### Regulatory and Administrative Matters (Reciprocity)

The Regulatory and Administrative Matters category included 11 escalated enforcement actions taken against material licensees in FY2023. Of those eleven, six were for the failure to file reciprocal recognition of an Agreement State materials license prior to using it to perform licensed activities in NRC jurisdiction under the terms of the general license in 10 CFR 150.20. The OpE review group considered these actions and determined that neither a trend nor a common root cause was evident. In two cases, licensees filed requests after starting the work. Two enforcement actions corresponded to the licensees filing incorrectly. In one instance, the licensee misunderstood whether the licensed activities were covered under the 10 CFR 31.6, "General license to install devices generally licensed in § 31.5." An order for the failure to

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<sup>3</sup> The events which involved international shipping included [EN56615](#), Agreement State Report of Lost and Found Radioactive Material; [EN56472](#), Agreement State Report of a Shipment Delayed and Sources Held at Interim Location; [EN56030](#), Agreement State Report of a Lost/Missing Category 2 Radioactive Material Shipment; and [EN56026](#), Agreement State Report of a Missing Radioactive Material Shipment.

<sup>4</sup> [EN56604](#), Agreement State Report of a Missing Radiography Camera; [EN56396](#), Agreement State Report of a Stolen Exposure Device; [EN56222](#), Report of a Lost/Recovered Radioactive Source; and [EN55923](#), Agreement State Report of a Delivered Source Not Secured.

respond to enforcement issued last year and to pay the civil penalty was also included. The OpE review group determined that no trend existed. No actions were recommended.

### Malfunctioning Devices

The OpE review group reviewed event notifications and corresponding entries within NMED for registered Sealed Source and Devices from January 1, 2022, to November 23, 2023 and found that the majority of the events notifications correspond to fixed and portable gauges. Many of the portable gauge events were related to external causes, such as being struck by a vehicle/ machinery or were not properly secured while being transported. The devices suffered damages that made them inoperable.

Fixed gauges are equipped with shutters. The shutters have a critical role in preventing unnecessary radiation exposure to the worker by shielding the radioactive source. The shutter should close once the power source is disengaged. If the shutter on a fixed gauge becomes stuck, the licensee must report it to the NRC per 10 CFR 30.50(c).

The OpE review group has found an increase of 29% in reported events with stuck shutters on malfunctioning devices (fixed gauges), when the reported events in calendar year (CY) 2022 were compared to CY 2023 (January 1 to November 23, 2023). The OpE review group created two subgroups for the NMED data which corresponded to the cause of the stuck shutter: mechanical failure and environmental factors. Mechanical failures may be caused by insufficient lubrication, corrosion, or other originating factors. Environmental factors, such as dust or other machinery interacting with the fixed gauges, may also inhibit the shutter from closing. For these two subgroups, the OpE review group analyzed reported events within CY 2022 as well as January 1 to November 23, 2023. Events in the subgroup regarding mechanical failures decreased by 61%, when compared to CY 2022 data, while those attributed to environmental factors increased and represented the majority of events reported over the same period.

The OpE review group requested a special event study of the events within NMED with a focus on mechanical failures of fixed gauges. This event study request was submitted to the NMED contractors in November 2023. The OpE review group recommends that the results of this special event study be reviewed during next year's OpE assessment and for the need of generic communications to be considered.

### Medical; Radiopharmaceutical Events

The Medical ATG reviewed the medical events from the NMED Annual Report for FY2022 and the Medical Events Involving Radiopharmaceuticals (Fiscal Year 2013-2022). The usage of new therapeutic radiopharmaceuticals as well as associated medical events have increased. An information notice is currently being developed to inform licensees of recent reported medical events that involved the administration of therapeutic radiopharmaceuticals.

### External OpE Assessments

The OpE review group reviewed the Department of Energy (DOE) Operating Experience Summaries that were issued within the assessment scope.<sup>5</sup> No similar trends were being discussed.

#### **4. Generic Issues**

The OpE review group contacted the NRC Generic Issues Program representative to inquire whether any generic issues were submitted for consideration during FY2023. No generic issues were proposed.

#### **5. Conclusions**

Based on the analysis above, the OpE review group concluded that:

1. 10 CFR 20.1101, "Radiation Protection Programs," section (c) was the most frequent cited requirement in FY2023. Recent findings were due to elevated turnover, particularly at the RSO position. Inspectors should continue to provide emphasis on the awareness of and accountability for radiation safety and regulatory compliance at the highest levels of a licensee's organization.
2. Compliance with physical inventory and leak testing requirements, as well as security requirements, should continue to be an inspector focus.
3. Nearly half of the security findings involving Category 3 material or less involved a portable gauge. Fortunately, only one was for the actual loss of a gauge. Inspectors should continue to focus on consistent and continuous compliance with security requirements for portable gauge licensees.
4. For the six escalated enforcement actions pertaining to reciprocity, neither a trend nor a common root cause was evident.

#### **6. Recommendations**

The OpE review group recommends the following actions:

1. Consider sharing this report, the Nuclear Materials User OpE Report FY 2023, with DRSS and the Agreement States.
2. Consider issuing generic communication to alert industrial radiography licensees about recent security events involving Category 2 sources.

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<sup>5</sup> The DOE Office of Environment, Health, Safety and Security (EHSS) Operating Experience Summaries are maintained on their public website; <https://www.energy.gov/ehss/listings/operating-experience-summaries>.



3. Consider incorporating the special event study of the events within NMED with a focus on mechanical failures of fixed gauges in next year's OpE assessment.
4. Consider issuing generic communication to inform licensees of recent reported medical events that involved the administration of therapeutic radiopharmaceuticals.