PNNL-31392

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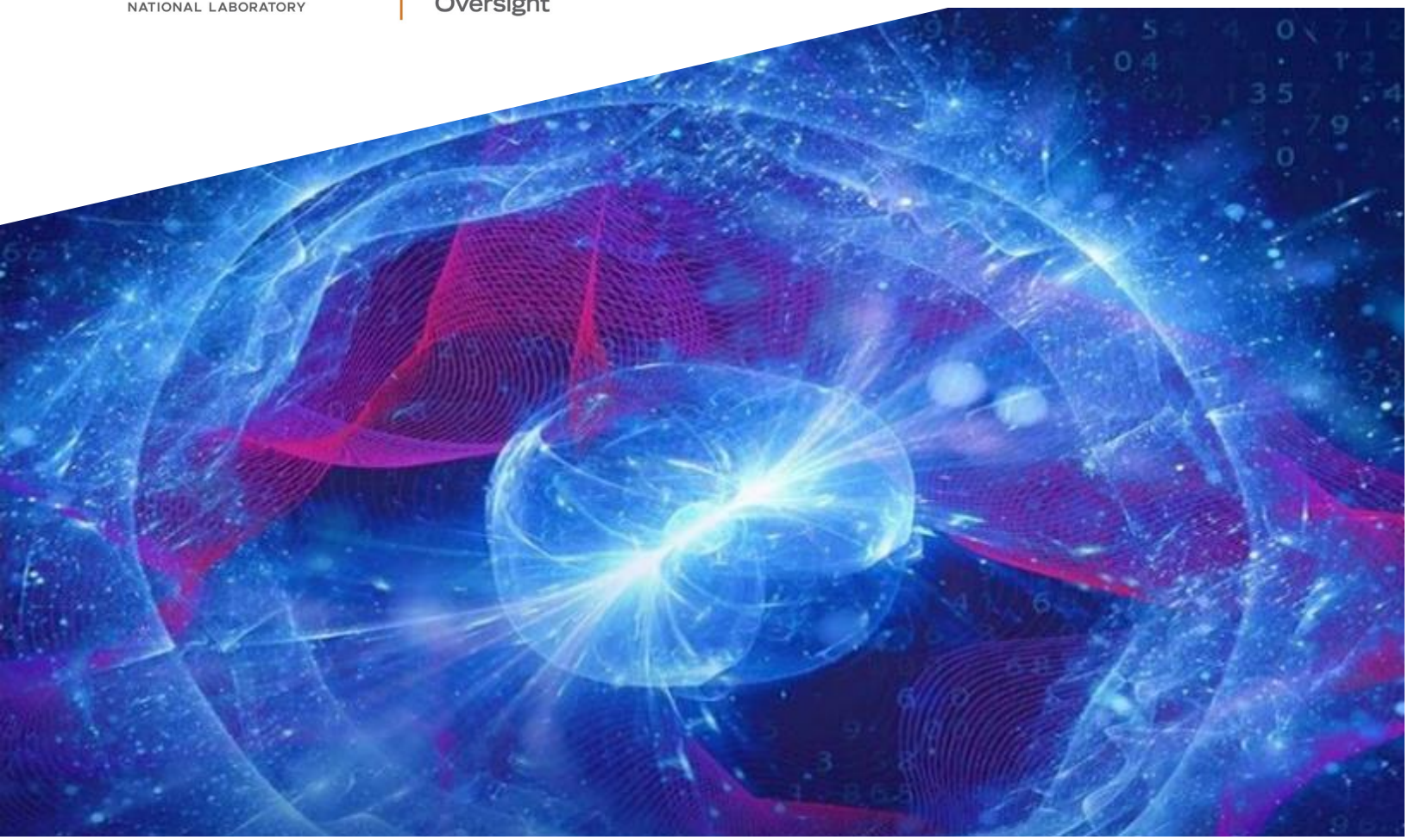
Oversight



Tracking and Protecting High-Value/High-Visibility Assets

(IO-FY21-01; AST 02333)

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[1] All select toxins associated with this assessment are below the permissible levels at PNNL

Acronyms

BioMS	Biological Management System
BSO	Biological Safety Officer
CDC	Centers for Disease Control
CMS	Chemical Management System
DOE	U.S. Department of Energy
ELM	Enterprise Learning Management
EMRS	Excess Materials and Redeployment Services
HDI	How Do I?
INL	Idaho National Laboratory
IO	Independent Oversight
IT	Information Technology
LOI	Lines of Inquiry
M&OP	Management and Operations Program
MTR	Material Transaction Report
OFI	Opportunity for Improvement
ORNL	Oak Ridge National Laboratory
PI	Principal Investigator
PMO	Project Management Office
PNNL	Pacific Northwest National Laboratory
PNSO	Pacific Northwest Site Office
SCoR	Safe Conduct of Research
SME	Subject Matter Expert
SRD	Source Requirement Document
TL	Team Leader
WSU	Washington State University

Executive Summary

Pacific Northwest National Laboratory's (PNNL's) Independent Oversight (IO) office led an assessment to evaluate PNNL's approach to tracking and protecting high-value/high-visibility assets. The approach used by the assessment team included a review of requirements (including records), staff interviews, on-site and virtual walkthroughs of lab spaces, review of data, and the development of three separate workflows to capture PNNL's current practices in the areas of controlled substances, select toxins,[1] and precious metals. Summary results are provided below, with findings and opportunities for improvement (OFIs) following.

- The Management and Operations Program (M&OP) support staff (called subject matter experts or SMEs) for controlled substances, select toxins, and precious metals were noted by the research staff as exceptional in their knowledge and assistance.
- The custodians/principal investigators (PIs) (i.e., research staff responsible for an inventory) for each of the three asset types demonstrated a thorough understanding of the requirements and the processes needed to implement the requirements. With all custodians interviewed, they knew the SME to contact for guidance and assistance when needed.
- The controls for "defense-in-depth" of physical protection of assets (put in place by the Lab's Physical Security, Safeguards and Security organization) are strong.
- Most new team leaders (TLs) interviewed were not aware of research work involving their staff in handling and managing controlled substances, precious metals, or select toxins (their role is to verify controls are implemented to mitigate risks). Gaps identified include a lack of management training and the availability of reports from the SMEs that could provide these managers with situational awareness.
- Transitions in staff and changes in project scope increase the risk of non-compliance. This increased risk was observed by the assessment team in terms of properly dispositioning a controlled substance during a custodial handoff.
- Data between the Biological Management System (BioMS) and the Chemical Management System (CMS) were inconsistent and intractable at the time of this assessment. This gap results in duplicative data entry efforts that are inefficient in terms of data management.
- While M&OP records from SMEs meet regulatory requirements, none are fully meeting PNNL's Records Management requirements for the storage of records in ERecords.

Findings and Opportunities for Improvement

The following findings and OFIs are listed in the order in which they are addressed in the Assessment Results section of this report. Several OFIs address all three asset types.

- Finding-1—The Worker, Safety, and Health M&O Program maintains records for select toxins. The SME has a file plan, but select toxin records are missing in ERecords.
- Finding-2—The Property Management M&OP has initiated an effort to develop a file plan and file program records; however, precious metals records are not currently filed in ERecords.
- Finding-3—One pair of gold rings have not been weighed annually, as required, because they are heavier (> 2 kg) than the available balance in the Limited Area where the items are stored (they are currently monitored by visual inspection). This is in non-compliance with 41-CFR-109-27.5104-4.
- OFI-1— Recommend that the SMEs provide reports on controlled substances, select toxins, and precious metals to TLs who have staff working with these asset types.
- OFI-2— Regulations require proper dispositioning of these materials when a custodial staff member leaves their position. Consider adding asset information to the Human Resources transition checklist.
- OFI-3— Consider adding a training module for new TLs regarding their responsibility for these assets, which is to understand and verify controls are implemented to mitigate risks.
- OFI-4—Data across the CMS, BioMS, and Purchasing systems do not always reconcile and

[1] All references to select toxins in this report are noted to be *below the regulated or permissible levels*.

lead to duplicative processes and systems for the information. The assessment team recommends stronger integration of the information between electronic systems as a part of the Laboratory's Unified Asset Management effort.

- OFI-5—While researchers are meeting the federal regulation to generate specific record types as a part of their project records, they are not captured in ERecords per Records Management requirements. The assessment team recommends that the M&OP perform routine assessments to verify that researchers using controlled substances are capturing the Controlled Substance Registration and Inventory records electronically in ERecords.
- OFI-6— Clarify the language in "How Do I?" (HDI) that assigns each select toxin to a PI per the Centers for Disease Control (CDC) definition (the CDC defines a *principal investigator* as "the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program").
- OFI-7— Revise the HDI statement in the Biological-General work control, "Work with select agents can only be performed at a select agent-registered facility," to "Select toxins below regulated amounts may be used at a non-select agent-registered facility with the proper controls established." This revision reflects PNNL's current practice.
- OFI-8— There are legacy select toxins and precious metals that have not been in use for some time. The Laboratory should consider the need for these assets and determine if and how they should be dispositioned.
- OFI-9—Custodial training for precious metals is provided through a training guide, which is not tracked through Enterprise Learning Management (ELM). The M&OP should consider tracking custodial training through ELM.
- OFI-10—The Material Transaction Report (MTRs) form does not have a field for recording balance identification numbers or calibration date information (information required by HDI) to assure the integrity of inventory weight information. The assessment team recommends adding this information to the form.

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Figures

Introduction

Pacific Northwest National Laboratory (PNNL or Laboratory) is responsible for the oversight and safekeeping of high-value/high-visibility assets, including controlled substances, precious metals, and select toxins (below the regulated limit)[1] in support of its research mission. The Laboratory implements biosafety and physical security measures to prevent these assets from being stolen, lost, or (in the case of controlled substances and select toxins) accidently released.

There are several electronic systems including PNNL's Property Management system (precious metals), Chemical Management System (CMS) (controlled substances and select toxins), and the Biological Management System (BioMS) (select toxins) that are used to keep track of these substances and assets. This assessment evaluated PNNL's practices for tracking and protecting high-value/high-visibility assets with a focus on two specific controls:

1) Inventory controls—i.e., how PNNL tracks controlled substances, precious metals, and select toxins from purchasing to disposal.
2) Access controls—i.e., how PNNL protects these assets through safeguards and anti-theft controls.

IO reviewed the records, policies, and procedures associated with inventory and access controls, but did not evaluate how these assets are used in the conduct of research or in verification of permits for use. This assessment captured best practices and identified 3 findings and 10 opportunities for improvement (OFIs) for consideration by PNNL's Laboratory Leadership Team.

Assessment Participants and Methodologies

The assessment team consisted of senior staff members from Idaho National Laboratory (INL), Oak Ridge National Laboratory (ORNL), and PNNL (see Appendix A). The assessment approach included:

- Interviews with management (select Project Management Office [PMO] directors, operations managers, group leaders, team leaders) and staff that are custodians or principal investigators (PIs) of projects using controlled substances, select toxins, and precious metals.
- A walkthrough of laboratory spaces on the Richland campus and at the Marine and Coastal Research Laboratory in Sequim, Washington.
- A review of relevant requirements (including records).
- An examination of data from BioMS, CMS, and the Property Management systems.
- The development of three workflows outlining the current processes for controlled substances, select toxins, and precious metals.

Lines of inquiry (LOIs) used to guide interviews are provided in Appendix B. The workflows outlining the current processes are highlighted in the Assessment Results section, with detailed workflows provided to the subject matter experts (SMEs) who manage those processes.

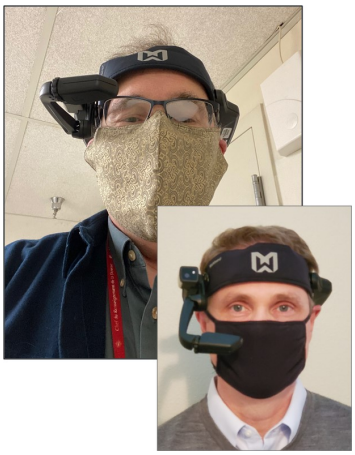

Figure 1. Headsets were used to conduct the virtual walkthroughs of laboratory spaces.

[1]All references to select toxins in the remaining sections of this report are noted to be "*below the regulated or permissible levels*" for PNNL use in research.

Importance of this Assessment

SCoR principles

Laboratory management Safe Conduct of Research (SCoR) principles define critical safety practices that underpin PNNL's culture. These principles and practices align with the Laboratory's goal of operational excellence and their successful implementation that assures research is performed without unnecessary risk and sustained without operational disruption. The following SCoR principles apply to this assessment:

- *Everyone is personally responsible for assuring safe operations.* Research staff interviewed understood that they were accountable for safety of controlled substances and the select toxins used in the conduct of their research. These staff rely on and consult with safety SMEs to assure that they are adhering to safe operations.
- *Cutting-edge science requires cutting-edge safety.* PNNL is committed to protecting precious metals, select toxins, and controlled substances through maintaining an accurate inventory of assets and providing physical protection (see Figure 2) to assure the Laboratory meets regulatory requirements, U.S. Department of Energy (DOE) expectations, and an adherence to PNNL's practices.

  Control of these assets is especially important because of the consequences of loss—i.e., the financial value of precious metals and the potential for harm to staff at PNNL and the public through accidental loss or release of select toxins and controlled substances. Maintaining accurate inventories from purchase to disposition of these assets gives PNNL leadership confidence that risks are mitigated, and the property is properly accounted for.
- *A questioning attitude is cultivated.* In the face of uncertainty, staff meet with SMEs to understand the requirements before proceeding with work.
- *A healthy respect is maintained for what can go wrong.* External reviews are conducted, and management engagement is viewed as an opportunity to reinforce good research practices. The assessment team identified a good practice by Kristin Omberg and her team, who are going above and beyond regulatory requirements to plan for and manage a controlled substance in FY 2021.

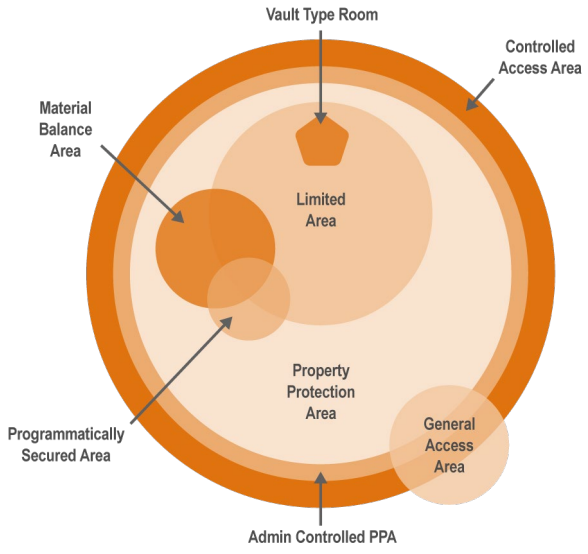

Figure 2. Safety and security measures have mulitple layers.

Assessment Results

This section is broken down into several subsections, including the three asset areas that were assessed—1) controlled substances, 2) select toxins, and 3) precious metals—followed by a subsection on requirements analysis and records management.

Controlled substances

Controlled substances are defined as "illegal" or prescription drugs regulated under existing federal law (Title 21 United States Code) known as the Controlled Substances Act (CSA). This Act categorizes all controlled substances into schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. The five classes of controlled substances include narcotics, depressants, stimulants, hallucinogens, and anabolic steroids.

Specific instructions under the Act are codified in 21-CFR-1304 and cover storage/control requirements, recordkeeping, reporting, and all physical and administrative controls practiced when possessing and handling controlled substances. To assess adherence to the requirements (21-CFR-1304 and WAC 246-887-030) and the level of rigor to which requirements were being followed, the assessment team interviewed staff at PNNL ranging from PMO directors to controlled substance registrants (custodians), and included procurement staff, chemical inventory staff, packaging/transportation staff, and researchers who use controlled substances in their research activities.

The following observations were noted via staff interviews and laboratory walkthroughs:

- At the time of this assessment, there are very few controlled substances used in the conduct of research at PNNL (four), and each was found to be in low quantities.[1]
- The controlled substances SME is excellent at translating requirements and effective at helping staff with needed implementations to comply with requirements.
- Significant effort has been made to maintain inventory controls where those controls require both physical barriers (e.g., locks) and written logbooks where quantity transaction records are kept. Physical barriers, as evidenced from the laboratory walkthroughs, included controlled access buildings, controlled access rooms within those buildings, and locked controlled substance storage areas.
- Staff accountability is high. Witnessed accounting is employed, and a minimum of two staff in the lab when materials are in use is a standard practice.
- Risk increases with staffing changes. Changes in the line managers, project managers, SMEs, and custodians all increase the potential to lose track of a controlled substance or to transfer those materials to unlicensed, unqualified staff.

  The assessment team identified one situation where a staff member had left PNNL, and their chemical inventory of over 300 chemicals was transferred to a TL to disposition. Within the inventory was a mistakenly identified controlled substance.[2] As a high-value asset, access to select controlled substance information is limited to a "need to know" basis. The TL had not been identified as having a need to know, resulting in a controlled substance that was not tracked when the staff member left the Laboratory. To address gaps in transferring custodianship when a staff member leaves the Laboratory, the assessment team recommends 1) providing reports to managers who have staff that work with controlled substances to increase situational awareness (OFI-1), and 2) consider adding asset information to the Human Resources transition checklist (OFI-2).
- Oversight of controlled substances is provided by line management who rely on PMO kickoff

[1]Due to the sensitive nature of controlled substances, the types of controlled substances and their locations are not provided in this report.

[2] The assessment found that the controlled substance had a waiver in place by the vendor because there were only fragments of a "controlled substance." While the waiver was captured in PNNL's procurement system, it was not captured through CMS, and as such was treated as any other controlled substance.

meetings with project managers, controls within Lab Assist, and appropriate risk changes to the Electronic Prep and Risk system. Group leaders interviewed have a good understanding of their responsibilities, and controls are effectively implemented. There was an inconsistent understanding, however, of responsibilities on the part of the TLs interviewed. These managers had not received training that could help them understand their role relative to oversight of controlled substances. As such, the assessment team recommends adding a module to training for new TLs regarding their oversight responsibilities (OFI-3).

- Data across electronic systems does not always reconcile well between the systems (e.g., the information in the Purchasing system that documented the waiver for the controlled substance did not get documented in CMS), leading to controls that were unnecessary. The assessment team recommends an OFI to assure integration of information between systems as a part of the Laboratory's Unified Asset Management initiative[1] (OFI-4).
- Each controlled substance registrant, with the assistance of the SME, performs a biennial inventory of the controlled substances as required by law. The completed biennial inventory form is maintained by the registrant at the controlled substance storage location.
- The SME notifies the CMS Program Administrator of any changes to the controlled substance inventory. The SME uses the Operations Tracking System to provide a self-reminder.
- While researchers are meeting the federal regulation to generate specific record types as a part of their project records, they are not captured in ERecords per Records Management requirements. The assessment team recommends that the M&OP perform routine assessments to verify that researchers using controlled substances are capturing the Controlled Substance Registration and Inventory records electronically in ERecords (OFI-5).

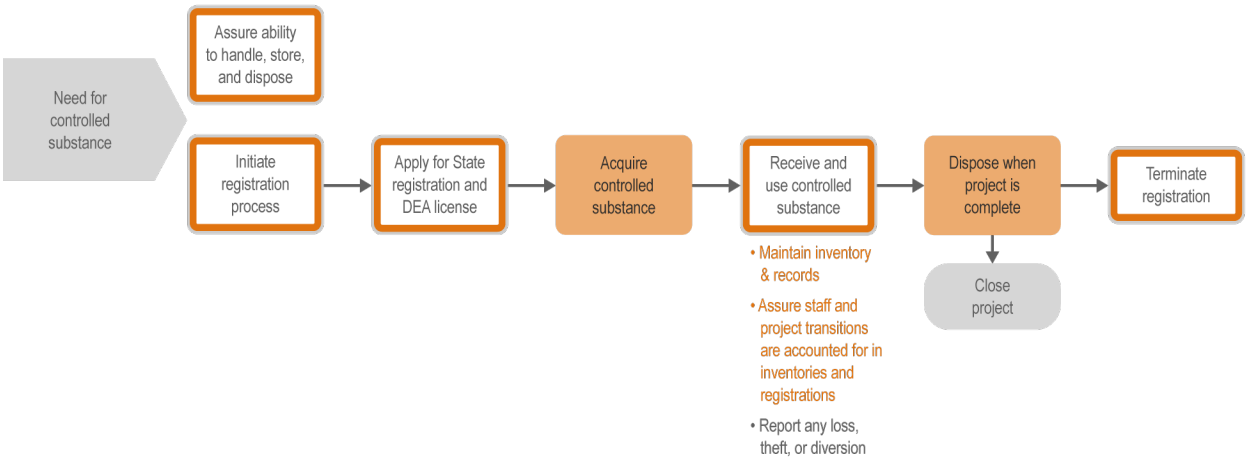

Figure 3. High-level workflow for controlled substances *(shaded boxes indicate gaps in the process as noted by this assessment).*

[1] The Unified Assets Management initiative represents a multiyear effort to re-engineer asset-management processes and Information Technology (IT) tools to make the processes and tools more responsive and valuable to research, while increasing efficiency and assuring compliance. This includes at-risk systems where potential failures could lead to financial loss of valuable controlled assets, including precious metals, drugs, and other valuable materials.

Select toxins

Select agents include both biological select agents and select toxins, which have the potential to pose a severe threat to public health and safety and, as such, are highly regulated. PNNL does not have within its inventory any biological select agents, and performs research using select toxins at levels below the regulatory limit (called permissible toxin amounts). PNNL's use of select toxins above regulatory amounts is strictly limited to the BioSafety Level-3 laboratory located at the University of Washington and was outside the scope of this IO assessment.

Select toxins on the Federal Select Agent Program, jointly comprised of the Centers for Disease Control and Prevention (CDC) and the Animal Plant Health Inspection Service, are regulated based on the amount under the control of an individual PI. Use of select toxins below regulatory limits are managed at PNNL (Richland and Sequim) under the requirements established for highly toxic chemicals, as documented in HDI's Chemical – Carcinogens and Toxics work control. The following represents observations by the assessment team:

- Inventories of select toxins are physically protected on-site using a multilayered approach, including prox-card access, cypher locks, and individual container lock entry controls. In addition, information on select toxins is restricted in CMS (with limited access in BioMS) so that only staff members with authorized access see the types and locations of toxins at PNNL in both Richland and Sequim, Washington.
- The SME (BioSafety Officer [BSO]) responsible for select toxin requirements is a highly valued resource in helping staff implement requirements.
- PIs interviewed were very knowledgeable and aware of the requirements for acquisition and protection of select toxins, including the need for maintaining inventories below regulated limits.
- Controls established for the acquisition of select toxins include limiting the procurement method to purchase orders (i.e., P-cards and B2B procurements are not authorized) and a pre-purchase review by the BSO, who verifies quantities will remain below regulated limits. After receipt at the Battelle Receiving and Shipping Warehouse and entry into CMS, the select toxins are turned over to the custodian, who has the responsibility for managing the select toxins while on-site.
- Two additional "acquisition" methods were reviewed during the assessment. Work at the Marine and Coastal Research Laboratory in Sequim, Washington, involves bio-organisms that produce a select toxin (saxitoxin). The saxitoxin levels produced are very small and are considered to be a low risk for exceeding regulated limits. The second method comes from research staff in Richland that have extracted select toxins from natural sources (e.g., low levels of ricin from castor beans). In this case, the select toxin content for a bean is well-characterized and allows for inventories to be updated based on the number of beans processed.
- Export control requirements are met through the implementation of access controls. The multilayered approach to access control (e.g., building, corridor, laboratory, and container) limits the number of staff with the ability to gain direct access to inventories. Additionally, much of the research involving select toxins is limited to staff who are U.S. citizens. Periodic reviews of access for staff who are non-U.S. citizens is performed by Safeguard and Security staff as an addition layer of protection.
- Managing select toxin inventories overlap two sets of laboratory requirements for chemicals and biological agents. As a result, their inventory is maintained in two electronic systems: CMS and BioMS. The systems are managed by separate processes, with CMS focused on implementation of chemical management requirements and BioMS focused on biological requirements. These systems do not interact with each other and implement inventory controls differently.

  At the time of this assessment, the assessment team tried to compare the lists of select toxin information between the two systems and found the data to be largely incomparable, leading to duplicative data entry efforts that are inefficient in terms of data records management. The assessment team recommends an OFI to integrate the information between CMS and BioMS as a part

of the Laboratory's Unified Asset Management initiative (OFI-4).

- CMS inventories are conducted by staff, independent of the PI, on a three-year cycle using radiofrequency identification (RFID) tags to provide verification of container presence. BioMS inventories are conducted annually, relying on the BSO to download the inventory by custodian into an Excel spreadsheet. The spreadsheet information is then verified by the custodian with any needed edits provided back to the BSO. Running inventories are maintained by the assigned custodian at the point of storage using a combination of a container log sheets and laboratory notebooks. These records are managed with log sheets and are transferred to follow-on work for any unused inventory. The Worker, Safety, and Health M&OP maintains records and has a file plan for select toxins. The M&OP is not, however, meeting PNNL's Records Management requirements for storing select toxin records in ERecords. (Finding-1).
- The HDI Biological-General work control describes "biological toxins are not regulated if the amount under the control of a PI, treating physician, veterinarian, or commercial manufacturer or distributor does not exceed, at any time, the amounts identified." HDI further calls out that "work with select agents can only be performed at a select agent-registered facility." In each case, the information relies on a nuanced definition of "principal investigator," as defined by the CDC. PNNL's processes rely on researchers and custodians to manage select toxins. As such, the assessment team recommends clarity be added to HDI by providing a definition for "principal investigator"[1] (OFI-6) and calling out that "select toxins below regulated limits may be used at a non-select agent-registered facility with the proper controls established" (this revision reflects PNNL's current practices) (OFI-7).

Staff transitions pose a risk to potential loss of select toxins. The assessment team noted one such transition where a legacy select toxin that had not been in use for a couple of years was moved from one laboratory to a new laboratory space and had not been updated in CMS. While the assessment team identified that the new laboratory space had the expected physical controls in place, interviews identified that the PI did not have access to the new laboratory, and thus, had not had the chance to confirm that this legacy select toxin was appropriately stored and accounted for. The assessment team recommends that the Laboratory SME work with management to consider the need for this select toxin and whether it should be dispositioned (OFI-8), and to assure access to the laboratory for oversight of the select toxin.

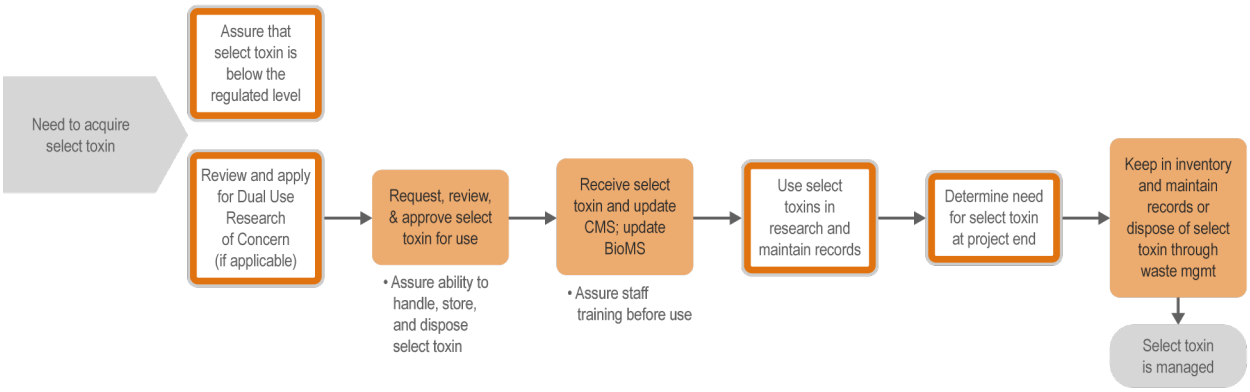

Figure 4. High-level workflow for select toxins.

[1]The CDC defines a *principal investigator* as "the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program."

Precious metals

Precious metals (i.e., gold, silver, platinum, palladium, rhodium, iridium, ruthenium, and osmium) are a group of rare, highly valuable metals characterized by their superior resistance to corrosion and oxidation. While not considered a health or safety hazard, these high-value assets require management attention to administratively and physically control them to prevent loss or theft.

PNNL maintains precious metals, which must be inventoried and reported annually to the Pacific Northwest Site Office (PNSO).[1] The Property Management group manages PNNL's precious metals with requirements provided through HDI (Property and Materials Requiring Additional Controls) and implemented by a group of trained and experienced precious metals custodians. These custodians are embedded in the research organizations that use precious metals in the conduct of research work.

Key observations from interviews and laboratory walkthroughs are as follows:

- Property management SMEs are knowledgeable about requirements and helpful to precious metal custodians. These SMEs schedule and conduct annual inventories to assure precious metals are inventoried and reconciled to support annual reporting requirements.
- Interviews conducted indicate that custodians were aware who the current property management SME is and who to contact with questions or problems. Custodians are aware and adhere to the requirements.
- During walkthroughs of lab spaces, physical protection for storage of precious metals was verified by observation of proximity card readers and the use of noncombustible combination locked repositories, as required.
- Physical security of precious metals while in use is the responsibility of the researcher, and was described as potentially less stringent.
- Precious metal program records are not currently filed in ERecords. Property Management has initiated an effort to develop a file plan and then file program records according to PNNL records management requirements in ERecords (Finding-2).
- Gold rings managed by one custodian were not being weighed annually, as required by 41-CFR-109-27.5104-4, because they are heavier than the available balance in the Limited Area where the items are stored. The interviewee stated that there is no loss of the material given its use, so annual visual inspection has been used in place of weighing to confirm inventory (Finding-3).
- Custodial training is accomplished via a "Custodian Training Guide" (December 2017) that is emailed to newly appointed custodians. Interviews indicated that new custodians were aware of the training guide; however, one long-time custodian could not recall receiving the training. The completion of this informal training is not tracked in ELM, and represents an opportunity for improvement (OFI-9).
- The Material Transaction Report (MTR) form does not contain a field for recording balance identification numbers or calibration date information to assure the integrity of inventory weight information. Interviews indicated that a small number of MTRs are submitted after the transfer has already occurred and that there tended to be a significant number of pen-and-ink changes on MTR forms to correct discrepancies.
- The Physical Inventory of Precious Metals form used for collecting annual inventory measurements includes the scale identification number (Scale ID No.) and scale calibration date fields; both which provide assurance for annual inventory reporting. The assessment team recommends adding balance identification and calibration dates per the requirements stated in PNNL's Basic Laboratory and Operations Practices (OFI-10).
- Situational awareness for line managers is inconsistent and based on what the line managers hear from staff. Some of the line managers interviewed were not aware that their staff managed precious metals, and none were

[1]With approval of PNSO, the annual precious metals inventory for FY 2020 was waived due to SARS-CoV-2 stay-in-place orders by DOE.

familiar with the quantity or value of the materials under the direct control of their staff. As such, the assessment team recommends providing reports/information to cognizant managers who have staff that work with precious metals to increase situational awareness (OFI-1).

- There is a significant amount of legacy precious metals held at PNNL. Metal inventories exceed the current research need. HDI requires custodians to "turn in precious metals that are no longer needed for programmatic activities to Excess Materials and Redeployment Services." 41-CFR-109.27-5105 and 5106 require excess materials to be promptly reported and returned to the DOE precious metals pool. The quantities of precious metals currently being managed by the Excess Materials and Redeployment Services (EMRS) custodian indicates they are using the EMRS as a "storehouse" due to obtaining new precious metals for projects. The assessment recommends that the Laboratory consider the need for these and how they should be dispositioned (OFI-8).

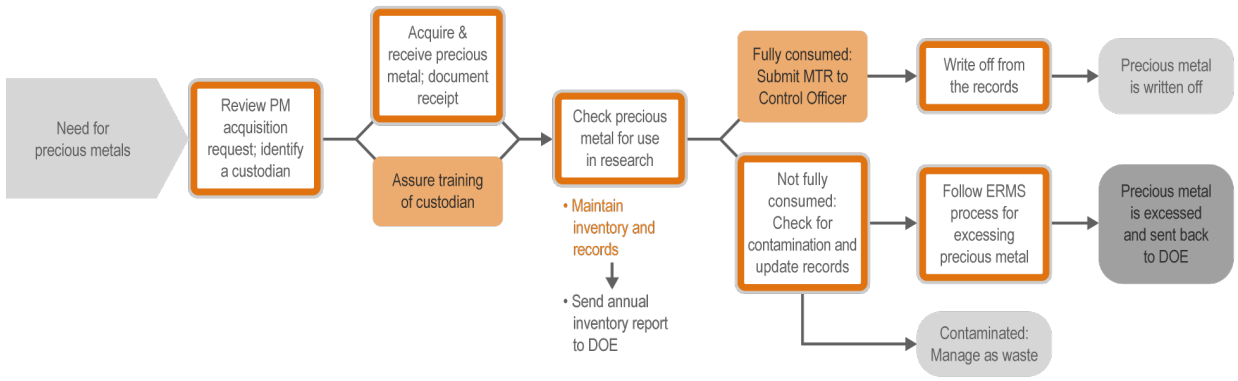

Figure 5. High-level workflow for precious metals.

Requirements management

The assessment team identified the source requirement documents (SRDs) that were related to high-value assets and performed an analysis on the PNNL requirements derived from those SRDs by using a keyword search and by reviewing known HDI processes around asset management. The SRDs included

- 21-CFR-1304 (controlled substances)
- WAC 246-887-020 and -030 (controlled substances)
- 10-CFR-851 and -852 (select toxins)
- 42-CFR-73 (select agents and toxins)
- The Laboratory Biosafety Manual (select toxins)
- 41-CFR-109 (property management)
- The DOE Accounting Handbook (property management).

The implementation methods included internal procedures (e.g., precious metals custodian training guide, finance manual), training (e.g., Biosafety Level 1 training), R2A2s (Roles, Responsibilities, Accountabilities, and Authorities), software (e.g., CMS), and various HDI workflows and work controls.

By reviewing all identified implementation methods, the team was able to verify that requirements were adequately addressed through the existing processes and procedures, with the exception of electronic records management (see the following section). All OFIs recommended are provided in the previous sections of this report.

Records management

The assessment team found that the SMEs for all high-value/high-visibility assets were meeting regulatory requirements, but not following through with PNNL's Records Management requirements. The PNNL requirement is that all programmatic electronic records be filed, maintained, and stored digitally in ERecords (requirement as of effective October 1, 2013). Individual findings and OFIs have been incorporated into the sections above.

Findings and Opportunities for Improvement

The suite of assessment activities resulted in the identification of three findings and ten OFIs.

- **Finding-1**— The Worker, Safety, and Health M&O Program maintains records for select toxins. The SME has a file plan, but select toxin records are missing in ERecords.

  Management Response: The SME will work with Records Management to identify the appropriate Worker, Safety, and Health M&OP records that need to be stored in ERecords (due date: September 30, 2021).

- **Finding-2**— The Property Management M&OP has initiated an effort to develop a file plan and file program records; however, precious metals records are not currently filed in ERecords.

  Management Response: The M&OP has set up ERecords training and will add precious metals records into ERecords (due date: August 1, 2021).

- **Finding-3**—One pair of gold rings have not been weighed annually, as required, because they are heavier (> 2 kg) than the available balance in the Limited Area where the items are stored (they are currently monitored by visual inspection). This is in non-compliance with 41-CFR-109-27.5104-4.

  Management Response: The M&OP will coordinate approved inventory weigh-in of gold rings with the custodian (Due date: June 30, 2021).

- **OFI-1**—To address gaps in TL's responsibility to provide oversight of controlled substances, select toxins, and precious metals, the assessment team recommends SMEs provide reports to managers who are responsible for oversight of these assets.

  Management Response: Management agrees with this OFI. The Environmental Management M&OP will update the recurring OTS-03958 biennial inventory actions to include sending a copy of the completed controlled substance biennial inventory reports to the registrant's team leader. (Due date: September 30, 2021) (Cheryl Duchsherer).

  The Property Management M&OP will confirm that a message goes to the line manager for all precious metals under their stewardship (due date: June 30, 3021) (Dan Kinion).

  Under the WS&H M&OP, the BSO will confirm the group manager is included on all Lab Assist activity collaboration and approval processes as the activities identify select toxins. The BSO will also provide a copy to the group manager the Toxin Request form when reviewed and approved by the BSO (due date: January 1, 2022).

- **OFI-2**— Regulations require proper dispositioning of these materials when a custodial staff member leaves their position. Consider adding asset information to the Human Resources transition checklist.

  Management Response: Each of the M&OP SMEs will work with HR to update the transition checklist to assure transition of controlled substances, select toxins, and precious metals from staff to new custodians or line management (due date: December 31, 2021) (Cheryl Duchsherer, Dan Kinion, Mylissia Smith).

- **OFI-3**—TLs have not received training that could help them understand their role relative to oversight of controlled substances, select toxins, and precious metals. Consider adding a training module for new TLs regarding their responsibility for these assets, which is to understand and verify controls are implemented to mitigate risks.

  Management Response: Management agrees with this OFI. The Learning and Development organization under Human Resources will work with the SMEs for each of the assets to determine the best path forward for training TLs when their staff are working with controlled substances, select toxins, and/or precious metals (due date: September 30, 2021).

- **OFI-4**—Data across the CMS, BioMS, and Purchasing systems do not always reconcile and lead to duplicative processes and systems for the information. The assessment team recommends stronger integration of the information between electronic systems as a part of the Laboratory's Unified Asset Management effort.

  Management Response: Management agrees with this OFI. As a part of an ongoing initiative called the Unified Asset Management effort, biological assets (retire BioMS) are part of the FY 2022 assets initiative roadmap and chemical assets (retire CMS) are part of the FY 2023 assets initiative roadmap. These two systems (among others) will be merged into Unified Assets as a single system utilizing the same processes. In FY 2022, an interim integration could be built to assure the shared information is in-sync (due date: FY 2023) (Doug Burkes, Nancy Washton).

- **OFI-5**—While researchers are meeting the federal regulation to generate specific record types as a part of their project records, they are not captured in ERecords per Records Management requirements. The assessment team recommends that the M&OP perform routine assessments to verify that researchers using controlled substances are capturing the Controlled Substance Registration and Inventory records electronically in ERecords.

  Management Response: Management agrees with this OFI. The Environmental Management M&OP will update the recurring OTS-03958 biennial inventory actions with verification steps to verify the completed controlled substance biennial inventory reports have been added to ERecords (due date: September 30, 2021) (Cheryl Duchsherer). In addition, the Environmental Management M&OP will update the recurring OTS-01176 State registration renewal actions and the recurring OTS-02707 DEA registration renewal actions with verification steps to verify the renewed registrations have been entered into ERecords (due date: September 30, 2021) (Cheryl Duchsherer).

- **OFI-6**— Clarify the language in "How Do I?" (HDI) that assigns each select toxin to a PI per the Centers for Disease Control (CDC) definition (the CDC defines a *principal investigator* as "the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program").

  Management Response: Management accepts this OFI. On November 20, 2020, the BSO submitted updated language in HDI for Section 1, Plan Use and Specify Biological Materials, that addresses select toxins under the control of a PI. This language was taken directly from the Federal Select Agent Program for Permissible Toxin Amounts. It is the view of the WS&H M&OP that this language also covers the CDC definition for a PI. (Completed February 16, 2021).

- **OFI-7**—Revise the HDI (Biological-General work control) statement, "Work with select agents can only be performed at a select agent-registered facility," to "Select toxins below regulated amounts may be used at a non-select agent-registered facility with the proper controls established." This revision reflects PNNL's current practice.

  Management Response: Management accepts this OFI. HDI was updated in February 2020 to address specific toxins not regulated by the Federal Select Agent Program (i.e., they are under the permissible levels) if the amount under the control of a PI does not exceed, at any time, the amounts indicated in a table that is referenced in HDI. The WS&H Program believes that this language essentially covers PNNL's practices for PNNL's current practices. (Completed February 16, 2021)

- **OFI-8**—There are legacy select toxins and precious metals that have not been in use for some time. The Laboratory should consider the need for these assets and determine how they should be dispositioned.

  Management Response: Management accepts this OFI. The Property Management M&OP will evaluate the need to return precious metals currently being held at LSW (due date: December 31, 2021) (Dan Kinion). The Worker, Safety and Health M&OP will work with the Operations Manager to schedule a legacy inventory on select toxins (due date: September 30, 2021) (Mylissia Smith).

- **OFI-9**—Custodial training for precious metals is provided through a training guide, which is not tracked through Enterprise Learning Management (ELM). The M&O Program should consider tracking custodial training through ELM.

  Management Response: Management accepts this OFI. The Property Management M&OP will talk with the Enterprise Learning Management team to understand how to include precious metal training in ELM (due date: September 30, 2021). (Dan Kinion)

- **OFI-10**—The MTR form does not have a field for recording balance identification numbers or calibration date information that is required by HDI to assure the integrity of inventory weight information. The assessment team recommends adding this information to the form.

  Management Response: Management disagrees with this OFI. The Property Management M&OP will evaluate HDI-property and materials requiring additional controls to better align with CFR 109. It has been determined that there will not be a need to update the MTR form (due date: December 31, 2021). (Dan Kinion)

Appendix A. Assessment Team Biosketches

Dan Gaspar, Ph.D. (PNNL)

Dr. Daniel Gaspar is a manager in the Energy Processes and Materials Division at PNNL. Dr. Gaspar received his Ph.D. in physical chemistry from the University of Chicago (1998) and a B.S. in chemistry from Duke University (1992). After a brief stint in industry, Dr. Gaspar joined PNNL in 2000. Dr. Gaspar currently helps lead the Co-Optimization of Fuels and Engines (Co-Optima) consortium, a nine national laboratory consortium aimed at increasing the efficiency and decreasing the environmental impact of fuels and engines. Over the past 20 years, Dan has served PNNL in many roles in surface analysis and clean energy science and technology. He has served as program manager for PNNL's solar energy and ARPA-E programs. In 10 years as a group manager for the Applied Materials Group, he led teams developing organic light emitting diodes, battery materials, and separations materials. Dr. Gaspar was previously detailed to DOE in two roles. In the first role, Dan supported the Scientific User Facility Division in Basic Energy Sciences, and in the second he was detailed to the Office of the Undersecretary for Science and Technology to support the National Laboratory Task Force of the Secretary of Energy Advisory Board. As an AVS member for more than 20 years, Dan has served as the chair of the Governance (2016–2019) and Constitution and By-Laws (2012–2015) Committees, chair of the Applied Surface Science Division (2008–2010), and is currently a member of the Governance Committee, as well as the chair of ASTM E42 Committee on Surface Analysis (2010–2015).

Robert Fox, Ph.D. (INL)

Dr. Robert Fox is a senior chemical research scientist actively involved in performing and directing innovative scientific research in the areas of supercritical fluid sciences, nanomaterials synthesis and characterization, metal-complexation reactions, lanthanide and actinide separations, renewable and biofuel synthesis, geochemistry, environmental radiochemistry, LIBS atomic spectroscopy, laser spectroscopy, and molecular spectroscopy. He is currently and has been the technical lead on research tasks and principal investigator of a number of successful internally funded and externally funded research programs for the U.S. Departments of Energy, Defense, and Homeland Security, as well as private industrial entities. He has received two international R&D 100 Awards for patented inventions: Precision Nanoparticles in 2009 and Supercritical Solid Catalyst in 2010. The Supercritical Solid Catalyst invention was awarded a 2010 Gordon Battelle Prize for Technology Impact, as well as receiving five other innovation awards. He has been issued 20 U.S. patents and authored more than 25 peer-reviewed publications. Fox is the recipient of an INL Laboratory Director's Award in 2009 and again in 2010. He was named the INL Inventor of the Year for 2009 and again in 2010. Most recently, he was selected as the Idaho Innovator of the Year at the 2010 Idaho Innovation Awards and was nominated R&D Magazine's 2010 Scientist of the Year.

Apeksha Gupta (PNNL)

Apeksha Gupta is a Business and Process Analyst in the Process Analysis organization at PNNL. She has over 9 years of work experience, of which she has spent around five years working with corporate industry and four years at the Laboratory. She is a certified Six Sigma Green belt and helps various teams across Laboratory in their mission for Business and Process Improvement by creating a process workflow, analyzing the gaps, and helping identify the people, process, and system Improvements. She has an eye for detail and is passionate about learning new processes to identify improvement opportunities using the Business Analysis Skills and Six Sigma methodology. She is currently helping the Export Control team with many of their process standardizations and gathering system requirements for new tools being developed. Before coming to PNNL, she has helped design and implement a project management framework, conducting internal quality audits to assure quality and timelines requirements were met. She holds a B.S. in computer applications and an M.S. in engineering and technology management from Portland State University.

Pam Hughes (PNNL)

Pam Hughes manages the PNNL IO office and is responsible for the planning and management of IO assessments to determine the efficiency, effectiveness, and adequacy of PNNL's systems, operations, programs, and processes. Pam previously managed PNNL's planning function, where new capabilities associated with scenario planning and multiyear planning were developed and implemented. Prior experience includes leading PNNL's institutional science and technology performance under the Office of the Deputy Director for Science and Technology, where new standards for Laboratory-level performance were developed and deployed. She managed PNNL's Laboratory Directed Research and Development program and instituted PNNL's science and technology investment process for major capability development initiatives. She developed and implemented technical review processes; trained with Conger and Elsea, Inc. on causal analysis; and has been involved in operational assessments. She has authored and coauthored a number of internal publications and several white papers on peer review for DOE, as well as on science and technology performance. Her undergraduate degree is in social sciences and biology from Washington State University (WSU), and she completed two years of graduate course work in neurophysiology.

Jeff Long (ORNL)

Jeff Long currently serves as a performance management analyst in the ORNL Laboratory Protection Division, which is responsible for providing emergency services, laboratory shift supervision, nuclear materials control and accountability, nuclear materials management, information security, physical security, security program management, personnel security, and armed protective force security services to all ORNL organizations and operations. Jeff's primary responsibilities are to support the division in the areas of performance management, quality assurance, self-assessment, and issues management. Jeff previously served as ORNL's nuclear materials representative and Nuclear Material Control and Accountability team leader. Prior DOE experience includes 10 years in quality assurance at ORNL and 9 years in weapons program management at the Y-12 National Security Complex. He is a graduate of the University of Tennessee, Knoxville, with B.S. degrees in operations management and marketing.

Lauren Perrault (PNNL)

Lauren Perrault is a quality and assurance specialist with PNNL's Prime Contract and Requirements Management organization. For 11 years, she worked in the HDI program, leading content revisions and recommending process improvements to procedure owners. She has a drive to connect people, processes, and tools to find the best way to provide information. In that context, she launched two internal projects to deliver experimental tools for research staff. She has also taken on stretch assignments across nearly every support organization to reintroduce and reinforce the basics of content management and document control. She has a B.A. in English from WSU and an M.A. in mass communication from the University of Florida.

Russell Swannack (PNNL)

Russell Swannack is a certified Senior Quality Engineer within PNNL's Performance Management organization. He joined PNNL in 1982 and spent 24 years as an IT engineer, providing support for real-time data acquisition and control systems, network infrastructure, software programming, databases, and server administration. He then spent six years as an IT project manager for Battelle Memorial Institute supporting analytical chemistry, biology, toxicology, and clinical pathology projects. For the past eight years, he has been in the PNNL Quality Assurance group providing support to all PNNL research and enterprise projects as their software quality practitioner. He holds a B.S. in computer science and an M.S. in technology management, both from WSU, and has been a certified project management professional since 2008. For the past 14 years, he has also been an adjunct professor at WSU for the College of Engineering and the College of Business.

John Wacker, Ph.D. (PNNL)

Dr. John Wacker is a Laboratory fellow at PNNL and currently works in nuclear signatures analysis, nuclear forensic analysis, and related fields. From 2007 to 2010, John was detailed to DOE in Washington, D.C., as the chief scientist in the Nuclear Materials Information Program, where he advised DOE and other government agencies and

departments on issues relating to nuclear materials and nuclear forensics. John returned to PNNL in 2010 and continues his advisory role within the government, as well as bringing his knowledge and experience to bear in various leadership roles at PNNL. He is a member of expert panels and advisory committees for the U.S. Department of Defense and the Office of the Director of National Intelligence and contributes to projects funded by DOE and other government sponsors. He is the principal investigator on projects funded through the National Nuclear Security Administration, the Defense Threat Reduction Agency, and other Department of Defense sponsors to cover nuclear materials analysis, analytical technology development, and post-detonation nuclear forensics. Prior to 2007, John proposed and managed many research and development projects at PNNL. From 1993 to 2004, he directed an analytical laboratory at PNNL that performs nuclear material analyses in support of government needs. John earned a Ph.D. in planetary sciences from the University of Arizona in 1982 and an S.B. in physics from the Massachusetts Institute of Technology in 1976.

Pat Weaver (PNNL)

Patrick Weaver has over 25 years of experience in various organizations across Battelle. He currently leads Operational Risk Management for the Operational Services Directorate and provides support to the broader Laboratory in emerging high-risk, scope-of-work projects. This includes leadership of efforts to manage significant operational issues while providing independent operational expertise across the Operational Services Directorate and PNNL. Prior to returning to PNNL in 2017, Patrick was the director of infrastructure operations for the National Bioanalysis and Countermeasures Center, responsible for all infrastructure systems and processes necessary to allow biological research to be safely conducted in environments up to and including Biological Safety Level 4. This included initial start-up of operations and transition from construction to an operating laboratory. He established a strong safety culture resulting in a best-in-class safety/biosafety program that was innovative, continuously improving and evolving to adapt to changing science needs. Patrick has also managed nuclear remediation at both PNNL and Battelle Columbus Operations, where he directed the decommissioning of a high-hazard radiological facility and secured unrestricted free release of the site under U.S. Nuclear Regulatory Commission regulations. Patrick has a B.S. in chemical engineering from the University of Washington and an M.S. in environmental sciences management from the National Technological University. He has held his professional engineering license from the state of Washington since 1992.

Molly Weinbender (PNNL)

Molly Weinbender is a senior records management professional within PNNL's Records Management organization. She joined PNNL in 1998 and has over 20 years of experience in the records and information management profession, providing consultation to staff at PNNL concerning all stages of the records management life cycle for programmatic, organizational, and project records management. She has been a certified records manager since 2011. Molly serves in the records management assurance role, which involves deploying, monitoring, and assessing Records Management M&OP requirements and extent of deployment. She is also the records management training SME, which involves creating and deploying records management training to all levels of staff at PNNL. She holds a B.A. in business administration from WSU.

Appendix B. Lines of Inquiry

General lines of inquiry that guided the interview process are described below:

- How well does the HDI subject areas and associated procedures provide assurance for inventorying, tracking, and protecting controlled substances, precious metals, and select toxins (below permissible limits) in accordance with applicable requirements?
- Do our procedures and practices provide effective controls for tracking and protection of controlled substances, precious metals, and select toxins (below permissible limits)?
- How is it assured that work is conducted in accordance with established processes and procedures for tracking and protecting controlled substances, precious metals, and select toxins (below permissible limits)?
- How effective are our work planning and controls processes for assuring against the manufacture of controlled substances (from precursors)?
- How effective is the training for tracking and protecting controlled substances, precious metals, and select toxins (below permissible limits)?

Appendix C. List of PNNL Interviewees

Brandon, Jill	Ibrahim, Yehia	Nuzum, Jennifer	Smith, Mylissia
Cooper, Billy D	Jagelski, John	Omberg, Kristen	Smith, Scott
Cort, John	Johannesen, Judy	Panisko, Mark	Southard, Susan
Coyle, Chris	Kinion, Dan	Pentecost, Amber	Stegen, Amanda
Duchsherer, Cheryl	Lidey, Lance	Pinza, Margaret	Stephens, Vicki
Elliott, Mike	Mackereth, Kailan	Richmond, Bill	Tyrrell, Kim
Ewing, Robert	McDermott, Tom	Robinson, Robby	Victry, Kristin
George, Jaime	Melville, Aaron	Rohlfing, Kerrie	Wahl, Karen
Gibbins, Teresa	Merkley, Eric	Roland, Tracie	Woodruff, Dana
Hallum, Cheryl	Moody, Don	Sather, Nichole	Wunschel, David
Hardy, John	Myers, Tanya	Simpkins, Paul	

Appendix D. Reference Library

- "Approval of the Battelle Memorial Institute (BMI), PNNL Property Management System," December 18, 2019.
- "Biosafety Level 2 Requirements"
- Center for Disease Control and Prevention, Division of Select Agents and Toxins: "What is a Select Agent?" Website: https://www.cdc.gov/cpr/dsat/what-is-select-agents.htm.
- Congressional Research Service, "The Controlled Substances Act (CSA): A Legal Overview for the 177th Congress," February 5, 2021.
- Cornell Law School, Legal Information Institute (LII), "21 U.S. Code 812, Schedules of Controlled Substances," https://www.law.cornell.edu/uscode/text/21/812.
- "Exhibit: Chemical-Controlled Substances," Pacific Northwest National Laboratory, April 16, 2020.
- "Exhibit: Property and Materials Requiring Additional Controls," Pacific Northwest National Laboratory, January 14, 2021.
- Johnson, Wayne. "Assets Digital Platform Blueprint," April 29, 2021.
- "Managing and Operating the Pacific Northwest National Laboratory Program Description," July 2020.
- "Research Operations Procedure for Schedule I Opioids and Schedule II Fentanyl Analogs (DRAFT)," Pacific Northwest National Laboratory, January 19, 2021.
- "Technical Assessment of the Pacific Northwest National Laboratory Personal Property Management System," August 2018.
- United States Department of Justice, Drug Enforcement Administration website: https://www.deadiversion.usdoj.gov/21cfr/21usc/.
- United States Drug Enforcement Administration website: https://www.dea.gov/controlled-substances-act.
- "Updated Safeguards and Security Plan (SSP) for PNNL," December 1, 2020.

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