



**OFFICE OF INSPECTOR GENERAL**

U.S. Department of Energy

# INSPECTION REPORT

DOE-OIG-23-02

October 2022

**PACIFIC NORTHWEST NATIONAL  
LABORATORY MANAGEMENT OF  
CONTROLLED SUBSTANCES**



**Department of Energy**  
Washington, DC 20585

October 18, 2022

MEMORANDUM FOR THE MANAGER, PACIFIC NORTHWEST SITE OFFICE

SUBJECT: Inspection Report on Pacific Northwest National Laboratory Management of Controlled Substances

The attached report discusses our review of the management of controlled substances at the Pacific Northwest National Laboratory. This report contains one recommendation that, if fully implemented, should help ensure that the Pacific Northwest National Laboratory properly manages its controlled substances as required. Management fully concurred with our recommendation.

We conducted our inspection from October 2021 through May 2022 in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation*. We appreciated the cooperation and assistance received during this evaluation.

A handwritten signature in black ink, appearing to read "Anthony Cruz".

Anthony Cruz  
Assistant Inspector General  
for Inspections, Intelligence Oversight,  
and Special Projects  
Office of Inspector General

cc: Deputy Secretary  
Chief of Staff



## **Department of Energy Office of Inspector General**

### **Pacific Northwest National Laboratory Management of Controlled Substances (DOE-OIG-23-02)**

#### **WHY THE OIG PERFORMED THIS REVIEW**

**Pacific Northwest National Laboratory (PNNL) promotes its controlled substances research capability as world-class and highlights its longstanding contribution to establishing fentanyl standards and detection technology. Poorly managed controlled substances could result in lost or stolen items that could cause serious harm to the public.**

**We initiated this inspection to determine the extent that PNNL effectively manages controlled substances.**

#### **What Did the OIG Find?**

Based on our inspection, we found that PNNL did not incorporate all applicable Federal property regulations into its management of controlled substances. Specifically, it did not classify them as personal property, did not categorize them as sensitive personal property, and did not follow prescribed inventory standards. This occurred because PNNL and the Pacific Northwest Site Office misclassified controlled substances as chemical assets.

#### **What Is the Impact?**

Failure to address all applicable Federal requirements resulted in PNNL not properly tracking and reporting controlled substances inventories, not sending disposition reports to the Pacific Northwest Site Office, and improper segregation of duties for physical inventory counts. Moreover, the lack of additional mechanisms for identifying lost, misplaced, or stolen controlled substances could pose a danger to public health and safety.

#### **What Is the Path Forward?**

To address the issues identified in this report, we made a recommendation that, if fully implemented, will improve management of controlled substances at PNNL.

## BACKGROUND

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The Pacific Northwest National Laboratory (PNNL) is 1 of 17 national laboratories operated by the Department of Energy. PNNL carries a broad portfolio of scientific activities within chemistry, earth science, biology, and data science. PNNL conducts research utilizing controlled substances in contributing to fentanyl standards establishment and detection technology. The Pacific Northwest Site Office (PNSO) oversees PNNL for the Department's Office of Science.

Controlled substances are those items the Drug Enforcement Administration (DEA) identifies and categorizes in Title 21 Code of Federal Regulations (CFR) § 1308, *Schedules of Controlled Substances*. Controlled substances are categorized in Schedule I through V, with Schedule I being the most restricted. Title 21 CFR §§ 1300–1317 also outline registration, record-keeping, inventory, records, physical security, and disposal requirements. Title 41 CFR § 109, *Department of Energy Property Management Regulation*, outlines the Department's basic requirements for the management and security of controlled substances. Title 41 CFR § 109 prescribes the development of effective procedures and practices that provide for safeguarding, proper use, adequate records, and compliance with applicable laws and regulations. Additional Federal and State regulations also govern management of controlled substances. For example, Title 41 CFR § 102, *Federal Management Regulation*, requires special handling for disposal of controlled substances similar to DEA requirements. Further, Federal Acquisition Regulation (FAR) 52.245–1, *Government Property*, categorizes controlled substances as belonging to the sensitive property subset of personal property that is subject to exceptional control and accountability, and Washington Administrative Code, Chapter 246–945, adopts DEA regulations and sets forth State-specific requirements (e.g., controls on chemicals that could be used to prepare controlled substances). PNNL implements its management of controlled substances through its procedures and practices. We initiated this inspection to determine the extent that PNNL effectively manages controlled substances.

## PNNL MANAGEMENT OF CONTROLLED SUBSTANCES

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Based on our inspection, we found that PNNL did not incorporate all applicable Federal property regulations into its management of controlled substances. Specifically, it did not classify them as personal property, did not categorize them as sensitive personal property, and did not follow prescribed inventory standards.

PNNL did not incorporate all applicable Federal property regulations into its management of the controlled substances program. For example, PNNL did not classify controlled substances as personal property even though they are specifically listed in Federal property regulations. Title 41 CFR § 102 lists controlled substances in its definitions section, and also prescribes special handling requirements for their disposition. Additionally, Title 41 CFR § 109 devotes a specific section to controlled substances. While PNNL had procedures and practices that addressed the general requirements of that section, (e.g., safeguarding, proper use, adequate record keeping, and the most applicable laws and regulations), it did not account for the other property requirements found in Title 41 CFR § 109. Namely, PNNL neither managed its inventory process nor shared its records with the PNSO in accordance with Title 41 CFR § 109 and FAR 52.245–1.

Moreover, PNNL did not categorize controlled substances as sensitive personal property, a subset of personal property that is subject to additional controls. For example, FAR 52.245–1 specifically lists controlled substances as an example of sensitive personal property. A sensitive personal property categorization, according to Title 41 CFR § 109, requires sensitive personal property to be inventoried annually with 100 percent accuracy. Title 41 CFR § 109 and Department of Energy Acquisition Regulation 970.5204–2, *Laws, Regulations, and DOE Directives*, require compliance with all applicable laws and regulations. Although FAR 52.245–1 was not explicitly stated in PNNL’s contract, we consider it to be applicable because it addresses the management of controlled substances.

Finally, PNNL’s inventory procedures and practices did not meet Title 41 CFR § 109 sensitive personal property standards; rather, they only addressed DEA standards. For example, Title 41 CFR § 109 requires annual accountability inventories for sensitive personal property. However, PNNL currently conducts biennial inventories according to DEA requirements. Moreover, Title 41 CFR § 109 requires a 100 percent inventory of all sensitive personal property. The DEA standard, however, requires 100 percent physical count of Schedule I and Schedule II drugs only, allowing Schedule III–V counts to be estimated. Further, Title 41 CFR § 109 indicates that physical inventories shall be performed by personnel other than the property custodians, unless staffing or other considerations apply, and requires second-party verification when custodians inventory Government property. DEA standards, on the other hand, do not require a similar segregation of duties in the inventory process. Lastly, Title 41 CFR § 109 requires inventory reports be submitted to Department property personnel, but we found no such equivalent DEA submission requirement.

## **MISCLASSIFICATION OF CONTROLLED SUBSTANCES**

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This issue occurred because PNNL and the PNSO misclassified controlled substances as chemical assets rather than recognizing them as sensitive personal property. During interviews, PNNL personnel stated that they managed controlled substances as chemicals and did not consider them to be sensitive personal property. Additionally, the PNSO also classified controlled substances as chemicals. This is significant because the Department’s *Chemical Management Handbook* focuses primarily on hazard analysis and employee health and safety, whereas Title 41 CFR § 109 addresses inventory requirements, processes, required records, and oversight responsibilities.

## **IMPACT**

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Failure to address all the applicable Federal requirements discussed above resulted in PNNL not properly tracking and reporting controlled substances inventories, not sending disposition reports to the PNSO, and improper segregation of duties for physical inventory counts. An absence of required inventory and disposition reports limited the PNSO’s oversight of controlled substances. Moreover, PNNL and the PNSO lack the additional mechanisms for identifying lost, misplaced, or stolen controlled substances, which could pose a danger to public health and safety. Finally, the additional Federal requirements, set forth above, have become increasingly important, as relied upon methods of oversight by DEA and State regulators have recently

decreased, and PNNL has begun to increase its work with controlled substances. We found that oversight of controlled substances at PNNL was mainly performed by DEA and State regulators. However, DEA and State regulators have scaled back their assessments of PNNL's program in recent years due to competing priorities and staffing shortages. For example, DEA has not conducted an on-site assessment since 2019, and it does not require PNNL to send in its inventory records for verification or review. State regulators also conduct project-specific site visits for new registration applicants but have not conducted a program review since prior to 2017 due to competing priorities and budget concerns. Similarly, the State does not require PNNL to send in its inventory or disposition records for verification or review. Meanwhile, PNNL plans to expand its controlled substances research. There are currently four projects underway with at least two additional projects to be initiated in the near future.

## **RECOMMENDATION**

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In light of the above observations, we recommend the Manager, PNSO:

1. Ensure PNNL incorporates all applicable Federal property regulations included in Title 41 CFR § 109 and FAR 52.245-1 into its management of controlled substances.

## **MANAGEMENT RESPONSE**

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Management fully concurred with our findings and recommendation.

Management's comments are included in Appendix 3.

## **INSPECTOR COMMENTS**

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Management's comments and corrective action are responsive to our recommendation.

## **Appendix 1: Objective, Scope, and Methodology**

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### **OBJECTIVE**

We initiated this inspection to determine the extent that Pacific Northwest National Laboratory (PNNL) effectively manages controlled substances.

### **SCOPE**

The inspection was performed from October 2021 through May 2022. We conducted the inspection at PNNL and the Pacific Northwest Site Office located in Richland, Washington. The scope was limited to a review of the adherence to controlled substance regulations, policies and procedures, registration requirements, and internal controls from fiscal year 2011 through fiscal year 2021. The inspection was conducted under Office of Inspector General project number S22RL002.

### **METHODOLOGY**

To accomplish our audit objective, we:

- Reviewed prior Office of Inspector General reports, and Department of Energy and PNNL internal and external program reviews;
- Reviewed PNNL's contract, applicable laws, regulations, policies, and procedures, and checked compliance with Drug Enforcement Administration registration requirements;
- Reviewed PNNL's inventory and disposition records for all six controlled substance projects occurring during our scope timeframe;
- Judgmentally selected and tested two of four active controlled substance projects;
- Judgmentally selected and tested two Schedule I controlled substances;
- Validated 100 percent of PNNL's training records and required controlled substance Registrations; and
- Interviewed key officials from PNNL, the Pacific Northwest Site Office, and the Drug Enforcement Administration.

We conducted our inspection in accordance with the Quality Standards for Inspection and Evaluation (December 2020) as put forth by the Council of the Inspectors General on Integrity and Efficiency. We believe that the work performed provides a reasonable basis for our conclusions.

Management officials waived an exit conference on September 27, 2022.

## **Appendix 2: Prior Report**

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Inspection Report on [\*Management of Controlled Substances at Los Alamos National Laboratory\*](#) (September 2019, DOE-OIG-19-54). We found that Los Alamos National Laboratory had not managed controlled substances in accordance with applicable Federal laws and regulations. Specifically, we identified four personnel that previously or currently possessed Drug Enforcement Administration registrations, three of which allowed researchers to possess/use controlled substances. A fourth registration was for a medical practitioner who did not possess or dispense controlled substances. Our inspection also found that Los Alamos National Laboratory possessed mislabeled procurement records, inaccurate inventories, and retained controlled substance inventories well beyond the conclusion of experiments. We determined that Los Alamos National Laboratory did not have appropriate institutional processes, procedures, or controls in place to monitor, track, account for, and dispose of controlled substances.

## Appendix 3: Management Comments

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**Department of Energy**  
**Office of Science**  
Pacific Northwest Site Office  
P.O. Box 350, K9-42  
Richland, Washington 99352

SEP 13, 2022

22-PNSO-0253

MEMORANDUM FOR: ANTHONY CRUZ  
ASSISTANT INSPECTOR GENERAL FOR INSPECTIONS,  
INTELLIGENCE, OVERSIGHT, AND SPECIAL PROJECTS  
OFFICE OF INSPECTOR GENERAL

FROM: THEODOR P. PIETROK **Theodore P. Pietrok**  
ACTING MANAGER Digitally signed by Theodore P. Pietrok  
Date: 2022.09.13 14:53:36  
-07'00'

SUBJECT: PACIFIC NORTHWEST SITE OFFICE (PNSO) RESPONSE TO  
OFFICE OF INSPECTOR GENERAL'S (OIG) DRAFT  
INSPECTION REPORT, "PACIFIC NORTHWEST NATIONAL  
LABORATORY MANAGEMENT OF CONTROLLED  
SUBSTANCES"

Thank you for the opportunity to comment on the OIG's draft report, "Pacific Northwest National Laboratory Management of Controlled Substances." Below is the PNSO response to the recommendation.

**Recommendation 1:** In light of the above observations, and to effectively manage controlled substances, we recommend the Manager, PNSO, ensure PNNL incorporates all applicable Federal property regulations included in Title 41 CFR 109 and FAR 52.245-1 into its management of controlled substances.

**Management Response:** Concur

PNSO will direct PNNL to incorporate all applicable Federal property regulations included in Title 41 CFR 109 and FAR 52.245-1 into its management of controlled substances.

**Estimated Completion Date:** June 30, 2023

## Appendix 3: Management Comments

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Mr. A. Cruz  
22-PNSO-0253

SEP 13, 2022

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If you or your staff have any questions or concerns, please contact Neomi Mendez, Business Division, at (509) 372-4503.

cc: T. D. Fuller, CF-20  
K. L. Johnson, CF-20  
T. J. Pooler, SC-CSC  
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Office of Inspector General (IG-12)  
Department of Energy  
Washington, DC 20585

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