



OFFICE OF INSPECTOR GENERAL

U.S. Department of Energy

INSPECTION REPORT

DOE-OIG-19-54

September 2019

**MANAGEMENT OF CONTROLLED
SUBSTANCES AT LOS ALAMOS
NATIONAL LABORATORY**



Department of Energy
Washington, DC 20585

September 30, 2019

MEMORANDUM FOR THE MANAGER, LOS ALAMOS FIELD OFFICE

A handwritten signature in black ink, appearing to read "Bruce Miller".

FROM: Bruce Miller
Assistant Inspector General
for Audits and Inspections
Office of Inspector General

SUBJECT: INFORMATION: Inspection Report on “Management of Controlled Substances at Los Alamos National Laboratory”

BACKGROUND

The Department of Energy’s Los Alamos National Laboratory (Los Alamos) is part of the National Nuclear Security Administration’s nuclear security enterprise. The primary mission at Los Alamos is to solve national security challenges through scientific excellence. Los Alamos executes work in all of the Department’s missions: national security, science, energy, and environmental management, as well as research and development for agencies such as the Department of Defense and the Intelligence Community. As part of its work, Los Alamos conducts research involving controlled substances.

Controlled substances are managed under several Federal regulations including Federal Acquisition Regulation (FAR), Part 52.245-1, *Government Property*, and Code of Federal Regulations, Title 21, Parts 1300-1317 (21 CFR 1300-1317). The latter regulation, administered by the Drug Enforcement Administration (DEA), categorizes controlled substances and specifies the requirements for registration and usage. The FAR stipulates that controlled substances be classified as sensitive property and “subject to exceptional physical security, protection, control, and accountability.”¹ Additionally, it requires that the Contractor have a system of internal controls to effectively and efficiently manage Government property. Due to the potential safety and health risks associated with controlled substances, we initiated this inspection to determine if Los Alamos National Laboratory, operated by Los Alamos National Security, LLC, managed controlled substances in accordance with applicable Federal laws and regulations.

¹ Fieldwork testing was conducted under Department Order 580.1A, *Personal Property Management Program*, which was cancelled by Contract Modification 0378 in March 2017, just after fieldwork testing concluded. According to the Department Order’s author, Office of Management, the Order was cancelled because it duplicated other Department regulations managing Government property. These regulations include 41 CFR 101, *Federal Property Management Regulations*; 41 CFR 109, *Department of Energy Property Management Regulation*; and FAR 52.245-1, *Government Property*.

RESULTS OF INSPECTION

We found that Los Alamos had not managed controlled substances in accordance with applicable Federal laws and regulations. Specifically, we identified four personnel that previously or currently possessed DEA 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 possessed mislabeled procurement records, inaccurate inventories, and retained controlled substance inventories well beyond the conclusion of experiments. We determined that Los Alamos did not have appropriate institutional processes, procedures, or controls in place to monitor, track, account for, and dispose of controlled substances.

FAR 52.245-1 lists controlled substances as sensitive property, and therefore, subject to exceptional physical security, protection, control, and accountability. It further states that the Contractor shall initiate and maintain the processes, systems, procedures, records, and methodologies necessary for effective and efficient control of Government property. Additionally, it requires the Contractor to establish and maintain procedures necessary to assess its property management system effectiveness and to perform periodic internal reviews, surveillances, self-assessments, or audits. We used information from interviews, the researchers' log books, and system queries to identify eight controlled substances by name in Los Alamos' official centralized database for chemicals, ChemDB. According to Los Alamos officials, this system was not designed to meet accountability requirements for controlled substances. However, according to researchers interviewed, ChemDB, was used because of the lack of an institutional database designed to account for controlled substances. In addition, our review of the eight controlled substances within two institutional databases and researcher records identified:

- Mislabeled procurement records;
- Incomplete and inaccurate inventory records; and
- Controlled substances held in inventory longer than necessary.

We attribute these weaknesses to a lack of institutional policy guidance. Specifically, Los Alamos did not apply consistent procedures across the lab to appropriately classify or account for controlled substances from acquisition to final disposition. These weaknesses reduce the Department's assurance that Los Alamos is protecting controlled substances from misuse or loss. In response to our inspection, Los Alamos recently approved a policy for the management of controlled substances, and should implement that policy to ensure that Los Alamos meets the requirements of FAR 52.245-1 and DEA regulations.

Summary of Findings

Our inspection identified mislabeled procurement records, incomplete and inaccurate inventory records, and unnecessary retention of controlled substances. Additionally, through interview data, we determined that officials from the Los Alamos Occupational Medicine and the Los Alamos Acquisition Services Management division were unaware of researchers procuring, retaining, and utilizing controlled substances for research work, despite current, internal

controls.² At the time of our fieldwork, we identified a total of four personnel that previously or currently possessed DEA registrations. Three of the identified personnel with DEA registrations conducted research with controlled substances, while the fourth registrant did not work with controlled substances. We subsequently identified eight controlled substances at Los Alamos within the scope of our work that were utilized for research by the three registrants who worked with controlled substances.

Drugs and other substances that are considered controlled substances under the *Controlled Substances Act* are divided into five schedules. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. The eight substances identified at Los Alamos included the following:

- Schedule II: cocaine, codeine, fentanyl, methamphetamine, morphine, and sodium pentobarbital. Schedule II controlled substances are those with a high potential for abuse that may lead to severe psychological or physical dependence.
- Schedule III: ketamine. Schedule III controlled substances have less potential for abuse than substances in Schedule I or II and may lead to moderate or low physical dependence or high psychological dependence.
- Schedule IV: chloral hydrate. Schedule IV controlled substances have a low potential for abuse relative to substances in Schedule III.

Mislabeled Procurement Records

We determined that the purchases we identified as being for controlled substances were mislabeled with the incorrect category description in the procurement system records of purchases made between 2005 and 2017. Specifically, we found that between 2005 and 2017:

- Two controlled substances, 1 gram of cocaine and 5 grams of methamphetamine, were categorized in the procurement system as “Drugs and Biologicals.”
- One controlled substance, fentanyl, was categorized in the procurement system as “Goods” on two separate procurement orders of 50 grams each.
- Two controlled substances, 1 milliliter of morphine and 7 milliliters of codeine (between two separate orders), were categorized in the procurement system as “Chemical.”

According to a Los Alamos Acquisition Services Management official, when procurements are improperly categorized, required management or subject matter expert reviews and approvals are bypassed. Therefore, procurement personnel may not know that they are requesting a controlled

² According to Los Alamos Document 3400.00.0410 (Dec 2016), controlled substances are managed, physically controlled, and disposed of by Los Alamos Occupational Medicine in accordance with applicable Federal and state guidelines.

substance or complete the documentation required by Los Alamos. Due to the inaccuracies in the procurement system records at Los Alamos, we could not be certain that we had identified all of the controlled substances onsite.

Inaccurate and Incomplete Inventory Records

Our inspection identified inaccurate and incomplete inventory records for controlled substances at Los Alamos. FAR 52.245-1 specifically identifies controlled substances as sensitive property, therefore subject to exceptional physical security, protection, control, and accountability. It further states that the Contractor shall maintain processes, systems, procedures, records, and methodologies necessary for effective and efficient control of Government property. Overall, we concluded that the documentation maintained by Los Alamos did not meet these standards. Specifically:

- Inventory records in Los Alamos' ChemDB overstated the amount of controlled substances. Specifically, on February 14, 2017, we observed controlled substances with active containers (e.g. chloral hydrate, cocaine, and methamphetamine) did not match the inventories maintained by individual researchers.
- One controlled substance, 50 grams of fentanyl, was procured on February 2, 2015, but was not added to the ChemDB until February 6, 2017, 1 week prior to the initiation of our inspection. The 2017 entry only showed 5 grams of fentanyl on hand and did not provide any record of the original procurement of 50 grams.
- One researcher's inventory understated the amount of fentanyl on hand. Specifically, the living inventory indicated that as of May 7, 2015, 48.5 grams were used for experiments out of the original 50 grams procured; however, on May 8, 2015, the inventory weight indicated that only 45 grams were actually consumed by experiment. This left 3.5 grams of fentanyl not readily accounted for. This occurred despite the researcher having an in-house policy outlining inventory and inventory discrepancy procedures.
- One researcher maintained a handwritten inventory accounting for pentobarbital and ketamine. An August 2006 inventory entry indicated that there were approximately (~) 8.4 milliliters (mL) of ketamine and 3.0 mL of pentobarbital. The next entry, August 2008, indicated 8.0 and 3.0 mL, respectively, without any notation on the use of 0.4 mL of ketamine. In the 2011 inventory, the amounts become illegible, and in 2012, the inventory entry indicates that there are 3.0 mL of ketamine and 8.0 mL of pentobarbital.

While we recognize that ChemDB was not designed or intended to account for controlled substances per Department requirements, records of controlled substances were nonetheless managed in this system. Instead, ChemDB was designed to track chemical containers and locations, not chemical usage. However, further review of ChemDB entries indicated controlled substances were tracked in the system as far back as 1993. According to an interview with a researcher, controlled substances were treated as chemicals and were input into ChemDB. Additionally, human errors in the researcher-maintained records created opportunities for controlled substances to be misused or lost without Los Alamos' knowledge.

Controlled Substances Retained Beyond Mission Requirements

Although there is no formal requirement to disposition controlled substances beyond mission need, our inspection identified two controlled substances that were retained unreasonably beyond their mission requirements. Specifically, one researcher maintained control of 8 mL of pentobarbital and 3 mL of ketamine, which are schedule II and III substances, respectively, for 10 years after concluding research. According to the researcher, disposal of the controlled substances was a challenge because Los Alamos lacked relevant policies on how to dispose of controlled substances considered Government property. In 2012, the controlled substances were transferred to the University of New Mexico to be disposed of in accordance with DEA requirements.

Contributing Factors

We found that Los Alamos lacked institutional management controls over controlled substances. We determined that Los Alamos did not have appropriate processes, procedures, or controls in place to monitor, track, dispose of, and account for controlled substances at Los Alamos because Los Alamos lacked an institutional policy governing controlled substances from procurement until final disposition. As a result, the management of controlled substances was conducted at an individual level and lacked appropriate institutional oversight and management as required by FAR 52.245-1. Specifically:

- Purchases were mislabeled, bypassing procurement controls, due to the lack of a policy establishing a clear definition of a controlled substance.
- Controlled substances were inappropriately entered into ChemDB because there was no official guidance specifying how controlled substances should be managed or in what system they should be managed.
- Individual researchers' records were inconsistently maintained and had inaccuracies because researchers used self-produced, unofficial policies and procedures to manage controlled substances in accordance with DEA regulations and not the Department requirements.
- Controlled substances were retained beyond mission requirements because researchers lacked institutional guidance for the disposal of excess substances when research concluded.

Impact

As a result of not implementing appropriate institutional management controls, Los Alamos did not accurately account for nor effectively manage its controlled substances. Without centralized policy guidance and monitoring, Los Alamos cannot fully ensure that controlled substances are managed from procurement to disposition appropriately. Los Alamos has unknowingly accepted the risk of misuse or loss. The potential for risk was especially evident when inventory errors caused an overstatement in the amount of fentanyl consumed by experiments, leaving an

unaccounted surplus. In this instance, the surplus amount created an opportunity for the misuse or loss of a Schedule II narcotic that is increasingly being linked to drug-overdose deaths in the United States. Fentanyl was detected in 56.3 percent of 5,152 opioid overdose deaths in 10 states during July-December 2016. According to the Environmental Protection Agency, fentanyl is 50-100 times more potent than morphine, with a fatal dose of 2 milligrams (0.002 grams) for previously unexposed adults. Based on this lethal dose amount, the loss or misuse of 3.5 grams of fentanyl due to an inventory error has the potential to cause 1,750 deaths.

PATH FORWARD

In response to Office of Inspector General concerns, Los Alamos identified corrective actions and is moving forward to address our concerns. Specifically, as of January 2019, Los Alamos drafted and approved an institutional policy for the management of controlled substances. This new policy particularly addresses procurement, inventory management, and disposition of controlled substances, which includes additional levels of review and accountability. In light of these actions, and in order to effectively manage controlled substances, we suggest that the Manager of the Los Alamos Field Office ensure that Los Alamos:

1. Implements its new institutional controlled substances policy; and
2. Completes an initial evaluation of the effectiveness of Los Alamos' institutional controlled substances policy.

Attachments

cc: Deputy Secretary
Chief of Staff

OBJECTIVE, SCOPE, AND METHODOLOGY

OBJECTIVE

We conducted this inspection to determine if Los Alamos National Laboratory (Los Alamos), operated by Los Alamos National Security, LLC, managed controlled substances in accordance with applicable Federal laws and regulations.

SCOPE

This inspection was conducted from February 2017 through September 2019 at Los Alamos in Los Alamos, New Mexico. Our scope included Los Alamos' controlled substance inventory records and procedures for fiscal year 2005 through June 2017. This inspection was conducted under Office of Inspector General project number S17IS005.

METHODOLOGY

To accomplish the inspection objective, we:

- Reviewed applicable laws, regulations, policies, and procedures, and tested for compliance with key provisions;
- Reviewed prior reports by the Office of Inspector General and external audit/review groups;
- Reviewed inventory and procurement logs at Los Alamos; and
- Interviewed key officials within Los Alamos Occupational Medicine and Acquisition Services Management, as well as officials who conducted research utilizing controlled substances.

We conducted this inspection in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation*. Those standards require that we plan and perform the inspection to obtain sufficient, appropriate evidence to provide a reasonable basis for our conclusions and observations based on our inspection objective. We believe that the evidence obtained provided a reasonable basis for our conclusions and observations based on our inspection objective. Accordingly, the inspection included tests of controls and compliance with laws and regulations to the extent necessary to satisfy the inspection objective. Because our review was limited, it would not necessarily have disclosed all internal control deficiencies that may have existed at the time of our inspection. We relied on computer-processed data to satisfy our objective. Based on our comparison of computer-processed data to supporting documents and inventory, we determined that the data was sufficiently reliable for our purposes.

Management officials waived an exit conference on September 4, 2019.

PRIOR REPORTS

- Inspection Report on [Management of Controlled Substances at Lawrence Livermore National Laboratory](#) (INS-O-11-01, February 2011). Due to the potential safety and health risks associated with controlled substances, the Office of Inspector General initiated this inspection to determine whether Lawrence Livermore National Laboratory (Livermore) was appropriately managing controlled substances to prevent misuse or misappropriation. The inspection found that with exception of the Health Clinic, Livermore was not appropriately managing its controlled substances in accordance with Federal regulations and Department of Energy policy intended to prevent misuse or misappropriation. Specifically, testing revealed that Livermore could not accurately account for quantities received, distributed, used, or on hand for at least 6 of the 33 controlled substances in the possession of the Analytical Laboratory. Also, despite requirements to the contrary, Livermore did not segregate accounting for substances listed on different schedules and under different business activities.
- Inspection Report on [Internal Controls Over Methamphetamine Precursor Chemicals at the Y-12 National Security Complex and the Oak Ridge National Laboratory](#) (IG-0650, June 2004). The Office of Inspector General initiated an inspection at two of the Department's major Oak Ridge facilities, the National Nuclear Security Administration Y-12 National Security Complex and the Oak Ridge National Laboratory, to determine whether there were adequate controls over precursor chemicals that could be stolen for use in the illegal production of methamphetamine. The inspection did not find any indicators of theft of precursor chemicals from either laboratory during the inspection. However, given the existence of precursor chemicals at these sites and the heightened concern that these chemicals could be targeted for theft, the report identified supplementary steps that could be taken to reduce the possibility of site chemicals being diverted for the illegal production of methamphetamines.

FEEDBACK

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