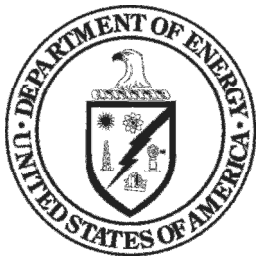

U.S. Department of Energy
Office of Inspector General
Office of Audits and Inspections

Inspection Report

Management of Controlled Substances at Lawrence Livermore National Laboratory

INS-O-11-01

February 2011

Department of Energy
Washington, DC 20585

February 10, 2011

MEMORANDUM FOR THE MANAGER, LIVERMORE SITE OFFICE

FROM: Sandra D. Bruce
Assistant Inspector General
for Inspections
Office of Inspector General

SUBJECT: INFORMATION: Inspection Report on "Management of Controlled Substances at Lawrence Livermore National Laboratory"

BACKGROUND

As part of its national defense mission, the Department of Energy's (Department) Lawrence Livermore National Laboratory (Livermore) actively engages in scientific, engineering, and environmental research activities. Livermore is managed and operated under contract by Lawrence Livermore National Security, LLC, for the National Nuclear Security Administration (NNSA). The Livermore Site Office (Site Office) is responsible for administering the contract. As part of its biomedical and forensic science mission, Livermore maintains 42 controlled substances, including drugs such as black tar heroin, cocaine, phencyclidine and steroids. Livermore's Health Clinic also maintains and dispenses other therapeutic controlled substances.

Federal regulations (21 CFR §1300-1316) and Department policy (DOE Order 580.1) establish requirements for management of controlled substances to prevent improper or illegal use. The CFR categorizes controlled substances under five different schedules, depending on the potential for abuse, the current accepted medical use, and safety concerns for use of the substances under medical supervision (Appendix 1). To dispense or conduct research with controlled substances, Livermore is required to register "business activities" with the U.S. Drug Enforcement Administration (DEA). Livermore's three business activities registered to possess controlled substances are: *Researcher* for bio-medical research; *Health Clinic* for medical treatment of Livermore personnel; and, *Analytical Lab* for forensic science work. The *Researcher* and *Analytical Lab* business activities are responsible for 33 controlled substances, while the *Health Clinic* is responsible for 9 controlled substances, for a total of 42. Different accountability rules apply to each different category of registrant. Because of potential safety and health risks, the Office of Inspector General initiated this inspection to determine whether Livermore was appropriately managing controlled substances to prevent misuse or misappropriation.

RESULTS OF INSPECTION

We found that, with the exception of the *Health Clinic*, Livermore was not appropriately managing its controlled substances in accordance with Federal regulations and Department policy intended to prevent misuse or misappropriation. Specifically, our 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 Lab;* and,

- Despite requirements to the contrary, Livermore failed to segregate accounting for substances listed on different schedules and under different business activities.

Livermore's inability to properly account for controlled substances in its possession occurred because officials did not devote adequate attention to developing and maintaining program accountability. We found, for example, that the *Researcher* and *Analytical Lab* business activities lacked adequate internal policies or guidance for the proper management of controlled substances. Also, Laboratory officials told us that when controlled substances were transferred between custodians, there were no internal procedures or requirements to conduct an inventory of these substances or to weigh them to ensure the integrity of the chain of custody. In addition, except for the *Health Clinic*, the Site Office had not performed oversight activities for controlled substances held or used by the *Researcher* or *Analytical Lab* business activities. As a result, there were incomplete records of quantities received, distributed, used or on hand for several of the controlled substances we reviewed.

The quantities of controlled substances discussed in this report are relatively small. Nonetheless, Livermore, as a DEA registered user of controlled substances, is required to account for and maintain its controlled substances in accordance with established requirements. We developed no evidence that misuse or misappropriation had occurred; however, failing to accurately account for quantities received, used, distributed and on hand could create an opportunity for improper or illegal use.

Additionally, non-compliance with the requirements of 21 CFR §1300-1316 can result in substantial penalties for registered users. Specifically, Title 21 of the U.S. Code, Section 842, *Prohibited Acts B*, considers the negligent failure to make or keep any record, report, notification, declaration, statement, invoice or information an unlawful act that can result in up to a $10,000 penalty per violation.

We shared an initial draft of this report with the Site Office to obtain technical comments on the findings identified. In response, the Site Office stated that controls were being implemented immediately to mitigate the risks identified in this report. To help ensure that the safeguards being developed are adequate, we have made several recommendations designed to improve the accountability over controlled substances at Livermore.

MANAGEMENT REACTION

NNSA management concurred with the report recommendations and agreed that there is a need for a rigorous system of controls for managing the inventory of controlled substances. We made technical changes to the report in response to management's comments and have included those comments in their entirety in Appendix 3.

Attachment

cc: Deputy Secretary
Administrator, National Nuclear Security Administration
Chief of Staff

REPORT ON MANAGEMENT OF CONTROLLED SUBSTANCES AT LAWRENCE LIVERMORE NATIONAL LABORATORY

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MANAGEMENT OF CONTROLLED SUBSTANCES AT LAWRENCE LIVERMORE NATIONAL LABORATORY

MANAGEMENT OF CONTROLLED SUBSTANCES

We found that with the exception of the *Health Clinic*, Lawrence Livermore National Laboratory (Livermore) was not appropriately managing its controlled substances in accordance with Federal regulations and the Department of Energy's (Department) policy intended to prevent misuse or misappropriation. This occurred because the *Researchers* and *Analytical Lab* business activities registered with the U.S. Drug Enforcement Administration (DEA) lacked adequate internal policies or guidance for the proper management of controlled substances. Specifically, our testing revealed that there were no internal procedures or requirements to conduct an inventory of these substances, to include weighing them, when they were transferred between custodians. Exacerbating the issues with managing controlled substances, we noted that, except for the *Health Clinic*, the Livermore Site Office (Site Office) had not performed oversight activities for controlled substances held or used by the *Researcher* or *Analytical Lab* business activities.

Requirements for the proper management of controlled substances are found at 21 CFR §1300-1316. In addition, DOE Order 580.1, *Personal Property Management Program,* requires that controlled substances be managed and physically controlled, from receipt to point of use, to prevent improper or illegal use. However, we identified significant internal control weaknesses relating to the accurate accounting and recordkeeping of controlled substances at Livermore that, in our judgment, increase the risk of misuse or misappropriation.

Accountability

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 Lab.* As a result, an accurate assessment of the quantities of controlled substances that should have been on hand could not be made.

Specifically, the *Analytical Lab* is required to accurately account for its controlled substances by documenting the total number of forms of the substance they received, such as grams of powder or milliliters of liquid, and the quantity distributed in any manner, to include the date and manner of distribution. However, of the 33 controlled substances inventory records that were the responsibility of the *Analytical Lab*, at least 6 of the 33 records did not accurately reflect quantities received or distributed as required by 21 CFR §1304 and DOE Order 580.1. Specific examples follow:

Cocaine Hydrochloride

Our review of Laboratory records disclosed that the initial inventory for the Schedule II substance "cocaine hydrochloride" did not show the actual quantity on hand. Inventories of controlled substances typically show the "Beginning Balance" in measurable quantities such as grams. However, the initial *Property Management Inventory of Narcotics and Dangerous Drugs* for "cocaine hydrochloride" dated April 1, 2006, did not specify the quantity of this substance. Instead, the "Beginning Balance" was identified as "1 bottle" with no reference to how many grams of cocaine were inside the bottle.

Follow-on inventories of this same controlled substance raised additional questions about the accuracy and reliability of the accountability record. Specifically, in July 2006, the "Beginning Balance" for this substance was stated for the first time as 1 gram, and the July and November 2006 inventories showed 1 additional gram under "Receivals" (received) during each of these two inventory periods. However, subsequent inventory records continued to show a "Balance On Hand" of 1 gram with no indication of distribution or use of this substance. It appears that the 1 gram "Receivals" noted in July and November 2006 may have represented the results of inventories performed on these dates, and were not related to the acquisition of additional quantities of "cocaine." Nevertheless, the inventory record did not present clear information on this issue. We noted that a subsequent inventory in July 2009 continued to show 1 gram on hand.

Officials were unable to determine from the inventory document what quantity should have been on hand. Since the actual quantity of the controlled substance was not specifically noted upon receipt and the inventory record created confusion with regard to the two notations of quantities received, the accuracy and reliability of the accountability record is further called into question.

3,4-Methylenedioxyamphetamine (MDA)

Issues also existed with the inventory of "3,4-Methylenedioxy-amphetamine (MDA)," a type of Schedule I amphetamine. The amount on hand was documented during an annual inventory in 2004 as 96 milligrams. However, 4 inventories later in 2007, the balance changed to 58 milligrams, and in the 2008 and 2009 inventories, the balance changed to 5.8 milligrams, with no documented explanation for the difference of 90.2 milligrams (96 milligrams minus 5.8 milligrams).

Opium and Black Tar Heroin

We found that two of five controlled substances weighed had actual weights significantly different than the weights documented in the inventory records. In an effort to confirm recorded balances, we selected a judgmental sample of controlled substances to be weighed in our presence. While the inventory records for the Schedule II substance "opium" showed there were 0.991 grams on hand, the actual weight was 5.17 grams, over 5 times the amount expected. In addition, the inventory records for the Schedule I substance "black tar heroin" indicated there were 0.0125 grams on hand, but the actual weight was 0.2442 grams, almost 20 times the amount expected. In both of these cases, Livermore was in possession of additional quantities of high risk controlled substances without any documentation showing that they existed.

We found that there was no record of used or distributed substances to account for difference in quantities of the controlled substances described above. Although we had no evidence that misuse or misappropriation has occurred, not accurately accounting for quantities received, used, distributed and on hand could create an opportunity for improper or illegal use.

Recordkeeping

In addition to the basic inventory problems, we also found that Livermore did not maintain appropriate records of account activity for controlled substances in accordance with applicable requirements. Specifically, 21 CFR §1304 requires that records for Schedules I and II controlled substances be maintained separately from all other records, and that records for Schedules III, IV and V substances be maintained either separately from other records, or in such form that the information required is readily retrievable from the ordinary business records of the registrant. In addition, in 21 CFR §1300-1316, Schedules I and II substances are often required to have a higher level of accountability than Schedules III, IV and V. For example, Schedules I and II are often required to have an inventory with an exact measurement of the substance, whereas Schedules III, IV and V may have an estimated amount.

Distinguishing Controlled Substances by Schedule

Our review of Livermore's *Analytical Lab* revealed that inventory records for Schedules I, II, III and IV substances were maintained together, and there was no distinction within these for the various schedules under which the substances fell. In fact, the schedule under which the controlled substance should have been accounted for was only identified on 3 of the 33 inventory documents. This

condition calls into question Livermore's ability to accurately account for its controlled substances since different schedules often require different levels of accountability.

Location of Controlled Substances

Contrary to Department policy, the *Analytical Lab's* records did not show the correct location for the 33 controlled substances under its control. Specifically, in all 33 controlled substances inventory records that were the responsibility of the *Analytical Lab*, the room or building indicating the location of these substances was inaccurate. This further complicated Livermore's ability to accurately record and account for its controlled substances.

Procurement Records for Controlled Substances

According to 21 CFR §1304, procurement records for controlled substances should be maintained for 2 years. However, we were only able to identify procurement records for 3 of the 33 controlled substances maintained by the *Analytical Lab*. Since inventory records did not properly account for all controlled substances in terms of quantities received, used, distributed and on hand, we could not determine which substances fell within this 2-year requirement. For example, as previously stated, additional quantities of "opium" were found but no record exists as to how or when they were acquired. Under these circumstances, including the lack of documentation of the beginning balances, any analyses of the controlled substances that should have been on hand would have been difficult to establish. Further, responsible personnel were not in a position to determine if controlled substances were purchased and then misused or misappropriated.

In explaining why no procurement records are currently retained, the National Nuclear Security Administration (NNSA) management in comments to a draft of this report stated that the *Analytical Lab* had not procured any controlled substances in the past 2 years. While we do not question management's assertion, we could not definitively determine whether procurements had or had not occurred for 30 of the substances because inventory records did not properly account for all controlled substances in terms of quantities received, used, distributed and on hand. Therefore, we could not establish which substances fell within the 2-year requirement established by 21 CFR §1304.

Records Maintained by Separate Business Activity

At least one controlled substance at Livermore was procured under one business activity but was being maintained by a different business activity. Specifically, 21 CFR §1304 requires that separate inventories be maintained for each independent business activity registered with the DEA, a requirement which dictated that inventories for Livermore's three registered business activities be maintained separately. However, our review of the procurement records available for the *Analytical Lab* (forensic science work) revealed that one of its controlled substances was procured under the *Researcher's* (bio-medical research) registration but was not identified as such in the *Analytical Lab's* inventory records.

This may seem like a minor paperwork issue, but combining controlled substance records and inventories procured under two separate business activities is inconsistent with 21 CFR §1304 requirements. More importantly, such treatment complicates the need to manage controlled substances in an accountable and transparent way. In the instant case, *Researchers* have more defined inventory requirements for Schedules I and II substances than do *Analytical Labs.* As such, combining controlled substance records and inventories procured under two separate business activities could result in controlled substances being maintained under incorrect accountability standards.

As previously noted, Laboratory officials told us they were unable to locate procurement records for the other 30 substances belonging to the *Analytical Lab.* As a result, we were unable to determine how many other substances may also have been procured under a separate business activity. This condition raises further concern with regard to the potential misuse or misappropriation.

RECOMMENDATIONS

We shared an initial draft of this report with the Site Office to obtain technical comments on the findings identified. In response, the Site Office stated that controls were being implemented immediately to mitigate the risks identified in this report. To help ensure that the safeguards being developed are adequate, we have made several recommendations designed to improve the accountability over controlled substances at Livermore.

In that respect, we recommend the Manager, Livermore Site Office, ensure that Federal oversight of these substances is appropriate and consistent with the requirements of Title 21, Code of Federal Regulations, *Drug Enforcement Administration,*

Department of Justice, §1300-1316 and DOE Order 580.1, *Department of Energy Personal Property Management Program*. To that end, we recommend that the Manager, Livermore Site Office, require Lawrence Livermore National Laboratory to:

1. Establish an accurate accounting process for controlled substances from receipt to point of use, with particular emphasis on maintaining accountability controls;

2. Conduct close-out inventories of controlled substances when there is a transfer of custodians; and,

3. Establish appropriate internal policies and procedures for the recordkeeping of controlled substances to include, at a minimum:

    a. Distinguish controlled substances by schedule;

    b. Identify the location of controlled substances;

    c. Assure procurement records for controlled substances are maintained, as required; and,

    d. Maintain separate controlled substance inventories for each independent business activity registered with the DEA.

MANAGEMENT AND INSPECTOR COMMENTS

NNSA management concurred with the report recommendations and agreed that there is a need for a rigorous system of controls for managing the inventory of controlled substances. Management identified planned corrective actions and provided a technical comment on the report.

We consider management's comments and corrective actions planned and/or taken responsive to our recommendations. We made technical changes to the report, as appropriate.

Management's comments have been provided in their entirety in Appendix 3.

Appendix 1

SCHEDULE DEFINITIONS

There are five schedules of controlled substances – Schedules I, II, III, IV and V. The definition of each schedule and the nature of the drug or other controlled substance is as follows:

Schedule I

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.
- An example of a Schedule I drug or other controlled substance is "heroin."

Schedule II

- The drug or other substance has a high potential for abuse.
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substances may lead to severe psychological or physical dependence.
- An example of a Schedule II drug or other controlled substance is "cocaine."

Schedule III

- The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

- An example of a Schedule III drug or other controlled substance is an "anabolic steroid."

Schedule IV

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.
- An example of a Schedule IV drug or other controlled substance is "Ativan."

Schedule V

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.
- An example of a Schedule V drug or other controlled substance is "Lyrica."

Appendix 2

OBJECTIVE

Because of 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.

SCOPE AND METHODOLOGY

We conducted our inspection from December 2009 through October 2010. We reviewed Livermore's internal inventory records for 42 controlled substances maintained by Livermore. Additionally, we reviewed the available procurement records for the controlled substances maintained by Livermore. We also reviewed the following laws, regulations and policies:

- Title 21, U.S. Code, *Food and Drugs,* Chapter 13, *Drug Abuse Prevention and Control;*
- Title 21, Code of Federal Regulations, *U.S. Department of Justice, Drug Enforcement Administration,* §1300-1316;"
- DOE Order 580.1, *Department of Energy Personal Property Management Program;*
- Lawrence Livermore National Security policy, *Procurement Standard Practices,* Section 8, *Required Sources of Supply,* Subject 8.7, *Controlled Substances*;
- Livermore policy *Medical and Pharmaceutical Waste Handling;* and,
- Livermore Health Services policies and procedures, to include *Clinical Pharmaceutical Management Plan, Controlled Substances Management, Clinical Programs Pharmaceutical Programs Formulary Operational Policy and Procedures,* and *Health Services Dispensing Protocol.*

This inspection was conducted in accordance with the Council of the Inspectors General on Integrity and Efficiency *Quality Standards for Inspections,* issued by the President's Council on Integrity and Efficiency, January 2005.

Department of Energy
National Nuclear Security Administration
Washington, DC 20585

January 24, 2011

MEMORANDUM FOR: SANDRA D. BRUCE
ASSISTANT INSPECTOR GENERAL FOR INSPECTIONS
OFFICE OF INSPECTOR GENERAL

FROM: GERALD L. TALBOT, JR.
ASSOCIATE ADMINISTRATOR
FOR MANAGEMENT AND ADMINISTRATION

SUBJECT: Comments to the IG Draft Report on Management of Livermore's Controlled Substances; Project No. S10IS002; IDRMS No. 2009-02873

The National Nuclear Security administration (NNSA) appreciates the opportunity to review the Inspector General's (IG) draft report, *Management of Controlled Substances at Lawrence Livermore National Laboratory.* Because of potential safety and health risks associated with controlled substances, the IG initiated this inspection to determine whether Livermore was appropriately managing controlled substances to prevent misuse or misappropriation.

As part of Lawrence Livermore National Laboratory's (LLNL) biomedical and forensic science mission, it maintains 42 controlled substances. The LLNL's Health Clinic also maintains and dispenses other therapeutic controlled substances for the treatment of its employees. As the report correctly identifies, we agree there is a need for a rigorous system of controls for managing the inventory of controlled substances.

We would like to point out a factual inaccuracy in the draft report. On page 4, paragraph 3, the IG cites the 21 CFR §1304 regulatory requirement to maintain procurement records for two years. As a matter of fact, the Lawrence Livermore National Laboratory's (LLNL) Analytical Lab has not procured any controlled substances in the past two years, which explains why there are no procurement records currently retained for the 33 substances in their possession.

NNSA actions to the recommendations are below:

Recommendation 1: Establishes an accurate accounting process for controlled substances from receipt to point of use, with particular emphasis on maintaining accountability controls.

Concur: Upon receipt of the IG's preliminary draft report, the LLNL Property Management immediately revised the institutional procedure for controlled substances inventory management with the objective of clarifying and enhancing

the accounting process. Based on additional information provided in the official draft report, the procedure has been further enhanced. The updated procedures were released on January 7, 2011. NNSA will close this recommendation after Site validation. Expected date of completion is June 2011.

Recommendation 2: Conducts close-out inventories of controlled substances when there is a transfer of custodians.

Concur: LLNL's updated controlled substances inventory management procedure now specifically addresses the process to be followed when materials are transferred between custodians. NNSA will close this recommendation after Site validation. Expected date of completion is June 2011.

Recommendation 3: Establishes appropriate internal policies and procedures for the recordkeeping of controlled substances to include, as a minimum: (a) distinguishes controlled substances by schedule; (b) identifies the location of controlled substances; (c) assures procurement records for controlled substances are maintained as required; and (d) maintains separate controlled substance inventories for each independent business activity registered with the DEA.

Concur: LLNL's updated controlled substances inventory management procedure specifically addresses all the issues identified in this recommendation. The LLNL Analytical Lab will prepare an enhanced log book that will accurately document all required information. NNSA will close this recommendation after Site validation. Expected date of completion is June 2011.

If you have any questions concerning this response, please contact JoAnne Parker, Director, Office of Internal Controls, 202-586-1913.

cc: Alice C. Williams, Site Manager
Frank Russo, Environment, Safety & Health Advisor

IG Report No. INS-O-11-01

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