University of California
San Francisco

UCSF

Audit Services

December 16, 2010

ROBERT EATON
Environmental Health and Safety Director
Office of Environmental Health and Safety

SUBJECT: Controlled Substances
Audit Services Project #11-021

As a planned audit for fiscal year 2010-2011, Audit Services has completed a review of internal controls surrounding controlled substances in the laboratories. Attached is the final report incorporating the observations and agreed upon management corrective actions.

The management actions specified in this report will be added to the Audit Services follow-up system. Periodically, the Environmental Health and Safety department will be contacted to ascertain the status of implementation for these corrective actions. Once implemented, additional audit procedures may be performed to validate actions taken. You will be notified when all corrective actions have been implemented and we consider this audit closed.

I would like to thank you for your assistance and cooperation during this review. Please do not hesitate to contact me at (415) 502-2238 should you have questions.

Sincerely,

Rick Catalano
Director

c: Interim Associate Vice Chancellor Roberts
Manager Suarez

Audit Committee Members

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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT SERVICES

CONTROLLED SUBSTANCES
Project #11-021

November 2010

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CONTROLLED SUBSTANCES
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MANAGEMENT SUMMARY

As a planned review for fiscal year 2010-2011, Audit Services assessed internal controls surrounding controlled substances in research laboratories. Controlled substances are classified in five schedules based on criteria established by the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA). At the University of California, San Francisco (UCSF), controlled substances are used regularly in research studies of non-human subjects, treatments, and clinical drug trial protocols. The regulations require a separate registration for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person. UCSF currently has five DEA registrations separately at Mission Bay Campus, Parnassus Campus and off-site laboratories. Together, these locations house over 550 active Principal Investigators and approximately 1,200 authorized users conducting research with controlled substances.

The purpose of this review was to evaluate the adequacy of existing controls surrounding the ordering, delivery/receipt, inventory and disposal of controlled substances with increased emphasis on physical security at the laboratories.[1]

Based on the procedures performed, we found that the established policies and procedures, primarily in the Controlled Substances Program and in OEH&S website, were generally adhered to by individuals and departments. The acquisition of controlled substances were ordered through Campus Procurement and Contracting (CPC) with approvals from the Principal Investigators and from authorized buyers who continuously monitors the annual quota limit on the controlled substances for the respective PIs. Access to controlled substances was properly limited to authorized users and OEH&S personnel. Controlled substances on hand were securely stored at the Controlled Substances Distribution Office at Parnassus and Mission Bay Campuses and at the laboratories. Records, including receiving and disposal logs, usage logs, were generally properly maintained at the Distribution Offices and laboratories.

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[1] Both Schedule Types I and V drugs are excluded in this review given the limited volume. The top three substances most frequently purchased are: Ketaset/Ketamine (Schedule III), Bupreenex/Buprenorphine (Schedule III), and Nembutal/Pentobarbital (Schedule II).

While no significant control deficiencies were identified, we noted some improvements to strengthen monitoring of controlled substances would be appropriate involving data capture in the Research Online System, more accurate recording of information on the dispensing logs, collection of required Authorized User of Controlled Substance forms, and updating the Controlled Substances Program Manual.

More detailed information can be found in the body of this report.

CONTROLLED SUBSTANCES
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I. BACKGROUND

As a planned review for fiscal year 2010-2011, Audit Services assessed internal controls surrounding controlled substances in research laboratories. Controlled substances are classified in five Schedules based on criteria established by the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA). At the University of California, San Francisco (UCSF), controlled substances are used regularly in research studies of non-human subjects, treatments, and clinical drug trial protocols. The Code of Federal Regulations require a separate registration for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person. UCSF currently has five DEA registrations separately at Mission Bay Campus, Parnassus Campus and off-site laboratories. (Together, these locations house over 550 active Principal Investigators and approximately 1,200 authorized users conducting research with controlled substances. During fiscal year 2009-2010, approximately 76 purchase orders were issued for the acquisition of Schedule Type II to IV substances.[1]

Registrants of controlled substances are to provide effective controls and procedures against theft and diversion and must comply with regulatory requirements related to drug security and recordkeeping. Many problems associated with drug abuse are the result of legitimately purchased controlled substances being diverted from their lawful purpose into illicit drug traffic.[2] The Controlled Substance Act (CSA) codified the regulations over the manufacture, import, possession, use and distribution of regulated substances. The Office of Diversion Control at the Drug Enforcement Administration has published guidelines with respect to controlled drugs including research protocols, procurement quotas, security requirements, and recordkeeping. At UCSF, the Office of Environmental Health and Safety (OEH&S) has developed a Controlled Substances Program Manual which meets UC BUS-50 guidelines and outlines the regulations and procedures governing the use of controlled substances locally.

The Controlled Substances Program Manual specifies the responsibilities of participating departments, faculty member participants, Materiel Management, and OEH&S in the administration of the Controlled Substance Program. It further establishes procedures in the receipt, transfer, security, disposal and recordkeeping of controlled substances as well as training of authorized users. Failure to properly manage any aspect of the Controlled Substances Program increases the risk of loss, theft, diversion and potential damage to institution.

[2] U.S. Drug Enforcement Administration Diversion Control Update 7/13/2010.

II. PURPOSE AND SCOPE

The purpose of this review was to evaluate the adequacy of existing controls surrounding the ordering, delivery/receipt, inventory and disposal of controlled substances with increased emphasis on physical security at the laboratories.

To complete the review, the following procedures were performed:

- University policies and procedures and federal regulations were reviewed to gain an understanding of the requirements governing controlled substances.
- OEH&S personnel were interviewed to gain an understanding of the process and procedures for the delivery, inventory, transfer, disposal and physical security of controlled substances.
- A sample of designated controlled substances recipients and/or laboratory contacts were interviewed to gauge their understanding of procedures in the security and disposal of controlled substances, the transfers of controlled substances between laboratories as well as protocols to report incidents of theft, loss, and mishaps in the laboratories.
- Several Department Safety Advisors (DSAs) were interviewed to obtain an understanding of their review and monitoring efforts over security controls and of their interaction with laboratory contacts and controlled substances authorized users.
- A designated Campus Procurement and Contracting (CPC) personnel was interviewed to determine the process and procedures in the acquisition of controlled substances.
- Inspections were conducted on selected laboratories to determine whether controlled substances were securely stored and segregated by schedule type, access was limited, non-controlled substances were separately stored, and usage logs were properly maintained.
- Samples of Purchase Orders (POs) from CPC were reviewed to determine whether proper approvals were obtained from Principal Investigators (PI's), CPC buyer, and Controlled Substances Officer at OEH&S for purchases that had exceeded the annual quota.
- Samples of purchase order reports from CPC were reviewed to determine the effectiveness of the monitoring procedures for miscoding of controlled substances in the purchase requisition.
- Records of controlled substances delivery, including dispensing logs and signature cards were reviewed to determine whether shipments were completely and accurately recorded and were released to authorized recipients.
- Samples of Controlled Substances Disposal Request Forms were reviewed to determine whether the correct disposal forms were completed for the schedule types of controlled substances and the forms

were properly signed by authorized lab users and OEH&S disposal personnel.

- Records of selected PIs in Research Online database were reviewed to determine whether authorized users have completed the required online safety training and/or refresher courses and whether year-to-date purchases have exceeded the annual quota(s).

The scope of the review was limited to the specific procedures described above and related to transactions and activities occurring between January 2010 and July 2010. As such, work completed is not intended, nor can it be relied upon to identify all instances of potential irregularities, errors and control weaknesses that may occur in departments and laboratories not specifically covered in this review. Fieldwork was conducted between July 2010 and October 2010.

III. CONCLUSION

Based on the procedures performed, we found that generally existing controls were adequate surrounding the ordering, delivery/receipt, inventory, disposal and physical security of controlled substances. The established policies and procedures, primarily in the Controlled Substances Program and in OEH&S website, that this review was measured against were generally adhered to by individuals and departments assigned with the specific responsibilities. Controlled substances on hand were securely stored at the Controlled Substances Distribution Office at Parnassus and Mission Bay Campuses and at the laboratories.

While no significant control deficiencies were identified, we noted some improvements to strengthen monitoring of controlled substances would be appropriate involving data capture in the Research Online System, more accurate recording of information on the dispensing logs, collection of required Authorized User of Controlled Substance forms, and updating the Controlled Substances Program Manual.

Further, it was recognized that one of the contributing factors resulting in the noted deficiencies was the reduction of existing workforce due to budget constraints and the manual systems. Although the management and monitoring of controlled substances have not been significantly impacted, prolonged redistribution of increased workload to existing staff will likely affect the effectiveness of the program and may subject the program to additional risks of non-compliance with regulatory requirements.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS

A. Authorization

Authorization forms for a few users of controlled substances were not completed as required.

All personnel working with controlled substances need to complete an *Information on Authorized User of Controlled Substance (IAUCS) form, which includes* attestation statements. Proper completion of the form is a critical part of the screening process to assess if an employee should be allowed to handle, use, or store controlled substances.

Audit Services examined records for forty-four users of controlled substances and found that two (5%) did not have a completed IAUCS form on file.

The system for collecting and recording information to authorized users of controlled substances is manual and paper-based and as such can be prone to human error. According to management, staffing for the function has been reduced. Nevertheless, appropriate steps and records for pre-screening employees who will have access to controlled substances is important to ensure proper management of security and other risks.

Management Corrective Actions

By December 31, 2011, IAUCS forms will be transferred from hard copy files and stored electronically on Research Information Online (RIO) for ease of verification of completion during the biennial Controlled Substance Application (CSA) renewal. Department Safety Advisors (DSA's) will verify submission of all user forms related to CSA renewal in RIO and request missing forms from Principal Investigators (PI's).

B. Recordkeeping

Records maintained at the Controlled Substances Distribution Office at the Parnassus Campus were not always updated timely and accurately.

Timely recording of controlled substances received into the inventory database, Research Online, provides up-to-date and complete

information to Principal Investigators, authorized users, and CPC buyer who may rely on the information in conducting their activities.[3]

- Seven of twenty-four (29%) purchases of controlled substances received between May 12, 2010 and July 22, 2010, according to the Dispensing Log, were not recorded in the inventory database.

- In matching the receipt information recorded in the Dispensing Log, three of twenty-four (13%) purchases either did not have the correct quantity received and/or the correct receipt date entered into Research Online database.

- Three of twenty-four (13%) packages released to authorized users did not have EH&S' technician initial on the Dispensing Log for the packages released. One of the packages had no pick-up date entered.

Properly recording of information in the database and signing-off and dating the Dispensing Log by EH&S technicians for the receipt and release of controlled substance packages to PI representatives assign accountability and prevent unauthorized individuals from accessing controlled substances.

Management Corrective Actions

Controlled Substance Officer from OEH&S will coordinate with Hazardous Materials Management (HMM) to provide training on the recordkeeping issues identified. Training will be completed on or before February 28, 2011.

C. Disposal

Proper forms were not consistently completed when disposing of controlled substances.

To facilitate the completion of various forms and paperwork required by DEA, two separate disposal forms were developed by OEH&S for Schedule II only and Schedule III to V substances. Appropriate controlled substance disposal request form must be completed to arrange for disposal.

[3] DEA requires that each registrant who maintains an inventory of controlled substances must maintain complete and accurate records of the controlled substances on hand and the date that the inventory was conducted.

The proper controlled substances disposal request form was not used on three of fifteen (20%) disposals of Schedule Type III substances at Parnassus Campus. The disposals were completed on an outdated request form for Schedule I – V substances.

Using an incorrect disposal form may create potential errors and additional processing time for EH&S technicians who are responsible for the collection and disposal of controlled substances. To comply with DEA regulations, controlled substances of different Schedule Type should be separately identified on the appropriate Disposal Forms.

Management Corrective Actions

1. Effective November 26, 2010, HMM technicians were instructed not to accept old Controlled Substances (CS) disposal forms. This issue will also be covered in the Controlled Substances training scheduled for HMM technician on or before February 28, 2011.

2. By December 31, 2010, DSA's will communicate to the laboratories the requirement to use the updated CS disposal forms.

D. Campus Policies and Procedures

UCSF Controlled Substances Program Manual has not been updated to incorporate changes and practices that have been implemented into the program since its last update in October 2001.

Policies and procedures provide guidelines and principles for personnel in the administration of control substances and ensure consistency in application of practices and compliance with regulatory requirements.

Some changes that have not been reflected in the Controlled Substances Program Manual include the requirement to order all controlled substances, DEA Schedule II-V, through Campus Procurement and Contracting (CPC) by creating a Procure-to-Pay (P2P) Special Request requisition, and a reference to the Standard Operating Procedures (SOP) for the disposal of Controlled Substances.

Having a current updated policy and procedure manual will serve to reduce inconsistencies in practices, and to reduce the risk that necessary steps for handling specific tasks are not missed or carried out incorrectly.

Management Corrective Actions

By August 31, 2011, Controlled Substance Officer from OEH&S will update Controlled Substances Program Manual to reflect the existing practices and to be consistent with information provided on EH&S web site.

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