

**UNIVERSITY OF CALIFORNIA, DAVIS
AUDIT AND MANAGEMENT ADVISORY SERVICES**

**UC Davis
Controlled Substances in Animal Labs
Audit & Management Advisory Services Project #20-08**

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Controlled Substances in Animal Labs**AMAS Project #20-08****MANAGEMENT SUMMARY****Background**

As part of the fiscal year (FY) 2020 audit plan, Audit and Management Advisory Services (AMAS) reviewed controls over the use of controlled substances in animal labs.

UC Davis is able to obtain controlled substances through valid registrations with the federal Drug Enforcement Agency (DEA). The ability to utilize controlled substances is integral to the teaching and research mission of UC Davis, and critical to the Animal Care Program if the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation is to be maintained.

UC Davis has four active DEA registrations that are used to procure controlled substances throughout the organization: one at the UC Davis campus, one at the UC Davis Medical Center (UCDMC), and two for the California Animal Health & Food Safety Laboratory System (CAHFS) at Davis and San Bernardino. AMAS reviewed controls in place only at the UC Davis campus.

The Office of Environmental Health and Safety (EH&S) shares responsibility with Supply Chain Management (SCM) for oversight of controlled substances and compliance with DEA regulations. Within SCM, Procurement is responsible for purchase requisitions and vendor agreements. Distribution Services is responsible for central receiving and distribution. EH&S is responsible for departmental authorization, handling, storage, and disposal of controlled substances. Department heads are responsible for determining the need for controlled substances and assuring that storage and use by department members complies with applicable laws, regulations, policies, and procedures. Tracking of authorized users¹ and usage of controlled substances is performed through the Online Controlled Substance Usage Log System (CS Log System), implemented in 2018.

Purpose and Scope

The purpose of this audit was to review controls over the use of controlled substances in animal labs including risk factors related to drug diversion, federal regulations, and personnel safety. A risk assessment performed during the preliminary phase of our review informed emphasis in the following areas: recordkeeping, management of authorized users, procurement, distribution, transfers, inventory, disposals, and site inspections.

¹ Authorized users include:

Authorized Custodian – The Principal Investigator (PI) or approved designee within the requesting department who is authorized by the program administrator to receive and store controlled substances.

Authorized End User – Person approved by the Authorized Custodian to pick-up, receive, and use the controlled substances.

Temporary Receiver – Individual physically located at the department with a designated delivery stop that has been identified in advance to SCM, Distribution Services to pick-up or receive controlled substance shipments prior to final delivery to the Authorized Custodian or End User.

In order to accomplish these objectives we performed the following procedures:

- Survey of relevant policies, procedures, and regulations;
- Interviews with key stakeholders;
- On-site process walkthroughs;
- Review of documentation showing compliance with authorization, purchase, delivery, inspection, inventory, transfers, and disposal requirements.

The scope of the review was limited to procedures performed by SCM and EH&S in animal labs. As such, oversight procedures by the department heads was not included in this review.

The timeframe under review was July 2018 to September 2019.

Conclusion

We were able to verify that roles and responsibilities within the Controlled Substance Program are clearly assigned to staff in the departments, EH&S, Distribution Services, and the Police Department. This prohibits a single individual from ordering, receiving, distributing, and disposing of controlled substances.

We also conclude that there is opportunity for improvement in the areas of personnel screening; facility evaluations; monitoring of the authorized user status; compliance by personnel; documentation of disposal, delivery, and inventory; and verification of completion of annual Laboratory Safety Professional (LSP) inspections.

We thank management in the Controlled Substance Program for agreeing to:

- Implement procedures to retain documentation of personnel screening and facility evaluations;
- Develop processes to ensure that the authorized user listing remains up-to-date;
- Enforce requirements related to training and screening for personnel;
- Strengthen documentation of disposal, delivery, and biennial inventory counts;
- Improve processes to ensure that LSP inspections are performed annually.

SUMMARY OF OBSERVATIONS

Obs. No	Brief Observation		Owner	Management Corrective Action	Completion Date
20-08.A	EH&S' recordkeeping process does not provide evidence that personnel screenings and facility evaluations were performed. In addition, EH&S does not have written procedures for documenting facility evaluations.	1	EH&S	EH&S will create an Initial Storage Site Evaluation form to document facility evaluations.	3/15/20
		2	EH&S	EH&S will move existing documentation, and begin to store new documentation of personnel screening, confirmation of background check clearance, and initial facility evaluations to an archive on its departmental shared drive.	4/15/20
20-08.B	EH&S does not have a process to revoke access to the CS Log System once users no longer have a business purpose.	1	EH&S	EH&S will work with Finance, Operations and Administration (FOA) Administrative IT to create a plan for a reporting process that will inform the program administrator of relevant changes in authorized users' employment status, department, and title.	5/15/20
		2	EH&S	FOA Administrative IT will implement the reporting process planned, and EH&S will update the authorized user listing based on changes reported.	10/15/20

Obs. No	Brief Observation		Owner	Management Corrective Action	Completion Date
20-08.C	Training refreshers and update of personnel screening forms are not required by EH&S.	1	EH&S	EH&S will inform Authorized Custodians that personnel screening forms must be updated every three years, and include this requirement in the LSP inspection checklist for monitoring purposes.	4/15/20
		2	EH&S	EH&S will submit a revision of UCD policy 290-70 to require all authorized users to complete a training refresher every four years.	5/15/20
		3	EH&S	EH&S will work with Staff Development and Professional Services to create a plan for a reporting process that will identify users with overdue training.	10/15/20
20-08.D	The current process for disposal of controlled substances does not include timely reconciliation of inventory stored for destruction, or generate evidence that controlled substances were properly destroyed.	1	EH&S	EH&S will obtain a DEA Form 41 for destruction of controlled substances that occurred on February 2019.	3/15/20
		2	EH&S	EH&S will submit a revision of UCD policy 290-70 to require receipt of DEA Form 41 or Certificate of Destruction for disposed controlled substances.	5/15/20
		3	EH&S	EH&S will implement a process to perform semi-annual inventory reconciliations at the ESF storage site. This will include a review of disposal request forms to ensure they were properly executed.	5/15/20
20-08.E	Delivery records do not always show that the final recipient of controlled substances is the Authorized Custodian or End User.	1	EH&S	EH&S will inform Authorized Custodians in writing that acknowledgement of receipt of controlled substances in the CS Log System must be made within 15 days from delivery.	4/15/20
		2	EH&S	EH&S will work with FOA Administrative IT to develop an automated notification process to advise EH&S when End Users are not meeting the 15 day acknowledgement requirements. In addition, EH&S will develop escalation procedures for non-compliance.	10/15/20

Obs. No	Brief Observation		Owner	Management Corrective Action	Completion Date
20-08.F	AMAS was unable to verify that biennial inventory counts are performed by two individuals.	1	EH&S	EH&S will allow for electronic signatures within the CS Log System, for attestation by the persons who perform and witness biennial inventory counts.	10/15/20
20-08.G	The current process does not ensure that all storage site locations are inspected on an annual basis.	1	EH&S	EH&S will enhance its workload spreadsheet to allow inspectors to document completion of inspections. In addition, on a semi-annual basis, EH&S will implement a process for monitoring the workload spreadsheet to ensure that all storage sites are inspected annually.	5/15/20

Observations, Recommendations and Management Corrective Actions

A. Recordkeeping of Personnel Screening and Facility Evaluation

EH&S' recordkeeping process does not provide evidence that personnel screenings and facility evaluations were performed. In addition, EH&S does not have written procedures for documenting facility evaluations.

UC Business and Finance Bulletin (BFB) BUS-50 and UC Davis (UCD) policy 290-70 require² personnel screening requirements to ensure that disqualified individuals cannot access controlled substances. At UC Davis, the completion of a personnel screening form is required for Custodians, and a background check is required for End Users and Temporary Receivers.

Additionally, BFB-BUS-50 and UCD policy 290-70 require³ EH&S to perform evaluations of proposed storage sites prior to granting access to controlled substances. Furthermore, BFB-BUS-50 requires "written procedures for the evaluation of a proposed storage site for controlled substances including control and security requirements."

During our review of authorized users, we noted that personnel screening forms, background check clearance confirmations⁴, and initial storage evaluations were retained only, if at all, in the prior program administrator's email. As result, we were not able to confirm that EH&S maintained required documentation for the period prior to July 2019. We also noted at least one instance subsequent to July 2019, when an initial storage site evaluation was performed but not documented.

Recommendation

We recommend that EH&S create a shared archive for documentation of personnel screening, background check clearance confirmation, and facility evaluations. In addition, we recommend that EH&S create an Initial Storage Site Evaluation form to document facility evaluations performed.

Management Corrective Actions

- 1) By March 15, 2020, EH&S will create an Initial Storage Site Evaluation form to document facility evaluations.
- 2) By April 15, 2020, EH&S will move existing documentation, and begin to store new documentation of personnel screening, confirmation of background check clearance, and initial facility evaluations to an archive on its departmental shared drive.

² In accordance with Code of Federal Regulations (CFR) 21 §1301.90 – Employee screening.

³ In accordance with CFR 21 §1301.71 – Security requirements.

⁴ Confirmations of background check clearance are received from Human Resources upon completion of live scan with the UC Police Department.

B. Authorized User Listing

EH&S does not have a process to revoke access to the CS Log System once users no longer have a business purpose.

EH&S maintains a list of authorized users in the CS Log System. The accuracy of this list is necessary to ensure delivery of controlled substances only to appropriate users and to restrict access to controlled substances records.

Currently, EH&S has two ways to remove users from the CS Log System: 1) notification from the department that an employee has separated or a project has been closed out, or 2) annual laboratory safety professional (LSP) inspection, during which the LSP confirms that authorized users are still part of the project.

During our review of authorized users, we noted that 7%⁵ of employees on the authorized user listing had previously separated. Of these separations, 27%⁶ occurred in FY 2018 and were not identified during annual LSP Inspections.

Recommendation

We recommend that EH&S implement a process for timely revocation of authorization within the CS Log System after a user's business purpose has expired.

Management Corrective Actions

- 1) By May 15, 2020, EH&S will work with Finance, Operations and Administration (FOA) Administrative IT to create a plan for a reporting process that will inform the program administrator of relevant changes in authorized users' employment status, department, and title.
- 2) By October 15, 2020, FOA Administrative IT will implement the reporting process planned, and EH&S will update the authorized user listing based on changes reported.

C. Personnel Compliance.

Training refreshers and update of personnel screening forms are not required by EH&S.

BFB-BUS-50 requires that "each training program should have a re-training component for the authorized individuals at an established frequency that is no longer than four years." However, training refreshers are not required by EH&S. As a result, 65%⁷ of Authorized

⁵ 44 out 667 authorized users.

⁶ 12 out 44 separations.

⁷ 117 out 180 Authorized Custodians.

Custodians, 39%⁸ of Authorized End Users, and 99%⁹ of Temporary Receivers have a training completion date over four years old.

In addition, The DEA personnel screening procedures¹⁰ notes that any recent unauthorized use of controlled substances should be subjected to inquiry to fairly assess the likelihood of an employee committing a drug security breach. However, personnel screening forms¹¹ are only completed once (during the initial authorization process), and an update is not pursued. At UC Davis, an updated personnel screening form was not obtained for an estimated¹² 77%¹³ of Authorized Custodians over the past three years (40% in the past six years). As a result, any recent disallowed use of controlled substances by these Authorized Custodians was not assessed to reduce the risk of diversion.

Recommendation

We recommend EH&S enhance its requirements for training and authorization of personnel, and implement a process to monitor for compliance.

Management Corrective Actions

- 1) By April 15, 2020, EH&S will inform Authorized Custodians that personnel screening forms must be updated every three years, and include this requirement in the LSP inspection checklist for monitoring purposes.
- 2) By May 15, 2020, EH&S will submit to the policy office a revision of UCD policy 290-70 that requires all authorized users to complete a training refresher every four years.
- 3) By October 15, 2020, EH&S will work with Staff Development and Professional Services to create a plan for a reporting process that will identify users with overdue training.

D. Documentation of Destruction.

The current process for disposal of controlled substances does not include timely reconciliation of inventory stored for destruction, or generate evidence that controlled substances were properly destroyed.

The Authorized Custodian, Authorized End User, or department having custody of an unused controlled substance submits a disposal request to Environmental Safety Facility services (ESF) at EH&S using the CS Log System. Two members of ESF pick up and

⁸ 159 out 409 Authorized End Users.

⁹ 77 out 78 Temporary Receivers.

¹⁰In accordance with CFR 21 §1301.90 – Employee screening.

¹¹ Personnel screening form - document used to fulfill screening requirements by BFB-BUS-50, UCD Policy 290-70 and the DEA to ensure that no individual has access to controlled substances who has been convicted of a felony offense relating to controlled substances within the past 5 years; or has knowingly used controlled substances other than those prescribed by a physician within the past 3 years.

¹² An estimation was performed based on the last training completion date per the CS Log System.

¹³ 140 out 180 Authorized Custodians.

transport the controlled substance for storage¹⁴ and document change of custody on a Disposal Request form. Controlled substances awaiting disposal are stored and inventoried at the ESF facility. Periodically, two members of ESF transport the inventory of controlled substances awaiting disposal to the UCD Police Department for destruction.

In order to ensure that all unused controlled substances are properly tracked, ESF services performs a reconciliation between disposal request forms and controlled substances on-site. However, this is not performed routinely, and only prior to submitting controlled substances to the UCD Police Department for destruction. We observed that the UCD Police Department did not destroy controlled substances during FY 2017 and FY 2018. As a result, no reconciliation was performed¹⁵ and potential risk events were not reviewed timely, such as disposal forms not properly executed and discrepancies in controlled substances counts.

In addition, BFB-BUS-50 requires¹⁶ the program administrator to document the destruction of controlled substances by receipt of a DEA Form 41 or Certificate of Destruction. However, EH&S does not request Form 41 from the UCD Police Department to confirm destruction of controlled substances. If requested, the UCD Police Department could produce documentation acceptable to the DEA. Possession of these forms by EH&S would expedite compliance with the regulator and strengthen operational transparency.

Recommendation

We recommend EH&S implement routine reconciliation of controlled substances stored at the ESF storage site, and begin to retain Form 41 documentation of destruction of controlled substances.

Management Corrective Actions

- 1) By March 15, 2020, EH&S will obtain a DEA Form 41 for destruction of controlled substances that occurred on February 2019.
- 2) By May 15, 2020, EH&S will submit to the policy office a revision of UCD policy 290-70 that requires receipt of DEA Form 41 or Certificate of Destruction for disposed controlled substances.
- 3) By May 15, 2020, EH&S will implement a process to perform semi-annual inventory reconciliations at the ESF storage site. This will include a review of disposal request forms to ensure they were properly executed.

¹⁴ Controlled substances to be disposed of are stored in the Environmental Safety Facility until they are submitted to the UC Davis PD for destruction.

¹⁵ An inventory reconciliation was performed on 2/7/2019 for FY 19.

¹⁶ In accordance with DEA CFR 21 §827 - DEA Form 41 must be kept as a record of destruction and be available by the registrant for at least two years.

E. Delivery Records.

Delivery records do not always show that the final recipient of controlled substances is the Authorized Custodian or End User.

To ensure that the final recipient of a controlled substance is the Authorized Custodian or End User, UCD policy 290-70 requires them to be the last to sign the delivery record.¹⁷ However, this requirement is not being enforced, and we observed instances of a Temporary Receiver providing the last signature.

As a mitigating control, EH&S requests Authorized Custodians or End Users to acknowledge receipt electronically through the CS Log System. This is not, however, performed timely. We observed cases of acknowledgement not documented until over a month after the delivery of controlled substances. As a result, there is an increased risk for diversion.

Recommendation

We recommend EH&S enhance its process for documenting chain of custody of controlled substances to show actual receipt by the approved final recipient.

Management Corrective Actions

- 1) By April 15, 2020, EH&S will inform Authorized Custodians in writing that acknowledgement of receipt of controlled substances in the CS Log System must be made within 15 days from delivery.
- 2) By October 15, 2020, EH&S will work with FOA Administrative IT to develop an automated notification process to advise EH&S when End Users are not meeting the 15 day acknowledgement requirements. In addition, EH&S will develop escalation procedures for non-compliance.

F. Biennial Inventory Count

AMAS was unable to verify that biennial inventory counts are performed by two individuals.

BFB-BUS-50 and UCD policy 290-70 require¹⁸ a biennial inventory of controlled substances. To ensure that the inventory count is properly performed, "electronic signatures must be obtained for the person performing the inventory, the witness, and the department head." However, the current practice is for an Authorized Custodian alone to confirm that inventory is accurate in the CS Log System. In these cases, when an appropriate separation of duties is not documented, opportunity exists for an Authorized Custodian to improperly remove drugs from a storage site and alter inventory records to prevent detection of the misappropriation.

¹⁷ The delivery record is used to document change of custody from distribution services to the department.

¹⁸In accordance with DEA CFR 21 §1304.11 – Inventory Requirements.

Recommendation

We recommend that EH&S enhance its process to confirm that inventory counts are performed by two individuals.

Management Corrective Action

- 1) By October 15, 2020, EH&S will allow for electronic signatures within the CS Log System, for attestation by the persons who perform and witness biennial inventory counts.

G. Laboratory Safety Professional Inspections

The current process does not ensure that all storage site locations are inspected on an annual basis.

EH&S employs Laboratory Safety Professionals (LSPs) who perform inspections of locations storing and using controlled substances. They verify that controlled substances are securely stored; the site location and users are authorized within the CS Log System; inventory matches the usage log; and expired substances are properly submitted for disposal.

LSP inspections are performed annually on the calendar year. EH&S has created a workload spreadsheet to track inspection assignments, and this is shared with all inspectors. The spreadsheet, however, does not document whether or not an inspection occurred and is not reconciled against the CS Log System to ensure that all storage sites were inspected. During our review, we noted that four sites were not inspected in 2018. LSP inspections in 2019 are under progress.

Recommendation

We recommend EH&S enhance its documentation and monitoring process to ensure that all inspections are performed annually.

Management Corrective Action

- 1) By May 15, 2020, EH&S will enhance its workload spreadsheet to allow inspectors to document completion of inspections. In addition, EH&S will implement a semi-annual process for monitoring the workload spreadsheet to ensure that all storage sites are inspected annually.
