

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT AND ADVISORY SERVICES**

**Lab Chemical Safety & Management
Project #17-039**

January 2017

University of California
San Francisco



Audit and Advisory Services

January 31, 2017

MICHAEL BADE

Associate Vice Chancellor
Real Estate, Planning and Capital Programs

BRIAN SMITH

Associate Vice Chancellor
Research Infrastructure and Operations

SUBJECT: Lab Chemical Safety & Management

As a planned internal audit for Fiscal Year 2017, Audit and Advisory Services (“AAS”) conducted a review to assess processes, procedures, and controls in place for the management of laboratory chemicals at UCSF.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the “IIA Standards”).

The preliminary draft report was provided to department management in November 2016. Management provided us with their final comments and responses to our observations in January 2017. The observations and corrective actions have been discussed and agreed upon with department management and it is management’s responsibility to implement the corrective actions stated in the report. In accordance with the University of California audit policy, AAS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

A handwritten signature in black ink, appearing to read 'Irene McGlynn', with a horizontal line extending to the right.

Irene McGlynn
Director, Audit and Advisory Services

EXECUTIVE SUMMARY

I. BACKGROUND

As a planned audit for Fiscal Year 2017, Audit and Advisory Services (AAS) completed a review of the processes in place for the management of laboratory chemicals used at the University of California, San Francisco (UCSF).

Environment, Health, and Safety (EH&S), a department within the UCSF Office of Research, is responsible for ensuring a safe and healthy environment at UCSF for all faculty, staff, students, patients, and visitors. To achieve these goals in relation to chemical safety, EH&S focuses on:

- Reviewing technical, environmental, and safety-related aspects of laboratory research and the use of hazardous and toxic substances;
- Disseminating a safety program that encourages best laboratory (lab) practices and satisfies federal, state, and local laws and regulations;
- Conducting regular inspections of laboratories to identify and mitigate chemical hazards and for assuring the laboratory's compliance with safety policies, guidelines, and regulations; and
- Development and maintenance of an effective emergency response program.

Other key individuals and committee for chemical safety at UCSF are the Hazardous Material Management Program Manager, the Chemical Hygiene Officer, and the Chemical and Environmental Safety Committee. Research Information Online (RIO) is the system of record for chemical inventory and lab inspections.

On July 27, 2012, the UC Regents and the Los Angeles District Attorney entered into a settlement agreement requiring UC campuses to provide and document certain lab safety training and resources to comply with California Code of Regulations (CCR) Title 8 requirements. This settlement agreement had a four-year term and expired on July 27, 2016. The University had the following obligations per the Settlement Agreement:

- Provide a list of laboratory chemistry and bio-chemistry facilities currently in operation;
- Maintain written Laboratory Safety Manual and Chemical Hygiene Plan that comply with applicable CCR Title 8 sections;
- Require all Principal Investigators (PIs) and lab personnel to complete training that covers the University's Lab Safety Manual and University policy concerning the PI's responsibility for lab safety;
- Ensure all laboratory facilities comply with CCR Title 8 requirements for Standard Operating Procedures (SOPs); and
- Have written procedures for pyrophoric materials.

II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to assess processes, procedures, and controls in place for the management of laboratory chemicals at UCSF. The scope of the review included Campus and Medical Center processes and procedures to determine that:

- Appropriate personnel have taken the required training;

- A Chemical Hygiene Plan has been developed (including detailed lab-specific SOPs);
- Online chemical inventory records are accurate and complete;
- Practices to respond to lab incidents and conduct lab inspections are effective; and
- Campus is in compliance with the terms of the 2012 Settlement Agreement and compliance with regulatory requirements.

The scope of the review included analyses of chemical purchases for the period June 2014 to July 2016 and the online chemical inventory as of September 13, 2016.

Procedures performed as part of the review included interviews of EH&S department personnel to understand departmental processes; review of observations from the July 2016 Cal/OSHA lab inspection; review of records documenting required training for lab personnel; review of the University's Chemical Hygiene Plan; analysis of purchase records and chemical inventories; and the inspection of a sample of research and clinical laboratories. For more detailed steps, please refer to Appendix A.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in October 2016.

III. SUMMARY

EH&S has created a Chemical Hygiene Plan and evaluates it at least annually. EH&S's practices to respond to lab incidents and conduct lab inspections appear to be effective. Appropriate processes have been implemented to help ensure compliance with the terms of the 2012 Settlement Agreement and the campus is in compliance with the terms of the Settlement Agreement.

Additionally, during the review, we noted adoption of sound practices at certain locations in managing their chemical inventory, including:

- Medical Center Pathology has established minimum and maximum stock levels for various chemical supplies that trigger replenishment of supplies
- Several labs maintain an internal inventory record to more effectively track their chemical supplies.

Opportunities for improvement exist in the areas of management of hazardous chemicals to assure better compliance with state regulations and the University's Chemical Hygiene Plan. The specific observations and areas for enhancement of processes are summarized below and discussed more thoroughly in the "Summary of Observation and Management Corrective Action" section that follows.

Management of Hazardous Chemicals

- Flammable chemicals are not always appropriately stored.
- There is no effective method of identifying the aggregate quantity of hazardous chemicals stored in University buildings.

- Excessive amounts of hazardous chemicals are being stored in University buildings.
- Compounds that may react with air and become explosive were not appropriately labeled.

Compliance with the University's Chemical Hygiene Plan

- Standard Operating Procedures (SOP) were not present for all Particularly Hazardous Chemicals.
- Refresher training of Lab employees on proper handling of chemicals was not current.
- Hazardous Chemicals On-line Inventory is neither complete nor updated annually as required.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (“MCA”)

A. Management of Hazardous Chemicals

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
1	<p><i>Flammable chemicals are not consistently, appropriately stored in research laboratories.</i></p> <p>During the inspection of a sample of research laboratories, we noted that flammable chemicals were stored on lab floors or in non-compliant flammable cabinets. This appears to be due to:</p> <ul style="list-style-type: none"> (1) Capacity of compliant flammable storage in laboratories is insufficient for the amount of material that the labs have on hand, and (2) Budgetary resource constraints have limited labs in purchasing compliant replacement cabinets. <p>This observation has been made on a number of EH&S lab inspections and is known to be a campus-wide issue. EH&S works with labs to evaluate their chemical needs and associated storage requirements.</p> <p>Per UCSF's Chemical Hygiene Plan, labs may store no more than 10 gallons of flammable liquids outside of flammable storage cabinets.</p> <p>Approved flammable cabinets must be self-closing and self-latching per Title 24, Part 9 of the California Fire Code.</p>	<p>Storage of excessive amounts of flammable materials outside of appropriate cabinets may increase the risk and severity of accidents in labs.</p>	<p>EH&S should continue to work with the labs to evaluate their chemical use requirements, ordering quantities and storage needs.</p> <p>Additionally, the Office of Research should work with labs and supply chain management to evaluate the feasibility of just in time ordering to limit the amount of chemicals being ordered so that they can safely store their chemical inventory.</p>	<p>Responsible Party: Executive Director EH&S</p> <p>Recently, EH&S conducted a survey identifying over 200 specific locations with non-compliant flammable cabinets.</p> <p>By April 30, 2017, EH&S, in partnership with Capital Programs, will develop a report, including Rough Order of Magnitude (ROM) costs of replacement / mitigation of non-compliant cabinets and a plan for phased replacement.</p> <p>Implementation of the plan is subject to approval by University Leadership.</p>

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
2	<p><i>There is not an effective tool or method of identifying the aggregate amount of hazardous chemicals stored in University buildings to determine our compliance level per building code.</i></p> <p>Labs certify their chemical inventories annually; however, labs perform this certification at different times of the year, rather than all on one single date. Additionally, the location of control areas within University buildings is not always known or integrated with the chemical inventory system. This makes it difficult in understanding the quantities of chemicals that can be stored or determining whether the hazardous chemicals exceed the allowable floor or control area level.</p> <p>Furthermore, currently neither the Fire Marshal (due to limited resources) nor the DSA inspections include verification of the quantity of hazardous chemicals stored in buildings on campus to ensure that these are within the allowable limits per the California State Building Code.</p> <p>As part of the Lead Designated Campus Fire Marshall's responsibilities, annual inspection of all existing facilities are required, including high rise structures and facilities containing chemical or biological laboratories and flammable materials.</p>	<p>Accumulation of excessive amounts of hazardous materials may increase the risk and severity of accidents in labs.</p>	<p>EH&S, in coordination with Capital Program and the UCSF Fire Marshal, should identify control areas for each building and determine the allowable limits for each control area. Periodic counts of hazardous materials stored in university buildings should be conducted to help mitigate the risk that the accumulation of these materials presents and to ensure that the University is in compliance with the California State Building Code.</p>	<p><u>Responsible Party:</u></p> <ul style="list-style-type: none"> - Executive Director EH&S - AVC Capital Programs & Chief Architect <p><u>Inventory Tools:</u></p> <ol style="list-style-type: none"> a) CIS – EH&S to migrate from current inventory system to UCOP Chemical Inventory System (CIS). This system will provide: <ol style="list-style-type: none"> 1) Hazard classes that align with California Fire Code 2) Ability to designate Control Areas 3) Ability to run Maximum Allowable Quantities (MAQ) reports per Control Area <p>EH&S & UCOP to migrate to CIS by February 28, 2017.</p> <ol style="list-style-type: none"> b) UC Chemicals – The UC Chemicals tool is currently under development. UC Chemicals provides additional functionality, such as barcode support, and a better user experience than RIO or CIS. EH&S plans to migrate the chemical inventory to UC Chemicals. This will be

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
				<p>accomplished in phases:</p> <ol style="list-style-type: none"> 1) Phase I of the UC Chemicals implementation will involve the conversion of labs identified in the Settlement Agreement and is expected to be completed by September 30, 2017. 2) Phase II involves the conversion of all other labs and is estimated to be completed by December 31, 2018 <p><u>Control Areas:</u> Capital Programs and EH&S to jointly identify a resource by February 28, 2017 to identify and record Control Areas for each building. This information will be provided to EH&S</p> <p>EH&S will enter Control Areas into CIS 30 days after Control Area information becomes available.</p> <p><u>Quality Control</u> EH&S will develop and submit a report to outline different chemical inventory QC methodologies to ensure sustained accuracy of chemical inventories. The</p>

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
				<p>report will include cost benefit analysis for each method proposed.</p> <p>Implementation of the proposal is subject to approval by Office of Research Services and Capital Programs leadership.</p> <p>As an interim action, and until all labs move to UC Chemicals, effective July 1, 2017, EH&S will conduct spot inventory counts as part of quarterly lab inspections.</p>
<p>3.</p>	<p>Excessive amounts of hazardous chemicals are being stored in University buildings.</p> <p>A review of the Research Information Online (“RIO”) Chemical Hazard Classification Reports for the Fifth Floor of Genentech Hall indicated that the amount of flammable liquids present exceeded the maximum allowable quantity per the building code.</p> <p>Issues with high levels of hazardous chemicals were also reported in the Chemical Inventory Survey and Code Analysis performed by Integrated Engineering Services of Health Sciences East and Health Sciences West (May 2014). The survey found several floors in these buildings exceeded the exempt amounts of hazardous materials (per the 2013 California Building Code).</p> <p>The California Building Code specifies special use and occupancy requirements, including the storage</p>	<p>Accumulation of excessive amounts of hazardous materials may increase the risk and severity of accidents in labs. Additionally, UCSF may face fines and other penalties for violating the building code.</p>	<p>EH&S should work with Supply Chain Management, Capital Programs, and space planning to evaluate the feasibility of central or bulk ordering and storage of chemicals so that the chemical loads of each building can be managed, and labs can be prevented from ordering and storing an excessive amount of chemicals.</p>	<p>Responsible Party:</p> <ul style="list-style-type: none"> - AVC Research Infrastructure & Operations - AVC Capital Programs & Chief Architect <p><u>Enforcement:</u> Develop a strategy for reduction of chemical inventories / enforcement of MAQs by December 31, 2017 and submit to University Leadership, the Chemical Environmental Safety Committee, and the Research Advisory Group for review / approval.</p> <p>This strategy document, at a minimum will identify:</p>

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
	of hazardous materials (CBC, Chapter 4).			<ul style="list-style-type: none"> - Roles & Responsibilities within the management of chemicals - Enforcement mechanism for non-compliance - Alternative storage / distribution models that lead to the reduction of chemical inventories.
4	<p><i>Compounds that may react with air and become explosive were not appropriately labeled.</i></p> <p>During the lab inspections, we noted that for two labs peroxide forming compounds did not have the date of receipt, opening date, or date of testing for peroxides. All peroxide forming compounds must have this information.</p> <p>Peroxides form after exposure to air. The rate of peroxide formation is dependent on the specific chemical, the amount of air exposure, and whether the chemical contains an inhibitor to retard peroxide formation. Therefore, it is imperative that the dates peroxide forming chemicals are opened and tested are noted.</p>	There is increased risk of peroxides forming that may result in explosions when exposed to heat, shock, or friction.	EH&S should re-educate the labs on labeling requirements for each peroxide forming chemical container. EH&S should develop monitoring reports to identify peroxide chemicals purchases and receipt dates to proactively focus on labs that carry such compounds.	Review of peroxides and their labeling is part of the DSA's inspection procedures and PIs are advised on any deficiencies. Additionally, effective November 1, 2016 EH&S has implemented a report to identify the purchase of peroxide chemical. This report will be shared monthly with the DSAs for their use during lab inspections.

B. Compliance with the University's Chemical Hygiene Plan

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
1	<p><i>Standard Operating Procedures (SOPs) were not present for all Particularly Hazardous Chemicals.</i></p> <p>We reviewed a judgmental sample of 109 Particularly Hazardous Chemicals (PHC) that did not have the SOP indicator in the Research Information Online</p>	All lab personnel who perform hazardous operations need to document that they have read	EH&S should devote sufficient resources to implement the revised SOP process to ensure that lab personnel are	<p>Responsible Party: Executive Director EH&S</p> <p>The new process of control banded SOPs is currently being rolled out by EH&S and</p>

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
	<p>(RIO) chemical inventory. We found the majority of these PHC (100) had a New Application status for their Chemical Use Authorization – meaning that the lab has not yet submitted a SOP for that chemical. However, nine PHC did not have a SOP in RIO.</p> <p>EH&S is revising its process to ensure site-specific SOPs are developed. Materials with similar hazards will be grouped together under one SOP.</p> <p>SOPs are written instructions that detail the requirements for working with hazardous chemicals and/or processes. The UCSF Chemical Hygiene Plan requires that Principal Investigators who work with hazardous chemicals need to develop SOPs and upload them to RIO system.</p>	<p>and understand all SOPs relevant to their research to help mitigate the risk of such operations.</p>	<p>appropriately informed of the hazards that they may encounter and mitigate this risk.</p>	<p>will be incorporated in the SOP module that is being developed and tested by UCOP. In the interim, EH&S will require PIs to maintain paper copies of their control banded SOPs in their labs.</p> <p>This is expected to be implemented in two phases:</p> <ul style="list-style-type: none"> - Phase I: Conversion of labs identified in the Settlement Agreement is expected to be completed by September 30, 2017. - Phase II: Conversion of all other labs and is estimated to be completed by December 31, 2018
<p>2</p>	<p><i>Refresher training of Lab employees on proper handling of chemicals was not current.</i></p> <p>In both Campus and Medical Center labs, training lapses were noted. While these do not appear to be repeat findings from previous inspections, we did note that training lapses were a common finding reported during lab inspections. Four of the forty researchers (10%) in the Campus labs inspected required “Lab Safety for Researchers” training updates. Of the five Medical Center labs inspected, two had not updated their Safety Assessment Survey within the last 12 months.</p> <p>Per UCSF's Chemical Hygiene Plan, all UCSF</p>	<p>Out of date or inadequate training may lead to an increased risk of lab accidents, which may result in the injury of lab personnel.</p>	<p>The noted lapses in training should be resolved. Additionally, EH&S should remind all lab employees of the importance of maintaining current training and the PI's responsibility to help ensure compliance with the training requirements.</p> <p>UCSF Medical</p>	<p>Responsible Party: Executive Director EH&S</p> <p>EH&S has evaluated UC Learning Management System's (LMS) ability to send multiple reminders to staff who have expired training. LMS cannot send multiple reminders for trainings that are not University wide.</p> <p>EH&S performs quarterly audits for all labs, where</p>

No.	Observation	Risk/Effect	Recommendation	Management Action Plans
	<p>employees and students are required to be trained before using hazardous chemicals in the laboratory. Principal Investigators are responsible for ensuring compliance with training requirements. Additionally, all UCSF laboratory workers must complete Laboratory Safety for Researchers training every three years.</p> <p>Per the UCSF Medical Center Environment of Care Manual, each department should complete a Departmental Annual Safety Assessment Survey that will aid in identifying unique risks to that department, and document how those risks are either being mitigated or require further evaluation.</p>		<p>Centers Safety Officer requires corrective actions to be documented via the online incident report. Follow up surveys are conducted within 12 months and corrective actions are verified.</p>	<p>expired trainings are noted as deficiencies. Recalcitrant deficiencies are referred to the appropriate Safety Officer and/or Safety Committee for enforcement.</p> <p>Additionally, EH&S will evaluate the suitability of the UC Laboratory Safety Refresher course to meet the three-year refresher training requirement.</p>
<p>3</p>	<p><i>Hazardous Chemicals On-line Inventory is neither complete nor updated annually as required.</i></p> <p>We noted the chemical inventory in one lab was not updated annually. We noted another site had Gasoline and Oxycide on hand that is not listed in the RIO inventory.</p> <p>Some labs maintain their own inventory lists in Excel files. As these lists cannot be uploaded into the current online inventory, a duplication of efforts is required to enter the inventory into RIO, thereby resulting in many labs not updating the inventory in RIO</p> <p>Per UCSF's Chemical Hygiene Plan, Principal Investigators are responsible for maintaining an accurate chemical inventory of their laboratory. Chemical inventories must be updated annually through RIO.</p>	<p>Accurate chemical inventories are required to help ensure that the hazards present in the lab are known to emergency responders.</p>	<p>EH&S management is aware of the limitations of the current chemical inventory system and is in the process of implementing a new system developed by UC Risk & Safety Solutions. In the new system, all lab chemicals will be entered into a barcode system.</p> <p>Upon implementation of the new system EH&S should validate that inventory records are current and kept updated.</p>	<p>See Observation A.2</p>

APPENDIX A

To conduct our review, the following procedures were performed for the areas in scope:

- Reviewed the following agreements, regulations and policies to gain an understanding of requirements relevant to the scope area:
 - Settlement Agreement between Los Angeles District Attorney and the Regents of the University of California,
 - California Occupational Safety Health Administration Title 8 Code of California Regulations,
 - UC Lab Safety Training Policy,
 - UC Personal Protective Equipment Policy,
 - Various UCSF Administrative Policies, and
 - UCSF Chemical Hygiene Plan.
- Interviewed key department personnel in EH&S to gain an understanding of procedures and practices of the department.
- Reviewed observations from the July 2016 Cal/OSHA lab inspection.
- Reviewed five campus sites and five medical center sites to determine if campus and medical center practices comply with regulations and university policies.
- Performed an analysis of data from the online chemical inventory to review materials identified as particularly hazardous chemicals that did not have the required SOP.
- Performed an analysis of chemical purchases between June 2014 and July 2016.
- Compared online chemical inventory records to a physical inventory for a sample of chemicals.
- Reviewed EH&S processes for responding to lab incidents and conducting lab inspections.
- Review documentation of training records to determine that the Emergency Response Team has received required training.
- Compared Principal Investigators from the inspection records to those from the online chemical inventory to determine if all applicable campus labs are reviewed.